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Tuesday
December 4, 1979

Highlights

69609 **Federal Paperwork Reduction** Executive orders

69732 **Indian Child Welfare** Interior/BIA announces grant applications and grant fund distribution formula; apply by 1-18-80 (2 documents)

69727 **Quiet Communities** EPA issues notice of intent to award financial assistance to State and local government and other eligible organizations and agencies

69673 **Small Cities Program** HUD/CPD issues advanced notice of proposed rulemaking regarding Community Development Block Grants; comments by 1-3-80

69650 **Iranian Assets Control** Treasury/Foreign Assets Control Office amends rules regarding judicial proceedings with respect to properties of Iran or Iranian entities; effective 11-29-79

69689 **Tactile Paging Devices** FCC proposes rules concerning operation of devices for deaf, blind, and physically handicapped; comments by 2-5-80, reply comments by 3-6-80

69868 **Land Withdrawals** Interior/BLM proposes amendments to withdrawal procedures; comments by 3-3-80 (Part III of this issue)

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Highlights

69912, 69915 **Super Bowl Charter Flights** CAB issues final rules and proposes rules on consumer protection, regarding proof of possession of game tickets or the contract for game tickets before being permitted to advertise or accept money for the charter; effective 11–30–79, comments by 12–20–79 (2 documents) (Part V of this issue)

69876 **Government Operations** OPM proposes demonstration project regarding pay, performance appraisal, and position classification for more effective operation; comments by 2–4–80, hearings 1–21, 1–22, and 1–31–79 (Part IV of this issue)

69694 **Privacy Act** USDA/Sec'y publishes a document affecting the systems of records

69651 **Improving Government Regulations** OPM publishes semiannual agenda of regulations

69768 **External Analgesic OTC Human Drug Products** HEW/FDA establishes a monograph and proposes conditions for sale and effective use; comments by 3–6–80; reply comments by 4–3–80 (Part II of this issue)

69670 **Erythromycin Estolate** HEW/FDA proposes revocation of provisions for certification of adult dosage forms; comments by 1–3–80

69633, 69640–69642 **Cargo Carriers** CAB provides for a simple registration procedure to grant operating authority to foreign air freight forwarders and foreign cooperative shippers associations (8 documents)

69732 **Operation Common Sense** HEW/PHS and CDC gives notice that it proposes to develop integrated rules to cover research investigations and health hazard evaluations.

69631 **Farm Credit System** FCA takes final action to amend its rules concerning the lending operations of the institutions; effective 12–4–79

69665 **Export Administration** Commerce/ITA proposes to clarify the application of its regulations to certain boycott restrictions on exports from boycotting countries; comments by 1–4–80 noon

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Presidential Documents

Title 3—

The President

Executive Order 12174 of November 30, 1979

Paperwork

By the authority vested in me as President by the Constitution and statutes of the United States of America, and in order to establish procedures that eliminate all paperwork burdens on the public above the minimum necessary to determine and implement public policy and ensure compliance with Federal laws, it is hereby ordered as follows:

1–101. Agencies shall minimize the paperwork burden—i.e., the time and costs entailed in complying with requests for information and recordkeeping requirements—imposed on persons outside the Federal government. Forms should be used only to the extent necessary to gather the basic information required to fulfill an agency's mission. When forms must be used, they should be as short as possible and should elicit information in a simple, straightforward fashion.

1–102. Each agency shall designate an existing official to be responsible for minimizing both the agency's use of forms and the paperwork burden resulting from proposed legislation and regulations.

1–103. Agencies shall pay particular attention to the special burdens faced by individuals and small organizations in responding to requests for information. To minimize these burdens agencies should, whenever possible, forego uniform or universal reporting requirements and rely instead on sampling, reduced frequency of reporting, differing compliance standards, or exemptions.

1–104. Each agency shall prepare an annual paperwork budget, i.e., an estimate of the total number of hours required to comply with requests for information. The budget should itemize each form used, describe its purpose and identify those affected by it. The Director of the Office of Management and Budget shall review and may modify each agency's proposed budget. After the Director has approved an agency's paperwork budget, it may be increased only by the Director upon request of the head of the agency.

1–105. Forms or similar requests for information shall be reviewed within two years after their initial issuance and then at least once every five years. Following review, they should be revised or abandoned to the extent they are not required to meet an agency's basic information needs. These reviews will be conducted by the agencies, and reports of the reviews will be submitted to the Director.

1–106. The Director shall audit compliance with this Order and may issue rules and regulations necessary to implement it. The Director may issue exemptions for agencies whose use of forms is limited. The Director also shall:

(a) Seek to eliminate duplication in requests for information by establishing a Federal information locator system, which will list all the types of information collected by Federal agencies and will be available for use by all agencies. This or similar systems will not contain any information obtained from the public. The Director shall take any other steps needed to prevent duplication, including the assignment to a particular agency of lead responsibility for the collection of certain types of information.

(b) Seek to inform the public and broaden public and agency comment by preparing and publishing in the **Federal Register** an annual paperwork calendar of significant requests for information. This calendar will be based on the information contained in the agencies' paperwork budgets.

(c) Report annually to the President on implementation of this Order and control of the paperwork burden generally.

1–107. The authority vested in the Director under this Order shall not affect any authority vested in him by any other Order. This Order shall be implemented in a manner consistent with all applicable Federal statutes.

1–108. For purposes of this Order, agency means those agencies covered by Executive Order 12044.

1–109. This Order will expire on September 30, 1983.

Jimmy Carter

THE WHITE HOUSE,
November 30, 1979.

[FR Doc. 79–37359
Filed 11–30–79; 3:03 pm]
Billing code 3195–01–M

EDITORAL NOTE: The President's remarks of Nov. 30, 1979, on signing Executive Order 12174, are printed in the Weekly Compilation of Presidential Documents (vol. 15, no. 48).

Rules and Regulations

Federal Register
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Tuesday, December 4, 1979

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 month.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 213

Excepted Service; National Foundation on the Arts and Humanities

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: This document corrects the paragraph designation of a National Foundation on the Arts and Humanities excepted appointing authority which was published on February 27, 1979; this is an editorial change only.

EFFECTIVE DATE: April 10, 1979.

FOR FURTHER INFORMATION CONTACT: On position authority: William Bohling, Office of Personnel Management, 202–632–4533.

On position content: Alan L. Taylor, National Endowment for the Humanities, 202–724–0356.

SUPPLEMENTARY INFORMATION: On February 27, 1979, the Office of Personnel Management published at 44 FR 26843 a Schedule B excepted appointing authority which incorrectly added § 213.3282(b)(27). Since a paragraph (27) already existed, this document corrects the paragraph designation to read (b)(28).

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

For clarity, the correctly designated § 213.3282(b)(28) is set out below.

§ 213.3282 National Foundation on the Arts and the Humanities.

* * * * *

(b) *National Foundation for the Humanities.*

* * * * *

(28 Until September 30, 1980, one position of Assistant Director, Program Development, Division of Special Programs, GS–14.

(5 U.S.C. 3301, 3302; EO 10577, 3 CFR 1954–1958 Comp., P. 218)

[FR Doc. 79-37220 Filed 12-3-79; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1435

Extended 1978 Crop Sugar Loans

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Final rule.

SUMMARY: This rule sets forth the terms and conditions under which the maturity dates of 1978 crop sugar loans may be extended. Sugar eligible for extension of loan maturity date is limited to that quantity outstanding under loan as of the maturity date specified in the Farm Storage Note and Security Agreement. The period of extension is until June 30, 1980, although Commodity Credit Corporation (CCC) may, in its discretion, accelerate the maturity date. While properly maintained in extended loan status in approved storage, such sugar will earn storage payments at the rate of $.0084 per pound per year. Processors may redeem all or any part of an extended loan at any time prior to its extended maturity date. After the extended maturity date, the processor may forfeit to CCC any unredeemed quantity. This rule is needed in order that 1978 crop sugar loans may be extended.

EFFECTIVE DATE: November 30, 1979.

FOR FURTHER INFORMATION CONTACT: Laurence E. Ackland, ASCS, PSD, (202–447–5647), P.O. Box 2415, Washington, D.C. 20013.

SUPPLEMENTARY INFORMATION: Section 902 of the Food and Agriculture Act of 1977 (Pub. L. 95–113, 91 Stat. 949, effective October 1, 1977) amended Section 201 of the Agricultural Act of 1949 to provide that the price of the 1977 and 1978 crops of sugarbeets and sugarcane shall be supported through loans or purchases with respect to the processed products thereof.

On November 11, 1977, a final rule was published in the Federal Register (42 FR 58734) implementing a program effective as of November 8, 1977, to support prices in the marketplace for producers of 1977 crop sugarbeets and sugarcane through nonrecourse loans made to sugar processors. The price support loan program for the 1977 crop was amended on May 17, 1978 (43 FR 21317), on August 23, 1978 (43 FR 37419), on August 30, 1978 (43 FR 38686), on October 30, 1978 (43 FR 50409), and on February 15, 1979 (44 FR 9733). Because of a then existing lack of market opportunity processors were provided, on November 29, 1978 (43 FR 55742), with the opportunity to extend 1977 crop loan maturity dates to September 30, 1979.

A final rule implementing a price support loan program for the 1978 crop of sugarbeets and sugarcane was published in the Federal Register on June 7, 1978 (43 FR 24663). Amendments to the 1978 crop program were published on August 23, 1978 (43 FR 37419), on August 30, 1978 (43 FR 38686), on October 30, 1978 (43 FR 50410), February 15, 1979 (44 FR 9733) and on June 22, 1979 (44 FR 36361).

Although prices now being received by processors are substantially higher than for the same time in 1978, loan rates for the 1978 crop were required by law to be significantly higher than for the 1977 crop (basic loan rate for raw cane sugar raised from 13.00 to 14.73 cents per pound). As a result, processors are again faced with a lack of market opportunity and indications are that as much as 900,000 tons of 1978 crop sugar now under loan to CCC may not be redeemed from loan by existing loan maturity dates. Extended loan maturity dates provide an additional option to processors, which offers advantages both to processors and to the government:

1. The processor can retain title to the sugar for a longer time and the opportunity for redemption and subsequent additional income to processors and producers will be enhanced.

2. Since a participating processor will have the opportunity for additional proceeds on the sugar at no risk (he can still forfeit at the end of the extended period), he will have additional incentive to construct or otherwise arrange for needed storage.

3. To the extent that market prices obtainable by processors rise to a level which will permit processors to recover loan redemption and transport costs,

extended loans are likely to be redeemed. CCC will, to the extent that loans are redeemed, avoid the burden of taking over such sugar.

4. To the extent that such loans are ultimately forfeited, CCC will be no worse off than if title were taken earlier because, in any case, CCC will incur storage costs from the original maturity date. The responsibility for maintaining quantity and quality will remain with the processor during this period.

The Department recognizes that any serious disparity between storage rates perceived by processors as achievable for storing forfeited sugar and those available for storing extended loan sugar would be a disincentive for extension. Storage rates for forfeited sugar are individually negotiated with each warehouseman. While regulations for the 1978 crop price support program provide a maximum rate of $.000833 per pound per month, this maximum is regarded as a "distress rate," to be considered only for short-term emergency storage. Long-term rates negotiated thus far have ranged well below the maximum and, additionally, have not varied as much between raw cane sugar and refined beet sugar as had been anticipated when 1977 crop extended loan regulations were adopted. The 1978 crop extended loan storage rate adopted, $.0007 (i.e., $.000023 per pound per day) per pound per month, represents the Department's best estimate of a set rate that will prove to be adequate in comparison to forfeited storage rates negotiated and yet to be negotiated for both refined beet and raw cane sugar.

Accordingly, Chapter XIV of Title 7 of the Code of Federal Regulations is amended by adding a new Subpart—Extended 1978 Crop Sugar Loans—to Part 1435 which reads as follows:

PART 1435—SUGAR

Subpart—Extended 1978 Crop Sugar Loans

Sec.

1435.66 General statement.
1435.67 Applicability of the regulations governing price support loans for 1978 crop sugarbeets and sugarcane.
1435.68 Eligibility requirements.
1435.69 Period of extension.
1435.70 Storage payment.
1435.71 Commingling.
1435.72 Substitution.
1435.73 Loss or damage.
1435.74 Loss of storage payments.
1435.75 Applicable forms.

Authority.—Secs. 201 and 401 et seq. of the Agricultural Act of 1949, as amended (7 U.S.C. 1446, 1421 et seq.).

§ 1435.66 General statement.

(a) The regulations in this subpart set forth the terms and conditions for the extension of maturity dates for 1978 crop sugar price support loans evidenced by Farm Storage Note and Security Agreements and by Sugar Loan Addenda thereto.

(b) In order to obtain an extended 1978 crop sugar loan, a processor must file an application requesting an extended loan with the loan making office and have such application approved by that office. The extended loan granted under this subpart will be due on June 30, 1980, or such earlier date as CCC may make demand for payment. A producer may redeem his loan, or deliver the sugar covered by such loan to CCC, on the terms and conditions contained in this subpart.

(c) As used in the regulations in this subpart "CCC" means the Commodity Credit Corporation.

§ 1435.67 Applicability of the regulations governing price support loans for 1978 crop sugarbeets and sugarcane.

The following sections of the regulations, as amended, governing the price support loan program for 1978 crop sugarbeets and sugarcane shall also be applicable to extended 1978 crop sugar loans: §§ 1435.35; 1435.36; 1435.38; 1435.41 (a), (b), (d), (f), and (g); 1435.42 (a); 1435.43; and 1435.44.

§ 1435.68 Eligibility requirements.

(a) *Processor.* A processor shall be eligible to obtain a loan extension if the processor has eligible raw cane sugar or the processed products thereof or refined beet sugar under a 1978 price support loan.

(b) *Quantity.* The quantity eligible for extension of loan and for storage payment credit shall not exceed the loan balance outstanding upon the original maturity date of the loan.

(c) *Final dates.* The processor must apply for an extension of loan no later than November 30, 1979, for loans maturing on November 30, 1979, and no later than two weeks prior to the original maturity date of the loan for other loans.

(d) *Inspections.* Prior to approval for an extension of loan, the sugar shall be inspected by a representative of the loan-making office. An extension of loan will not be approved unless it is determined that the storage structure is eligible and the quality of the sugar is such that it can reasonably be expected to be stored with safety for the extended storage period.

§ 1435.69 Period of extension.

The maturity date for all loans extended shall be June 30, 1980, or such earlier date as CCC may make demand for payment.

§ 1435.70 Storage payment.

(a) *Storage credit.* Credit will be given for each full day of storage beginning on the day following the original loan maturity date. Storage credit will cease, for the extended loan quantity involved, on (1) the date of loan repayment (2) the date of approval for removal of loan collateral from storage for delivery to a buyer prior to repayment of the loan (3) the date of occurrence of any loss or damage to be assumed by CCC, or (4) the date a shortage in loan collateral is determined, whichever is earlier.

(b) *Storage rate.* The payment rate shall be $.000023 per pound per day for extended loan sugar receiving storage credit.

(c) *Frequency and method of storage payments.* Storage payments shall be made on a quarterly basis during the extended loan term. Final storage payments will be made at the time loan collateral is redeemed or upon settlement. Disbursement of storage payments will be made by means of sight drafts drawn on CCC and issued by the loan-making office.

§ 1435.71 Commingling.

(a) *When permitted.* The loanmaking office may permit:

(1) A processor to commingle quantities of sugar which are under more than one extended loan.

(2) Two or more processors to commingle quantities of sugar under extended loan.

(3) Sugar under extended loan to be commingled with sugar under 1979 crop price support loan and sugar not under price support loan (including forfeited sugar owned by CCC).

(b) *Special conditions.* Notwithstanding any other provision governing extension of loans, if it is determined that the total quantity determined to be in a storage facility is less than the total loan collateral and CCC-owned sugar required to be therein maintained, the shortage shall be pro rated to each processor whose loan sugar is in the facility based on the ratio of that portion of his outstanding loan quantity which is represented to be in the facility to the total outstanding loan collateral contained in the storage facility. Any shortage of sugar attributed to a processor shall be considered to be, to the extent possible, from the loan with the earliest disbursement date.

§ 1435.72 Substitution.

Sugar of the same or a subsequent crop year may be substituted for existing extended loan collateral if the required quantity of extended loan collateral is maintained in approved storage space at all times and if prior permission for substitution is obtained from the loanmaking office.

§ 1435.73 Loss or damage.

The processor is responsible for any loss in quantity or quality of sugar under loan, except that CCC will bear the loss, or its pro rata share of the loss in the case of sugar stored on a commingled basis, less any insurance proceeds and salvage value of the sugar to which CCC may be entitled, if the processor establishes to the satisfaction of CCC each of the following conditions: (a) The loss or damage occurred without fault or negligence on the part of the processor; (b) The processor gave the State committee immediate notice if the loss or damage resulted solely from an external cause such as theft, fire, lightning, explosion, windstorm, cyclone, tornado, flood, or other act of God; (c) If the processor knew or should have known that the sugar was going out of condition or was in danger of going out of condition, the processor notified the loan-making office and confirmed such notice in writing; and (d) The processor made no fraudulent representation in the loan or loan extension documents or in obtaining or extending the loan.

§ 1435.74 Loss of storage payments.

Notwithstanding any other provisions concerning price support sugar loans, in no case will any storage payment for any quantity of sugar designated for extension of loan be made: (a) If the processor has made any false representation in the extension of the loan or in its settlement; or (b) If there has been unauthorized disposition of the commodity with intent to defraud on the part of the processor. If a processor received payment of any amount to which he is not entitled, he shall refund such amount plus interest thereon promptly upon demand.

§ 1435.75 Applicable forms.

The forms for use in connection with extended sugar loans will be made available by the State committee.

Note.—In order for processors with 1978 crop sugar loans maturing on November 30, 1979, to have the opportunity to extend such loans, this rule must be promulgated immediately.

Therefore, pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this final rule are impracticable and contrary to the public interest and good cause is found for making this final rule effective less than 30 days after publication of this document in the **Federal Register.**

Further, this final rule has not been designated as "significant," and is being published in accordance with the emergency procedures in Executive Order 12044 and Secretary's Memorandum 1955. It has been determined by Ray V. Fitzgerald, Administrator, Agricultural Stabilization and Conservation Service, that the emergency nature of this final rule warrants publication without opportunity for public comment at this time.

An impact analysis statement has been prepared and is available from Laurence E. Ackland, Room 5768—South Building, USDA, Washington, D.C. 20250.

Signed at Washington, D.C. on November 28, 1979.

Jim Williams,

Acting Secretary.

[FR Doc. 79-37164 Filed 12-3-79; 8:45 am]

BILLING CODE 3410-05-M

Food Safety and Quality Service

7 CFR Part 2852

Standards for Grades of Fruit Preserves or Jams [1]

AGENCY: Food Safety and Quality Service, USDA.

ACTION: Final rule.

SUMMARY: This rule amends the grade standards for fruit preserves or jams. The action is taken at the request of the International Jelly and Preserve Association and a member of the preserving industry. It improves the quality of fruit preserves used for remanufacturing and small, individual serving packages used in restaurants.

EFFECTIVE DATE: January 4, 1980.

FOR FURTHER INFORMATION CONTACT: Thomas E. Crider, Processed Products Branch, Fruit and Vegetable Quality Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-6248.

SUPPLEMENTARY INFORMATION: At the request of the International Jelly and Preserve Association and a member of the preserving industry, the U.S. Standards for Grades of Fruit Preserves or Jams are amended to allow a more firm consistency preserve for remanufacturing and more broken fruit particles in small individual serving packages used in restaurants.

A preserve, made firm enough to be used as an ingredient in pastries, ice cream and other similar products, would now qualify for the top grade for remanufacturing, which is "U.S. Grade A for Manufacturing." These preserves are intentionally made more firm than preserves found at retail stores to withstand blending, reheating and other similar processing. Adequate safeguards are provided to prevent preserves for remanufacturing from entering consumer channels.

Fully ripened and more flavorful fruit, which partially disintegrates during cooking and processing, may be used without discrimination. Previously, less ripe and usually less flavorful fruit was used to comply with the requirements for "consistency." By relaxing this requirement, better utilization of fruit and a more flavorful preserve is possible.

Descriptive grade terms, such as "U.S. Fancy," are eliminated in favor of a consumer preference for a single letter grade term, such as "U.S. Grade A."

Proposed changes to the U.S. standards for preserves or jams, published in the **Federal Register** of December 8, 1978 (43 FR 57608-57609), received four comments. Two comments endorsed the changes, one comment favored the manufacturing grade but opposed the change in "consistency" to allow for riper, more flavorful fruit, and one comment opposed the consideration of jam being graded as preserves. Neither of the comments which objected to specific details in the standards presented data to support that preserves in the Nation's marketplace are any different than the descriptions provided in the standards, especially with respect to small individual servings found in the restaurant trade.

After consideration of all comments, Subpart—United States Standards for Grades of Fruit Preserves or Jams (7 CFR 2852), sections 2852.1111, 2852.1114, and 2852.1118 are hereby amended to read as follows:

§ 2852.1111 Identity.

"Fruit preserves or jams" means preserves or jams as defined in the Definitions and Standards of Identity for Preserves, Jams (21 CFR 150.160) issued pursuant to the Federal Food, Drug, and Cosmetic Act. The solids content of the finished fruit preserves or jams shall be not less than 65 degrees Brix. No

[1] Compliance with the provisions of these standards shall not excuse failure to comply with the provisions of the Federal Food, Drug, and Cosmetic Act, or with applicable State laws and regulations.

correction is made for water-insoluble solids.

* * * * *

§ 2852.1114 Grades of fruit preserves or jams.

(a) "U.S. Grade A" or "U.S. Grade A for Manufacturing" is the quality of fruit preserves or jams that have a good consistency; that have a good color; that are practically free from defects; that have a good flavor; and that score not less than 85 points when scored in accordance with the scoring system outlined in this subpart, Provided: That no fruit preserve or jam shall be graded, inspected and/or certified as a manufacturing grade product unless it is suitably designated and/or labeled. Manufacturing grade product shall not be packaged in containers smaller than the equivalent of a number ten (No. 10) metal can (603 × 700).

* * * * *

§ 2852.1118 Consistency.

(a) *General.* The factor of consistency refers to the extent of the dispersion and size of the fruit or fruit particles throughout, and the gel-like properties of the product; Provided: That any requirements for wholeness of fruit are waived for products packaged in one and one-half (1½) ounce and smaller containers; And further provided: That, fruit puree as a single fruit ingredient may not be used.

(b) *A classification.* (1) Fruit preserves or jams that have a good consistency may be given a score of 17 to 20 points. "Good consistency" means that the fruit or fruit particles are dispersed uniformly throughout the product; that the product has a tender gel or may have no more than a very slight tendency to flow, except that a slightly less viscous consistency may be present when the fruit is chiefly in the form of whole or almost whole units; and that in the following kinds the product does not have a macerated or pureed appearance, and is made from whole or almost whole fruit as indicated:

(i) *Apricot.* Halves or pieces or combinations thereof.

(ii) *Cherry.* Whole or almost whole or pieces of pitted cherries or combinations thereof.

(iii) *Gooseberry.* Whole or almost whole berries or combinations thereof.

(iv) *Peach (clingstone and freestone).* Slices or pieces or combinations thereof.

(v) *Pineapple.* Crushed pieces or small pieces or combinations thereof.

(vi) *Strawberry.* Whole or almost whole berries or combinations thereof.

(2) Fruit preserves or jams for manufacturing that have a good consistency may be given a score of 17 to 20 points. "Good consistency" means that the product meets all of the requirements of (b)(1) of this section; Provided, That the product may have a moderate to very firm gel but may not be rubbery.

(c) *B Classification.* * * *

(d) *Substandard classification.* Fruit preserves or jams that fail to meet the requirements of paragraph (c) of this section may be given a score of 0 to 13 points and shall not be graded above Substandard, regardless of the total score for the product (this is a limiting rule). (Agricultural Marketing Act of 1946; 60 Stat. 1087; 7 U.S.C. 1621–1627.)

This final rule has been reviewed under the USDA criteria established to implement Executive Order 12044 "Improving Government Regulations". A determination has been made that this action should not be classified "significant" under those criteria. A Final Impact Statement has been prepared and is available from Thomas E. Crider, Processed Products Branch, Fruit and Vegetable Quality Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250.

Done at Washington, D.C., on: November 28, 1979.

Donald L. Houston,

Acting Administrator, Food Safety and Quality Service.

[FR Doc. 79-37112 Filed 12-3-79; 8:45 am]

BILLING CODE 3410-DM-M

DEPARTMENT OF THE TREASURY

Comptroller of the Currency

12 CFR Part 11

Securities Exchange Act; Disclosure Rules

AGENCY: Comptroller of the Currency.

ACTION: Final rules.

SUMMARY: This document amends the Securities Exchange Act Disclosure Rules (12 CFR Part 11) promulgated by the Comptroller of the Currency ("Comptroller") under Section 12(i) of the Securities Exchange Act of 1934 ("1934 Act") in order to clarify those regulations, and to substantially conform them to corresponding rules and regulations issued by the Securities and Exchange Commission ("SEC"). Section 12(i) requires that the Comptroller issue substantially similar regulations to those issued by the SEC under sections 12, 13, 14(a), 14(c), 14(d), 14(f) and 16 of the 1934 Act unless the Comptroller finds that such rules are not necessary or appropriate in the public interest or for the protection of investors, and publishes such findings and the reason therefor in the Federal Register. This amendment is intended to respond to the statutory mandate and covers the following areas: (1) Beneficial ownership; (2) shareholder proposals; (3) corporate governance; (4) management remuneration; and (5) changes in independent accountants and auditors fees.

EFFECTIVE DATE: The amendments will be effective as of December 31, 1979, except as to the requirements of Item 6(g) of 12 CFR § 11.51 which will be effective as of January 1, 1981.

FOR FURTHER INFORMATION CONTACT: Ralph Janvey, Attorney, Securities Disclosure Division, Comptroller of the Currency, Washington, DC at (202) 447–1954.

SUPPLEMENTARY INFORMATION: On June 4, 1979, the Comptroller published in the Federal Register (44 FR 31984) for comment proposed amendments to its Securities Exchange Act Disclosure Rules (12 CFR Part 11) in order to clarify the rules and respond to changes made to corresponding SEC regulations. Interested persons were afforded the opportunity to submit, not later than August 3, 1979, their views regarding the proposed amendments. The Comptroller received 21 comment letters which were carefully considered in the adoption of the definitive rules. A summary of the comments by topic and the Comptroller's responses follow:

A. *Beneficial Ownership*—The Comptroller is adopting amendments as proposed to its rules (12 CFR 11.4(g)) and Form F–11, Acquisition Statement (12 CFR 11.47) and Form F–13, Tender Offer Form (12 CFR 11.54) pertaining to the beneficial ownership of national bank securities and has adopted a new Form F–11A, Short Form Ownership Statement (12 CFR 11.48). The Comptroller received three comment letters on the subject. Two commentators raised no objections to the proposals while the other suggested that the 5% reporting threshold be raised to 10%. The 5% reporting threshold was set by Congress in Sections 13(d) and 14(d) of the 1934 Act and cannot be changed by rule or regulation.

B. *Proposals of security holders*—The Comptroller is adopting an amendment as proposed to its proxy rules (12 CFR 11.5(k)) to require that where management intends to include in its proxy statement a statement in opposition to a shareholder's proposal, management must, within prescribed time periods, promptly forward a copy of its statement to the shareholder. If the shareholder believes that the statement

is false or misleading, the shareholder may send a letter to the Comptroller, forwarding a copy to the bank, setting forth the basis for that belief. The amendment should be considered along with the corporate governance amendments (*see* discussion in preamble of proposed amendments, 44 FR 31985).

The Comptroller received two comment letters addressing the subject of shareholder proposals. One commentator expressed the view that the proposed requirements would be "cumbersome, at best, and unnecessary" and would slow down the process of preparing, printing and mailing management's proxy materials. The other commentator objected to including a shareholder's proposal in management's proxy materials. A shareholder's right to include a proposal in management's proxy materials has existed under the Rules for a number of year. The Comptroller believes that the amendments are equitable in enabling a proponent to review management's opposing statement before it is mailed to shareholders. It would appear to be in the best interest of both management and shareholders to resolve questions concerning the factual accuracy of opposing statements during the comment process. The amendment should promote dialogue between the parties which will foster better understanding of their respective positions and in some instance promote mutual accomodation.

C. *Management Remuneration*—The Comptroller has amended as proposed Item 7, Remuneration and Other Transactions With Management, Form F–5, proxy statement format, (12 CFR 11.51). Also, Form F–1, registration statement (12 CFR 11.41), has been amended to combine Item 10, Remuneration of Directors and Officers, and Item 13, Interest of Management and Others in Certain Transactions, into a new Item 10, the requirements of which are cross-referenced to Item 7 of 12 CFR 11.51.

Item 7(a) of 12 CFR 11.51 has been amended to require disclosure of all remuneration to the five (5) most highly compensated officers or directors whose total remuneration exceeded $50,000. The table has been expanded from three to five columns, and the instructions have been modified to more accurately reflect the types of remuneration common to national banks.

Columns A and B of the former table required by Item 7(a) remain unchanged. Column C of the table has been subdivided into Column C1, which includes reporting of all cash remuneration distributed or accrued in the form of salaries, fees, directors' fees, commissions and bonuses; and Column C2, which includes all cash or cash equivalent remuneration attributable to securities or property, insurance benefits, and personal benefits. New Column D requires disclosure of contingent forms of remuneration.

Former Items 7(e) and 7(f) of 12 CFR 11.51 have been relabelled as Items 7(d) and 7(e), respectively, and the language has been revised to clarify the disclosures required for indebtedness of, and transactions with management.

The Comproller received nine comment letters addressing the subject of management remuneration. Three commentators suggested that the three person coverage be retained, while all commentators favored raising the dollar threshold to a minimum of $50,000. The Comptroller believes the requirements as proposed and adopted are reasonable and provide shareholders with valuable information in judging the performance of management. The Comptroller will monitor the disclosure threshold in the future and will consider raising the dollar level to a higher amount if supported by an adequate factual basis.

One commentator objected to the proposal to define "bank" for purposes of Item 7 of 12 CFR 11.51 to include the bank's subsidiaries based on the belief that the definition is too broad and will lead to confusion. After considering the comment, the Comptroller has adopted the amended definition as proposed. For the large majority of national banks with securities registered under the 1934 Act the new definition should not result in any confusion. As in the past, if a particular requirement does result in interpretive problems it will be handled expeditiously through staff interpretation.

One commentator stated that the requirements proposed with respect to newly designated item 7(d), Indebtedness of Management, are not necessary and go beyond the provisions of Title IX of the Financial Institutions Regulatory and Interest Rate Control Act of 1978, Public Law 95–630, 92 Stat. 3641–3741 ("FIRICA"). The Comptroller has adopted the amendments to Item 7(d) as proposed. Title IX of FIRICA does not cover directors of a bank nor does it prescibe the types of loans which would be disclosed pursuant to Item 7(d). The Annual Report which a bank must file with the Comptroller pursuant to FIRICA need not be sent to shareholders in order to inform them in voting for the election of directors. Also, there is no indication in the legislative history to FIRICA that Congress intended by the legislation to preempt disclosure by banks to shareholders pursuant to the requirements of the 1934 Act. The Comptroller does intend, once Title IX is finally implemented to attempt to interface the reporting requirements of Part 11 with FIRICA to the extent practicable.

D. *Corporate Governance*—The Comptroller is adopting, with minor modifications, the corporate governance amendments proposed with respect to Form F–5, proxy statement format (12 CFR 11.51); Form F–1, registration statement (12 CFR 11.41); and, Form F–2, annual report (12 CFR 11.42). The amendments are intended to improve the quantity and quality of information available to shareholders regarding: (1) The structure, composition and functioning of a bank's board of directors; (2) the resignation of directors; (3) the attendance of directors at board and committeee meetings; and (4) the terms of proxy contest settlements.

In proposing amendments to Item 6, Nominees and Directors, of 12 CFR 11.51, the informational requirements were inadvertantly expanded beyond just nominees and directors, to officers and certain significant employees. Information as to officers is already required under Item 11 of Form F–2, annual report (12 CFR 11.42), so that the expanded requirements would have been duplicative. Expanded informational requirements as to certain significant employees were appropriate, but were properly presented in the context of the initial Form F–1 registration statement (12 CFR 11.41).

Consequently, the definitive amendments reflect (i) the deletion of information on officers and certain significant employees from Item 6 of 12 CFR 11.51; and, (ii) the movement of the proposed requirements for information on certain significant employees to Item 8 of Form F–1 (12 CFR 11.41) and Item 11 of Form F–2 (12 CFR 11.42).

The Comptroller received nine comment letters which addressed the subject of corporate governance. A number of commentators objected to the requirement that a bank disclose the total number of board of director meetings held during the last full fiscal year and the name of each incumbent director who attended fewer than 75 percent of the meetings. While adopting the substantive amendment as proposed, the Comptroller has deferred the effective date of the new requirements of Item 6(g) of 11.51 until January 1, 1981 in order to avoid their retroactive application. Of course, banks may elect to include such information in proxy materials in the interim.

E. *Changes in Independent Accountants and Auditors Fees*—The Comptroller has amended Form F–3,

current report, Item 4, Changes in Bank's Certifying Accountant (12 CFR 11.43), and Form F–5, proxy statement format, Item 8, Selection of Auditors, (12 CFR 11.51) to affirmatively require disclosure of whether a decision to change independent accountants was recommended by the audit or similar committee of the board of directors of a bank.

The Comptroller, in response to the suggestion of one commentator, has revised Item 8(b) of 12 CFR 11.51 to change the phrase "certified public accountant" to read "independent public accountant." This change recognizes the fact that public accountants as well as certified public accountants can perform auditing and accounting services.

Also, in response to a number of comments, the Comptroller has amended Item 8(b), Instruction 2 of 12 CFR 11.51 increasing from 3% to 10% the disclosure threshold of fees for nonaudit services as a percentage of audit fees. The Comptroller believes that the 3% threshold was too low and therefore unrealistic for the vast majority of national banks subject to 12 CFR Part 11, and would not provide shareholders with meaningful information.

F. *Technical Accounting Amendment*—The Comptroller has amended Item 14(b)(7)(ii) of 12 CFR 11.51 to conform the requirements to those of the SEC. Although the effect of the previous language had been intended to be identical to that of the corresponding SEC regulation, this amendment should eliminate any confusion that has arisen.

G. *Proposed Simplification of Part 11*—The Comptroller in connection with the proposed amendments requested comments on the concept of simplifying and clarifying 12 CFR Part 11. The purpose of the simplification process would be to produce a shorter, more readable and understandable regulation that will reduce the costs to banks and other filing persons in terms of time, paperwork and staff.

The Comptroller received eight comment letters addressing the subject of simplification. All the commentators, while differing as to the format and method of simplifying, were in favor of the project. Two of the commentators strongly favored devising a format whereby Call Reports could be filed and used in lieu of the Form F–2, annual report and the Form F–4, quarterly report.

Based upon the comments received and consistent with the Comptroller's objective to ease the regulatory burden on banks where consistent with adequate shareholder and public investor protection, the simplification process will continue. The Comptroller plans to publish in the near future the first of the three steps set forth in the preamble to the June 4, 1979 proposed amendments. It is anticipated that these three steps will be coordinated with similar proposals by the Federal Deposit Insurance Corporation and the Board of Governors of the Federal Reserve System.

The amendments will be effective as of December 31, 1979 except for the requirements of Item 6(g) of 12 CFR 11.51 which will be effective as of January 1, 1981.

(Section 12(i) of the Securities Exchange Act of 1934, 15 U.S.C. 78*l*(i))

Based on the foregoing, 12 CFR Part 11 is amended as set forth below:

Amendments

12 CFR Part 11 is amended as follows:

1. Section 11.4(g) is amended by revising paragraphs (g)(2), (g)(3), (g)(4) and adding paragraphs (g)(5), (g)(6), and (g)(7) to read as follows:

§ 11.4 Registration statements and reports.

* * * * *

(g) * * *

(2)(i) Any person who, after acquiring directly or indirectly the beneficial ownership of any equity security of a national or District bank of a class which is registered pursuant to Section 12 of the Act, *provided,* such term shall not include securities of a class of nonvoting securities, is directly or indirectly the benefical owner of more than five percent of such class shall, within 10 days after such acquisition, send to the bank at its principal executive office, by registered or certified mail, and to each exchange where the security is traded, and file with the Comptroller of the Currency, a statement containing the information required by Form F–11. Four copies of the statement, including all exhibits, shall be filed with the Comptroller of the Currency one of which should be manually signed.

(ii)(A) A person who would otherwise be obligated under paragraph (i) of this section to file a statement on Form F–11 may, in lieu thereof, file with the Comptroller of the Currency within 45 days after the end of the calendar year in which such person because so obligated four copies, including all exhibits of a short form statement on Form F–11A and send one copy of each such form to the bank at its principal excutive office by registered or certified mail and to the principal national securities exchange where the security is traded *Provided.* That it shall not be necessary to file a Form F–11A unless the percentage of the class of equity security specified in paragraph (i) of this section beneficially owned as of the end of the calendar year is more than five percent: And *provided further,* That:

(*1*) Such person has acquired such securities in the ordinary course of his business and not with the purpose nor with the effect of changing or influencing the control of the bank, nor in connection with or as a participant in any transaction having such purpose or effect, including any transaction subject to § 11.4(g)(4)(4)(ii); and

(*2*) Such person is:

(*i*) A broker or dealer registered under Section 15 of the Act:

(*ii*) A bank as defihned in Section 3(a)(6) of the Act:

(*iii*) An insurance company as defined in Section 3(a)(19) of the Act;

(*iv*) An investment company registered under Section 8 of the Investment Company Act of 1940;

(*v*) An investment adviser registered under Section 203 of the Investment Advisers Act of 1940;

(*vi*) An employee benefit plan, or pension fund which is subject to the provisions of the Employee Retirement Income Security Act of 1974 ("ERISA") or an endowment fund;

(*vii*) A parent holding company, provided the aggregate amount held directly by the parent, and directly and indirectly by its subsidiaries which are not persons specified in paragraph (g)(2)(ii)(A)(*2*)(*1*) through (*vi*) of this section, does not exceed one percent of the securities of the subject class;

(*viii*) A group, provided that all the members are persons specified in paragraph (g)(2)(ii)(A)(*2*)(*i*) through (*vii*) of this section; and

(*3*) Such person has promptly notified any other person (or group within the meaning of Section 13(d)(3) of the Act) on whose behalf it holds on a discretionary basis securities exceeding five percent of the class of any acquisition or transaction on behalf of such other person which might be reportable by that person under Section 13(d) of the Act. This paragraph only requires notice to the account owner of information which the filing person reasonably should be expected to know and which would advise the account owner of an obligation he may have to file a statement pursuant to Section 13(d) of the Act or an amendment thereto.

(B) Any person relying on § 11.4(g)(2)(ii)(A) and § 11.4(g)(3)(ii) shall, in addition to filing any statements required thereunder, file a statement on Form F–11A, within ten days after the end of the first month in

which such person's direct or indirect beneficial ownership exceeds ten percent of a class of equity securities specified in § 11.4(g)(2)(i) computed as of the last day of the month, and thereafter within ten days after the end of any month in which such person's beneficial ownership of securities of such class, computed as of the last day of the month, increases or decreases by more than five percent of such class of equity securities. Four copies of such statement, including all exhibits, shall be filed with the Comptroller of the Currency and one each sent by registered or certified mail, to the bank at its principal executive office and to the principal national securities exchange where the security is traded. Once an amendment has been filed reflecting beneficial ownership of five percent or less of the class of securities, no additional filings are required by this paragraph (ii)(B) unless the person thereafter becomes the beneficial owner of more than ten percent of the class and is required to file pursuant to this provision.

(C)(*1*) Notwithstanding paragraphs (ii)(A) and (ii)(B) and § 11.4(g)(3)(ii), a person shall immediately become subject to § 11.4(g)(2)(i) and § 11.4(g)(3)(i) and shall promptly, but not more than 10 days later, file a statement on Form F–11 if such person:

(*i*) Has reported that it is the beneficial owner of more than five percent of a class of equity securities in a statement on Form F–11A pursuant to paragraph (ii)(A) or (ii)(B), or is required to report such acquisition but has not yet filed the form:

(*ii*) Determines that it no longer has acquired or holds such securities in the ordinary course of business or not with the purpose nor with the effect of changing or influencing the control of the bank, nor in connection with or as a participant in any transaction having such purpose or effect including any transaction subject to § 11.4(g)(4)(ii); and

(*iii*) Is at that time the beneficial owner of more than five percent of a class of equity securities described in § 11.4(g)(2)(i).

(*2*) For the ten day period immediately following the date of the filing of a Form F–11 pursuant to this paragraph (ii)(C), such person shall not vote or direct the voting of the securities described in paragraph (ii)(C)(*1*)(*i*) nor acquire an additional beneficial ownership interest in any equity securities of the bank of such securities, nor of any person controlling the bank.

(D) Any person who has reported an acquisition of securities in a statement on Form F–11A pursuant to paragraph (ii)(A) or (ii)(B) and thereafter ceases to be a person specified in paragraph (ii)(A)(2) shall immediately become subject to § 11.4(g)(2)(i) and § 11.4(g)(3)(i) and shall file, within ten days thereafter, a statement on Form F–11 in the event such person is a beneficial owner at that time of more than five percent of the class of equity securities.

(iii) Any person who, as of December 31, 1979, or as of the end of any calendar year thereafter, is directly or indirectly the beneficial owner of more than five percent of any equity security of a class specified in paragraph (g)(2)(i) and who is not required to file a statement under paragraph (g)(2)(i) by virtue of the exemption provided by Section 13(d)(6)(A) or (B) of the Act, or because such beneficial ownership was acquired prior to December 22, 1970, or because such person otherwise (except for the exemption provided by Section 13(d)(6)(C) of the Act) is not required to file such statement, shall, within 45 days after the end of the calendar year in which such person became obligated to report under this paragraph, send to the bank at its principal executive office, by registered or certified mail, and file with the Comptroller of the Currency, a statement containing the information required by Form F–11A. Four copies of the statement, including all exhibits, shall be filed with the Comptroller of the Currency.

(iv) For the purposes of Sections 13(d) and 13(g), any person, in determining the amount of outstanding securities of a class of equity securities, may rely upon information set forth in the bank's most recent quarterly or annual report, and any current report subsequent thereto, filed with the Comptroller of the Currency pursuant to this Act, unless he knows or has reason to believe that the information contained therein is inaccurate.

(v)(A) Whenever two or more persons are required to file a statement containing the information required by Form F–11 or Form F–11A with respect to the same securities, only one statement need be filed, provided that:

(*1*) Each person on whose behalf the statement is filed is individually eligible to use the Form on which the information is filed;

(*2*) Each person on whose behalf the statement is filed is responsible for the timely filing of such statement and any amendments thereto, and for the completeness and accuracy of the information concerning such person contained therein; such person is not responsible for the completeness or accuracy of the information concerning the other persons making the filing, unless such person knows or has reason to believe that such information is inaccurate; and

(*3*) Such statement identifies all such persons, contains the required information with regard to each such person, indicates that such statement is filed on behalf of all such persons, and includes, as an exhibit, their agreement in writing that such a statement is filed on behalf of each of them.

(B) A group's filing obligations may be satisfied either by a single joint filing or by each of the group's members making an individual filing. If the group's members elect to make their own filings each such filing should identify all members of the group but the information provided concerning the other persons making the filing need only reflect information which the filing person knows or has reason to know.

(3)(i) Form F–11—If any material changes occur in the facts set forth in the statement required by § 11.4(g)(2)(i) including, but not limited to, any material increase or decrease in the percentage of the class beneficially owned, the person or persons who were required to file such statement shall promptly file or cause to be filed with the Comptroller of the Currency and send or cause to be sent to the bank at its principal executive office, by registered or certified mail, and to each exchange on which the security is traded, an amendment disclosing such change. An acquisition or disposition of beneficial ownership of securities in an amount equal to one percent or more of the class of securities shall be deemed "material" for purposes of this section; acquisitions or dispositions of less than such amounts may be material, depending upon the facts and circumstances. The requirement that an amendment be filed with respect to an acquisition which materially increases the percentage of the class beneficially owned shall not apply if such acquisition is exempted by Section 13(d)(6)(B) of the Act. Four copies of each such amendment shall be filed with the Comptroller of the Currency.

(ii) Form F–11A—Notwithstanding paragraph (i) of the section and provided that the person or persons filing a statement pursuant to § 11.4(g)(2)(ii) continues to meet the requirements set forth therein, any person who has filed a short form statement on Form F–11A shall amend such statement within 45 days after the end of each calendar year to reflect, as of the end of the calendar year, any changes in the information reported in the previous filing on that Form, or if there are no changes from the previous filing, a signed statement to that effect

under cover of Form F-11A. Four copies of such amendment, including all exhibits, shall be filed with the Comptroller of the Currency and one each sent, by registered or certified mail, to the bank at its principal executive office and to the principal national securities exchange where the security is traded. Once an amendment has been filed reflecting beneficial ownership of five percent or less of the class of securities, no additional filings are required unless the person thereafter becomes the beneficial owner of more than five percent of the class and is required to file pursuant to § 11.4(g)(2).

Note.—For persons filing a short form statement pursuant to § 11.4(g)(2)(ii), see also § 11.4(g)(2)(iii), (iv) and (v).

(4)(i) For the purposes of Sections 13(d), 13(g) and 14(d) of the Act, a beneficial owner of a security includes any person who, directly or indirectly, through any contract, arrangement, understanding, relationship, or otherwise has or shares:

(A) Voting power which includes the power to vote, or to direct the voting of, such security; and/or

(B) Investment power which includes the power to dispose, or to direct the disposition of, such security.

(ii) Any person who, directly or indirectly, creates or uses a trust, proxy, power of attorney, pooling arrangement, or any other contract, arrangement, or device with the purpose or effect of divesting such person of beneficial ownership of a security or preventing the vesting of such beneficial ownership as part of a plan or scheme to evade the reporting requirements of Sections 13(d), 13(g) and 14(d) of the Act shall be deemed for purposes of such sections to be the beneficial owner of such security.

(iii) All securities of the same class beneficially owned by a person, regardless of the form which such beneficial ownership takes, shall be aggregated in calculating the number of shares beneficially owned by such person.

(iv) Notwithstanding the provisions of paragraphs (i) and (iii) of this section:

(A)(*1*) A person shall be deemed to be the beneficial owner of a security, subject to the provisions of paragraph (ii) of this section, if that person has the right to acquire beneficial ownership of such security, as defined in § 11.4(g)(4)(i) within sixty days, including but not limited to any right to acquire: (*i*) through the exercise of any option, warrant, or right; (*ii*) through the conversion of a security; (*iii*) pursuant to the power to revoke a trust, discretionary account, or similar arrangement; or (*iv*) pursuant to the automatic termination of a trust, discretionary account or similar arrangement; provided, however, any person who acquires a security or power specified in paragraph (g)(4)(iv)(A)(*1*) (*i*), *(ii)* or *(iii)* of this section with the purpose or effecting of changing or influencing the control of the bank, or in connection with or as a participant in any transaction having such purpose or effect, immediately upon such acquisition shall be deemed to be the beneficial owner of the securities which may be acquired through the exercise or conversion of such security or power. Any securities not outstanding which are subject to such options, warrants, rights or conversion privileges shall be deemed to be outstanding securities of the class owned by such person but shall not be deemed to be outstanding for the purpose of computing the percentage of the class owned by any other person.

(*2*) Paragraph (A)(*1*) remains applicable for the purpose of determining the obligation to file with respect to the underlying security even though the option, warrant, right or convertible security is of a class of equity security, as defined in § 11.4(g)(2)(i) and may therefore give rise to a separate obligation to file.

(B) A member of a national securities exchange shall not be deemed to be a beneficial owner of securities held directly or indirectly by it on behalf of another person solely because such member is the record holder of such securities and pursuant to the rules of such exchange may direct the vote of such securities, without instruction, on other than contested matters or matters that may affect substantially the rights or privileges of the holders of the securities to be voted, but is otherwise precluded by the rules of such exchange from voting without instruction.

(C) A person who in the ordinary course of business is a pledgee of securities under a written pledge agreement shall not be deemed to be the beneficial owner of such pledged securities until the pledgee has taken all formal steps necessary which are required to declare a default and determines that the power to vote or to direct the vote or to dispose or to direct the disposition of such pledged securities will be exercised provided that:

(*1*) The pledge agreement is bona fide and was not entered into with the purpose nor with the effect of changing or influencing the control of the bank, nor in connection with any transaction having such purpose or effect, including any transaction subject to § 11.4(g)(4)(ii):

(*2*) The pledgee is a person specified in § 11.4(g)(2)(ii)(A)(2), including persons meeting the conditions set forth in paragraph (g) thereof; and

(*3*) The pledge agreement, prior to default, does not grant to the pledgee:

(i) The power to vote or to direct the vote of the pledged securities; or

(ii) The power to dispose or direct the disposition of the pledged securities other than the grant of such power(s) pursuant to Regulation T (12 CFR §§ 201.1 to 220.81) and in which the pledgee is a broker or dealer registered under Section 15 of the Act.

(D) A person engaged in business as an underwriter of securities who acquires securities through his participation in good faith in a firm commitment underwriting through the use of an offering circular filed pursuant to 12 CFR Part 16 shall not be deemed to be the beneficial owner of such securities until the expiration of forty days after the date of such acquisition.

(5) Any person may expressly declare in any statement filed that the filing of such statement shall not be construed as an admission that such person is for the purposes of Sections 13(d), 13(g) or 14(d) of the Act, the beneficial owner of any securities covered by the statement.

(6)(i) A person who becomes a beneficial owner of securities shall be deemed to have acquired such securities for purposes of Section 13(d)(1) of the Act, whether such acquisition was through purchases or otherwise. However, executors or administrators of a decedent's estate generally will be presumed not to have acquired beneficial ownership of the securities in the decedent's estate until such time as such executors or administrators are qualified under local law to perform their duties.

(ii)(A) When two or more persons agree to act together for the purpose of acquiring, holding, voting or disposing of equity securities of a bank, the group formed thereby shall be deemed to have acquired beneficial ownership, for purposes of Sections 13(d), 13(g) and 14 (d) of the Act, as of the date of such agreement, of all equity securities of that bank beneficially owned by any such persons.

(b) Notwithstanding the previous paragraph, a group shall be deemed not to have acquired any equity securities beneficially owned by the other members of the group solely by virtue of their concerted actions relating to the purchase of equity securities directly from a bank in a transaction not involving a public offering; provided that:

(1) all the members of the group are persons specified in § 11.4(g)(2)(ii)(A)(2);

(2) The purchase is in the ordinary course of each member's business and not with the purpose nor with the effect of changing or influencing control of the bank, nor in connection with or as a participant in any transaction having such purpose or effect, including any transaction subject to § 11.4(g)(4)(ii);

(3) There is no agreement among or between any members of the group to act together with respect to the bank or its securities except for the purpose of facilitating the specific purpose involved; and

(4) The only actions among or between any members of the group with respect to the bank or its securities subsequent to the closing date of the non-public offering are those which are necessary to conclude ministerial matters directly related to the completion of the offer or sale of the securities.

(7) The acquisition of securities of a bank by a person who, prior to such acquisition, was a beneficial owner of more than five percent of the outstanding securities of the same class as those acquired shall be exempt from Section 13(d) of the Act, provided that:

(i) The acquisition is made pursuant to preemptive subscription rights in an offering made to all holders of securities of the class to which the preemptive subscription rights pertain;

(ii) Such person does not acquire additional securities except through the exercise of his pro rata share of the premptive subscription rights; and

(iii) the acquistion is duly reported, if required, pursuant to section 16(a) of the Act and the rules and regulations thereunder.

2. Section 11.5(k) is amended by adding a new subparagraph (5) to read as follows:

§ 11.5 Proxies, proxy statements, and statements where management does not solicit proxies.

* * * * *

(k) *Proposals of security holders* * * *

(5) If management intends to include in the proxy statement a statement in opposition to a proposal received from a proponent, it shall, not later that ten calendar days prior to the date the preliminary copies of the proxy statement and form of proxy are filed pursuant to § 11.5(f), or, in the event that the proposal must be revised to be includable, not later than five calendar days after receipt by the bank of the revised proposal, promptly forward to the proponent a copy of the statement in opposition to the proposal. In the event the proponent believes that the statement in opposition contains materially false or misleading statements within the meaning of § 11.5(h) and the proponent wishes to bring this matter to the attention of the Comptroller, the proponent should promptly provide the Comptroller with a letter setting forth the reasons for this view and at the same time promptly provide management with a copy of such letter.

3. Section 11.5(l) is amended by revising subparagraph (1) as follows:

(l) *Tender Offers.* (1) No person, directly or indirectly by use of the mails or any means or instrumentality of interstate commerce or any facility of a national securities exchange or otherwise, shall make a tender offer for, or a request or invitation for tenders of any class of equity security, which is registered pursuant to Section 12 of the Act, of a national bank or a bank operating under the Code of Law for the District of Columbia, if, after consummation thereof, such person would, directly or indirectly, be the beneficial owner of more than 5 percent of such class, unless, at the time copies of the offer or request or invitation are first published or sent or given to security holders, such person has filed with the Comptroller of the Currency a statement containing the information and exhibits requred by Form F-13. The definition of beneficial owner set forth in § 11.4(g) for the purposes of Section 13(d)(1) of the Act shall apply also for purposes of Section 14(d)(1) of the Act

* * * * *

4(a) Section 11.41, Item 4, Instruction 3 is added; Items 8, 10, 11 and 12 are amended to read as follows:

§ 11.41 Form for registration of securities of a bank pursuant to section 12(b) or section 12(g) of the Securities Exchange Act of 1934 (Form F-1)

* * * * *

Item 4—Summary of Operations

* * * * *

3. Fully discuss the changes in earnings for the last two fiscal years. Material changes in the revenue and expense accounts should be described in percentage terms and absolute amounts and fully explained.

Item 8—Directors and Officers

(a) *Identification of directors and officers.* List all directors and officers of the bank and all persons chosen to become directors or officers. Indicate all positions and offices with the bank held by each person named. State the age of the persons named, their terms of office, and the periods during which each such person has served. Briefly describe any arrangement or understanding between each director and officer and any other person pursuant to which such director or officer was selected to serve in that capacity. The term "officer" is defined in § 11.2(o).

Instructions. Do not include any arrangements or understandings with directors or officers of the bank acting solely in their capacities as such.

(b) *Family relationships.* The information required by Item 6(b) of § 11.51 shall be reported for both directors and officers pursuant to this Item 8(b).

(c) *Identification of certain significant employees.* Where the bank employs persons such as special consultants or attorneys who are not officers, but who make or are expected to make significant contributions to the business of the bank, such persons should be identified and their background disclosed to the same extent as in the case of officers.

(d) *Business experience.* (1) Give a brief account of the business experience during the past five years of each director, officer or person chosen to become a director and officer and each person named in response to paragraph (c), including principal occupations and employment during that period, and the name and principal business of any corporation or other organization in which such occupations and employment were carried on. When an officer or person named in response to paragraph (c), has been employed by the bank or a subsidiary of the bank for less than five years, a brief explanation should be included as to the nature of the responsibilities undertaken by the individual in prior positions in order to provide adequate disclosure of his prior business experience. What is required is information relating to the level of his professional competence which may include, depending upon the circumstances, such specific information as the size of the operation surpervised.

(2) Indicate any other directorships held by each director or person chosen to become a director in any company with a class of securities registered pursuant to Section 12 of the Act.

(e) *Involvement in certain legal proceedings.* The information required by Item 6(d) of § 11.51, shall be reported for both directors and officers pursuant to this Item 8(e).

Item 10—Remuneration and Other Transactions With Management and Others

The information required by Item 7 of § 11.51 shall be reported pursuant to this Item.

Note.—The information required by Item 7(c) of § 11.51 need not be reported pursuant to this Item. Also, the information required by Items 7 (d), (e) and (f) of § 11.51 need not be included for any nominee for election as a director.

Item 11—Options to Purchase Securities

The information required by Item 7(c) of § 11.51 shall be reported pursuant to this Item.

Item 12—Security Ownership of Certain Beneficial Owners and Management

The information required by Items 5 (d), (e) and (g) of § 11.51, shall be reported pursuant to this Item.

Note.—The information required by Item 5(e) of § 11.51 need not be included for any nominee for election as a director.

(b) Present Item 13, Interest of Management and Others In Certain Transactions has been combined with and into New Item 10, Remuneration and Other Transactions with Management and Others. Accordingly, present Items 14, 15, 16, 17, 18, 19 and 20 are renumbered respectively Item 13, 14, 15, 16, 17, 18 and 19.

* * * * *

5. Section 11.42, Item 4, Instruction 3 is added; Item 5, Instruction 2 and Item 11 are amended to read as follows:

§ 11.42 Form for annual report of bank (Form F–2)

* * * * *

Item 4—Summary of Operations

* * * * *

3. Fully discuss the changes in earnings for the last two fiscal years. Material changes in the revenue and expense accounts should be described in percentage terms and absolute amounts and fully explained.

Item 5—Pending Legal Proceedings

* * * * *

2. Any material proceedings to which any director, officer, or affiliate of the bank, any person holding in excess of 5 percent of the bank's outstanding stock, or any associate of any such director, officer or security holder is a party or has an interest materially adverse to the bank or any of its subsidiaries shall also be described.

* * * * *

Item 11—Officers of the Bank

(a) *Identification of officers.* List all officers of the bank and all persons chosen to become officers. Indicate all positions and offices with the bank held by each person named. State the age of the person named, their term of office, and the periods during which each such person has served. Briefly describe any arrangement or understanding between the person and any other person pursuant to which the person was elected as an officer.

Instructions. Do not include any arrangements or understandings with officers of the bank acting solely in their capacities as such.

(b) *Family relationships.* The information required by Item 6(b) of § 11.51 shall be reported pursuant to this Item 11(b).

(c) *Identification of certain significant employees.* The information required by Item 8(c) of § 11.41 shall be reported pursuant to this Item 11(c).

(d) *Business experience.* (1) Give a brief account of the business experience during the past five years of each officer or person chosen to become an officer, and each person named in answer to paragraph (c), including principal occupations and employment during that period, and the name and principal business of any corporation or other organization in which such occupations and employment were carried on. When an officer or person named in response to paragraph (c), has been employed by the bank or a subsidiary of the bank for less than five years, a brief explanation should be included as to the nature of the responsibilities undertaken by the individual in prior positions in order to provide adequate disclosure of his prior business experience. What is required is information relating to the level of his professional competence which may include, depending upon the circumstances, such specific information as the size of the operation supervised.

(2) Indicate any other directorship held by each officer or person chosen to become an officer in any company with a class of securities registered pursuant to Section 12 of the Act.

(e) *Involvement in certain legal proceedings.* The information required by Item 6(d) of § 11.51 shall be reported pursuant to this Item 11(e).

* * * * *

6. Section 11.43, Item 2, Instruction 6 is revised; Item 4(e) is added; Present Items 5 and 6 are redesignated 6 and 7; new Item 5 is added. Item 6 is presented for clarity and Item 7 is amended as shown below.

§ 11.43 Form for current report of a bank (Form F–3)

* * * * *

Item 2—Acquisition or Disposition of Assets

* * * * *

Instructions. 1. * * *

* * * * *

6. Attention is directed to the requirements in Item 7 of the form with respect to the filing of financial statements for businesses acquired and to the filing of copies of the plans of acquisition or disposition as exhibits to the report.

Item 4—Changes in Bank's Certifying Accountant

* * * * *

(e) State whether the decision to change accountants was recommended or approved by:

(1) Any audit or similar committee of the Board of Directors, if the bank has such a committee; or

(2) The Board of Directors, if the bank has no such committee.

Item 5—Resignations of Bank's Directors

(a) If a director has resigned or declined to stand for re-election to the Board of Directors since the date of the last annual meeting of shareholders because of a disagreement with the bank on any matter relating to the bank's operations, policies, or practices, and if the director has furnished the bank with a letter describing such disagreement and requesting that the matter be disclosed, the bank shall state the date of such resignation or declination to stand for re-election and summarize the director's description of the disagreement.

(b) If the bank believes that the description provided by the director is incorrect or incomplete, it may include a brief statement presenting its views of the disagreement.

(c) The bank shall file a copy of the director's letter as an exhibit with all copies of this Form F–3.

Item 6—Other Materially Important Events

The Bank may, at its option, report under this item any events, with respect to which information is not otherwise called for by this form, which the bank deems of material importance to security holders.

Item 7—Financial Statements and Exhibits

* * * * *

Exhibits

Subject to the rules as to incorporation by reference, the following documents shall be filed as exhibits to this report.

1. * * *

2. Letters from directors furnished pursuant to Item 5.

* * * * *

7. Section 11.44, Items 1, Instruction 3 is revised; Item 6(d) is added; and Instruction 6 is added. Such provisions to read as follows:

§ 11.44 Form for quarterly report of bank (Form F–4.)

* * * * *

Item 1—Legal Proceedings

* * * * *

3. Notwithstanding the foregoing instructions, any bankruptcy, conservatorship, receivership or similar proceedings with respect to the bank or any of its significant subsidiaries shall be described. Any material proceeding to which any director, officer or affiliate of the bank any person holding in excess of 5 percent of the bank's outstanding stock, or any associate of any such director, officer or security holder is a party or has an interest materially adverse to the bank or any of its subsidiaries shall also be described.

Item 6—Submission of Matters to a Vote for Security Holders

* * * * *

(d) Describe the terms of any settlement between the bank and any other participant (as defined in § 11.5(i)) terminating any solicitation subject to § 11.5(i) including the cost or anticipated cost to the bank.

Instructions. 1.

* * * * *

6. If the bank has furnished to its security holders proxy soliciting material containing the information called for by paragraph (d), the paragraph may be answered by reference to the information contained in such material.

* * * * *

8. Section 11.47, Form F–11 is amended to read as follows; in Item 2, paragraphs (b), (d) and (e) are revised; new (f) is added; Item 5 is revised. Such provisions to read as follows:

§ 11.47 Form for statement filed pursuant to § 11.4(g)(2) of Part 11 (Form F–11).

Comptroller of the Currency Form F–11

Acquisition Statement To Be Filed Pursuant to Section 13(d) of the Securities Exchange Act of 1934 and § 11.4(g)(2) (Amendment No. ——)

(Name of Bank)

(Title of Class of Securities)

(CUSIP No.)

(Name, Address and Telephone Number of Person Authorized to Receive Notices and Communications)

(Date of Event which Requires Filing of this Statement)

If the filing person has previously filed a statement on Form F–11A to report the acquisition which is the subject of this Form F–11, and is filing this form because of § 11.4(g)(2)(ii) (C) or (D), check the following box [ ].

Note.—Four copies of this form, including all exhibits, should be filed with the Comptroller of the Currency. See § 11.4(g)(2)(i) for other parties to whom copies are to be sent.

The information required in the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Note).

CUSIP No.

(1) Name of Reporting Person: S.S. or I.R.S. Identification Nos. of Above Person

(2) Check the Appropriate Box if a Member of a Group (See Instructions)
(a)
(b)

(3) Source of Funds (see Instructions)

(4) Check if disclosure of Legal Proceedings is Required Pursuant to Item 2(e)

(5) Citizenship or Place of Organization

Number of shares beneficially owned by each reporting person with:
(6) Sole Voting Power
(7) Shared Voting Power
(8) Sole Dispositive Power
(9) Shared Dispositive Power

(10) Aggregate Amount Beneficially Owned by Each Reporting Person

(11) If the Aggregate Amount in Row 10 Excludes Certain Shares List the Number of Excluded Shares

(12) Percent of Class Represented by Amount in Row 10

(13) Type of Reporting Person (See Instructions)

Instructions for Cover Page

(1) Names and Social Security Numbers of Reporting Persons. Furnish the full legal name of each person for whom the report is filed—*i.e.*, such person required to sign the form itself—including each member of a group.

Do not include the name of a person required to be identified in the report but who is not a reporting person. Reporting persons are also requested to furnish their Social Security or I.R.S. identification numbers, although disclosure of such numbers is voluntary, not mandatory (see "Special Instructions for Complying with Form F–11" below).

(2) If any of the shares beneficially owned by a reporting person are held as a member of a group and such membership is expressly affirmed, please check row 2(a). If the membership in a group is disclaimed to the extent that the reporting person describes a relationship with other persons but does not affirm the existence of a group, please check row 2(b) (unless a joint filing pursuant to § 11.4(g)(2)(v) in which case it may not be necessary to check row 2(b)).

(3) Classify the source of funds or other consideration used or to be used in making the purchases as required to be disclosed pursuant to Item 3 of Form F–11 and insert the appropriate symbol (or symbols if more than one is necessary in row (3)):

Category of source:	Symbol
Subject Bank (Bank whose securities are being acquired)	SB
Another Bank	BK
Affiliate (of reporting person)	AF
Working Capital (of reporting person)	WC
Personal Funds (of reporting person)	PF
Other	OO

(4) If disclosure of legal proceedings or actions is required pursuant to Item 2(e) of Form F–11 row 4 should be checked.

(5) *Citizenship or Place of Organization*—Furnish citizenship if the named reporting person is a natural person. Otherwise, furnish its place of organization. (See Item 2 of Form F–11).

(6)–(10), (12) *Aggregate Amount Beneficially Owned by Each Reporting Person, etc.*—Rows (6) through (10), inclusive, and (12) are to be completed in accordance with the provisions of Item 5 of Form F–11. All percentages are to be rounded off to nearest tenth (one place after decimal point).

(13) *Type of Reporting Person*—Please classify each "reporting person" according to the following breakdown and place the appropriate symbol (or symbols, *i.e.*, if more than one is applicable, insert all applicable symbols) on the form:

Category	Symbol
Broker Dealer	BD
Bank	BK
Insurance Company	IC
Investment Company	IV
Investment Adviser	IA
Employee Benefit Plan, Pension Fund, or Endowment Fund	EP
Parent Holding Company	HC
Corporation	CO
Partnership	PN
Individual	IN
Other	OO

Note.—Filing persons may, in order to avoid unnecessary duplication, answer items on the form by appropriate cross references to an item or items on the cover page(s). This approach may only be used where the cover page item or items provide all the disclosure required by the form item. Moreover, such a use of a cover page item will result in the item becoming a part of the form and accordingly being considered as "filed" for purposes of Section 18 of the Securities Exchange Act or otherwise subject to the liabilities of that section of the Act.

Special Instructions for Complying With Form F–11

Under Sections 13(d) and 23 of the Securities Exchange Act of 1934 and the rules and regulations thereunder, the Comptroller of the Currency is authorized to solicit the information required to be supplied by this schedule by certain security holders of certain banks.

Disclosure of the information specified in this schedule is mandatory, except for Social Security or I.R.S. identification numbers, disclosure of which is voluntary. The information will be used for the primary purpose of determining and disclosing the holdings of certain beneficial owners of certain equity securities. This statement will be made a matter of public record. Therefore, any information given will be available for inspection by any member of the public.

Failure to disclose the information requested by this schedule, except for Social Security or I.R.S. identification numbers, may result in civil or criminal action against the persons involved for violation of the Federal securities laws and rules promulgated thereunder.

General Instructions

* * * * *

Item 2—Identity and Background

* * * * *

(b) Residence or business address;
(c) * * *
(d) Whether or not, during the last five years, such person has been convicted in a criminal proceeding (excluding traffic violations or similar misdemeanors) and, if so, give the dates, nature of conviction, name and location of court, any penalty imposed, or other disposition of the case;
(e) Whether or not, during the last full five years, such person was a party to a civil proceeding of a judicial body of competent jurisdiction and as a result of such proceeding was or is subject to a judgment, decree or final order enjoining future violations of, or prohibiting or mandating activities subject to federal or state securities laws, or finding any violation with respect to such laws; and if so, identify and describe such proceedings and summarize the terms of such judgment, decree or final order, and
(f) Citizenship.

* * * * *

Item 5—Interest in Securities of the Bank

(a) State the aggregate number and percentage of the class of securities identified pursuant to Item 1 (which may be based on the number of securities outstanding as contained in the most recently available filing with the Comptroller of the Currency by the bank unless the filing person has reason to believe such information is not current) beneficially owned (identifying those shares which there is a right to acquire) by each person named in Item 2. The above mentioned information should also be

furnished with respect to persons who, together with any of the persons named in Item 2, comprise a group within the meaning of Section 13(d)(3) of the Act;

(b) For each person named in response to paragraph (a), indicate the number of shares as to which there is sole power to vote or to direct the vote, shared power to vote or to direct the vote, sole power to dispose or to direct the disposition, or shared power to dispose or to direct the disposition. Provide the applicable information required by Item 2 with respect to each person with whom the power to vote or to direct the vote or to dispose or direct the disposition is shared;

(c) Describe any transactions in the class of securities reported on that were effected during the past sixty days or since the most recent filing on Form F–11, whichever is less, by the persons named in response to paragraph (a).

Instruction. The description of a transaction required by Item 5(c) shall include, but not necessarily be limited to: (1) the identity of the person covered by Item 5(c) who effected the transaction; (2) the date of the transaction; (3) the amount of securities involved; (4) the price per share or unit; and (5) where and how the transaction was effected.

(d) If any other person is known to have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, such securities, a statement to that effect should be included in response to this item and, if such interest relates to more than five percent of the class, such person should be identified.

(e) If applicable, state the date on which the reporting person ceased to be the beneficial owner of more than five percent of the class of securities.

Instruction. For computations regarding securities which represent a right to acquire an underlying security, see § 11.4(g)(4)(iv) and the note thereto.

* * * * *

9. Section 11.48, Form F–11A is added to Part 11 and reads as follows:

§ 11.48 Short form ownership statement to be filed pursuant to § 11.4(g)(2)(ii) and amendments thereto filed pursuant to § 11.4(g)(3)(ii) of Part 11 (Form F–11A).

Comptroller of the Currency Form F–11A

Short Form Ownership Statement To Be Filed Pursuant to Section 13(d) of the Securities Exchange Act of 1934 § 11.4(g)(2)(ii) and Amendments Thereto Filed Pursuant to § 11.4(g)(3)(ii)

(Amendment No. ———)

(Name of Bank)

(Title of Class of Securities)

(CUSIP Number)

The information required in the remainder of this cover page shall not be deemed to be "filled" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Note).

(1) Names of Reporting Person S.S. or I.R.S. Identification Nos. of Above Person

(2) Check the Appropriate Box if a Member of a Group (See Instructions).
(a) ———
(b) ———

(3) Citizenship or Place of Organization

Number of Shares Beneficially Owned by Each Reporting Person With:
(4) Sole Voting Power ———
(5) Shared Voting Power ———
(6) Sole Dispositive Power ———
(7) Shared Dispositive Power ———
(8) Aggregate Amount Beneficially Owned by Each Reporting Person ———
(9) If the Aggregate Amount in Row 8 Excludes Certain Shares list the Number of Excluded Shares (See Instructions) ———
(10) Percent of Class Represented in Row 8

(11) Type of Reporting Person (See Instructions) ———

Instructions for Cover Page

(1) *Names and Social Security Numbers of Reporting persons*—Furnish the full legal name of each person for whom the report is filed—*i.e.*, each person required to sign the form itself—including each member of a group. Do not include the name of a person required to be identified in the report but who is not a reporting person. Reporting persons are also requested to furnish their Social Security or I.R.S. identification numbers, although disclosure of such numbers is voluntary, not mandatory (see "Special Instructions for Complying With Form F–11A," below).

(2) If any of the shares beneficially owned by a reporting person are held as a member of a group and such membership in a group is disclaimed or the reporting person describes a relationship with other persons but does not affirm the existence of a group, please check row 2(b) [unless a joint filing pursuant to § 11.4(g)(2)(v) in which case it may not be necessary to check row 2(b)].

(3) *Citizenship of Place of Organization*—Furnish citizenship if the named reporting person is a natural person. Otherwise, furnish place of organization.

(4)–(8). (10) *Aggregate Amount Beneficially Owned By Each Reporting Person etc.*—Rows (4) through (8) inclusive, and (10) are to be completed in accordance with the provisions of Item 4 of Form F–11A. All percentages are to be rounded off to the nearest tenth (one place after decimal point).

(12) *Type of Reporting Person.*—Please classify each "reporting person" according to the following breakdown (see Item 3 of Form F–11A) and place the appropriate symbol on the form:

Category:	Symbol
Broker Dealer	BD
Bank	BK
Insurance Company	IC
Investment Company	IV
Investment Adviser	IA
Employee Benefit Plan, Pension Fund, or Endowment Fund	EP
Parent Holding Company	HC
Corporation	CO
Partnership	PN
Individual	IN
Other	OO

Note.—Filing person may, in order to avoid unnecessary duplication, answer items on the form by appropriate cross references to an item or items on the cover page(s). This approach may only be used where the cover page item or items provide all the disclosure required by the schedule item. Moreover, such use of a cover page item will result in the item becoming a part of the schedule and accordingly being considered as "filed" for purposes of Section 18 of the Securities Exchange Act or otherwise subject to the liabilities of that section of the Act.

Special Instructions for Complying With Form F–11A

Under Section 13(d), 13(g), and 23 of the Securities Exchange Act of 1934 and the rules and regulations thereunder, the Comptroller of the Currency is authorized to solicit the information required to be supplied by this schedule by certain security holders of certain banks.

Disclosure of the information specified in this schedule is mandatory, except for Social Security or I.R.S. identification numbers the disclosure of which is voluntary. The information will be used for the primary purpose of determining and disclosing the holdings of certain beneficial owners of certain equity securities. This statement will be made a matter of public record. Therefore, any information given will be available for inspection by any member of the public.

Failure to disclose the information requested by this schedule, except for Social Security or I.R.S. identification numbers, may result in civil or criminal action against the persons involved for violation of the Federal securities laws and rules promulgated thereunder.

Item 1(a)—Name of Bank

Item 1(b)—Address of Bank's Principal Office

Item 2(a)—Name of Person Filing

Item 2(b)—Address of Principal Business Office or, if None, Residence

Item 2(c)—Citizenship

Item 2(d)—Title of Class of Securities

Item 2(e)—CUSIP Number

Item 3—If This Statement Is Filed Pursuant to §§11.4(g)(2)(i) or 11.4(g)(3)(ii), Check Whether the Person Filing is a

(a) [ ] Broker or Dealer registered under section 15 of the Act

(b) [ ] Bank as defined in Section 3(a)(6) of the Act

(c) [ ] Insurance Company as defined in Section 3(a)(19) of the Act

(d) [ ] Investment Company registered under Section 8 of the Investment Company Act

(e) [ ] Investment Adviser registered under Section 203 of the Investment Advisers Act of 1940

(f) [ ] Employee Benefit Plan, Pension Fund which is subject to the provisions of the Employee Retirement Income Security Act of 1974 or Endowment Fund

(g) [ ] Parent Holding Company, in accordance with § 11.4(g)(2)(ii)(A)(*2*)(*vii*) (Note: See Item 7)

(h) [ ] Group, in accordance with § 11.4(g)(2)(ii)(A)(*2*)(*viii*)

Item 4—Ownership

If the percent of the class owned, as of December 31 of the year covered by the statement, or as of the last day of any month described in § 11.4(g)(2)(b) if applicable, exceeds five percent, provide the following information as of that date and identify those shares for which there is a right to acquire.

(a) Amount Beneficially Owned

(b) Percent of Class

(c) Number of shares as to which such person has:

(i) sole power to vote or to direct the vote ————

(ii) shared power to dispose or to direct the disposition of ————

(iii) shared power to dispose or to direct the disposition of ————

Instruction: For computation regarding securities which represent a right to acquire an underlying security see § 11.4(g)(4)(iv)(A).

Item 5—Ownership of 5 Percent or Less of a Class

If this statement is being filed to report the fact that as of the date hereof the reporting person has ceased to be the beneficial owner of more than five percent of the class of securities, check the following [ ].

Instructions: Dissolution of a group requires a response to this item.

Item 6—Ownership of More Than 5 Percent on Behalf of Another Person

If any other person is known to have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, such securities, a statement to that effect should be included in response to this item and, if such interest relates to more then five percent of the class, such person should be identified. A listing of the shareholders of an investment company registered under the Investment Company Act of 1940 or the beneficiaries of employee benefit plan, pension fund or endowment fund is not required.

Item 7—Identification and Classification of the Subsidiary Which Acquired the Security Being Reported on by the Parent Holding Company

If a parent holding company has filed this schedule, pursuant to § 11.4(g)(2)(ii)(A)(*2*)(*vii*), so indicate under Item 3(g) and attach an exhibit stating the identity and the Item 3 classification of the relevant subsidiary. If a parent holding company has filed this schedule pursuant to § 11.4(g)(2)(iii), attach an exhibit stating the identification of the relevant subsidiary.

Item 8—Identification and Classification of Members of the Group

If a group has filed this schedule pursuant to § 11.4(g)(2)(ii)(A)(*2*)(*viii*), so indicate under Item 3(h) and attach an exhibit stating the identity and Item 3 classification of each member of the group. If a group has filed this schedule pursuant to § 11.4(g)(2)(iii), attach an exhibit stating the identity of each member of the group.

Item 9—Notice of Dissolution of Group

Notice of dissolution of a group may be furnished as an exhibit stating the date of the dissolution and that all further filings with respect to transactions in the security reported on will be filed, if required, by members of the group, in their individual capacity. See Item 5.

Item 10—Certification

The following certification shall be included if the statement is filed pursuant to § 11.4(g)(2)(ii).

By signing below I certify that, to the best of my knowledge and belief, the securities referred to above were acquired in the ordinary course of business and were not acquired for the purpose of and do not have the effect of changing or influencing the control of the bank and were not acquired in connection with or as a participant in any transaction having such purposes or effect.

Signature.

After reasonable inquiry and to the best of my knowledge and belief, I certify that the information set forth in this statement is true, complete and correct.

Date

Signature

Name/Title

The original statement shall be signed by each person on whose behalf the statement is filed, or by his authorized representative. If the statement is signed on behalf of a person by his authorized representative (other than an executive officer or general partner of the filing person), evidence of the representative's authority to sign on behalf of such person shall be filed with the statement. The name and any title of each person who signs the statement shall be typed or printed beneath his signature.

Note.—Four copies of this statement, including all exhibits, should be filed with the Comptroller of the Currency.

10. Section 11.51, items 3(b), 5(d), 5(e), 5(f), 5(g), 6, 7, 8 and 14(b)(7)(ii) are amended as follows:

§ 11.51 Form for proxy statement or statement where management does not solicit proxies (Form F–5).

* * * * *

Item 3—Persons Making the Solicitation

(a) * * *

(b) * * *

(6) If any such solicitation is terminated pursuant to a settlement between the bank and any other participant in such solicitation, describe the terms of such settlement, including the cost or anticipated cost thereof to the bank.

Instructions. 1. * * *

2. The information required pursuant to paragraph (b)(6) of this item should be included in any amended or revised proxy statement or other soliciting material relating to the same meeting or subject matter furnished to security holders by the bank subsequent to the date of settlement.

* * * * *

Item 5—Voting Securities and Principal Holders Thereof

(a) * * *

(b) * * *

(c) * * *

(d) *Security ownership of certain beneficial owners.* Furnish the following information as of the most recent practicable date in substantially the tabular form indicated, with respect to any person (including any "group" as the term is used in Section 13(d)(3) of the Securities Exchange Act of 1934) who is known to the bank to be the beneficial owner of more than five percent of any class of the bank's securities. Show in Column (3) the total number of shares beneficially owned and in Column (4) the percent of class so owned. Of the number of shares shown in Column (3), indicate by footnote or otherwise the amount of shares with respect to which such listed beneficial owner has the right to acquire beneficial ownership, as specified in § 11.4(g)(4)(iv)(A).

(1) Title of class	(2) Name and address of beneficial owner	(3) Amount of and nature of beneficial ownership	(4) Percent of class

(e) *Security ownership of management.* Furnish the following information, as of the most recent practicable date in substantially the tabular form indicated, as to each class of equity securities of the bank or any of its parents or subsidiaries other than directors qualifying shares, beneficially owned by all directors and nominees, naming them and directors and officers of the bank as a group, without naming them. Show in Column (2) the total number of shares beneficially owned and in Column (3) the percent of class so owned. Of the number of shares shown in Column (2), indicate, by footnote or otherwise, the amount of shares with respect to which such persons have the right to acquire beneficial ownership as specified in § 11.4(g)(4)(iv)(A).

(1) Title of class	(2) Amount and nature of beneficial ownership	(3) Percent of class

(f) If, to the knowledge of the persons on whose behalf the solicitation is made, a change in control of the bank has occurred since the beginning of its last fiscal year, state the name of the person(s) who acquired such control, the amount and the source of the consideration used by such person(s), the basis of the control, the date and a description of the transaction(s) which resulted in the change of control, the percentage of voting securities of the bank now beneficially owned directly or indirectly by the person(s) who acquired control, and the identity of the person(s) from whom control was assumed. If the source of all or any part of the consideration used is a loan made in the ordinary course of business by a bank as defined by Section 3(a)(6) of the Act, the identity of such bank shall be omitted,

provided a request for confidentiality has been made pursuant to Section 13(d)(1)(B) of the Act by the person(s) who acquired control. In lieu thereof, the material shall indicate the identity of the bank so omitted and shall be filed separately with the Comptroller of the Currency. If the source of all or any part of the funds used to acquire control of the bank was a loan made by a bank as defined by Section 3(a)(6) of the Act, indicate whether there exists any agreement, arrangement, or understanding pursuant to which the bank maintains or would maintain a correspondent deposit account at such lending bank.

Instructions. 1. State the terms of any loans or pledges obtained by the new control group for the purpose of acquiring control, and the names of the lenders or pledgees.

2. Any arrangement or understandings among members of both the former and new control groups and their associates with respect to the election of directors and other matters should be described.

(g) *Changes in Control.* Describe any arrangements, known to the bank, including any pledge by any person of securities of the bank or any of its parents, the operation of which may at a subsequent date result in a change in control of the bank. A description is not required of ordinary default provisions contained in any charter, trust indentures or other governing instruments relating to securities of the bank.

Instructions. 1. The percentages are to be calculated on the basis of the amount of outstanding securities, excluding securities held by or for the account of the bank or its subsidiaries, plus securities deemed outstanding pursuant to § 11.4(g)(4)(iv)(A).

2. For the purposes of this item, beneficial ownership shall be determined in accordance with § 11.4(g)(4). Include such additional subcolumns or any other appropriate explanation of Column (3) necessary to reflect amounts as to which the beneficial owner has (1) sole voting power, (2) shared voting power, (3) sole investment power, and (4) shared investment power.

3. The bank shall be deemed to know the contents of any statement filed with the Comptroller of the Currency pursuant to Section 13(d) of the Exchange Act. When applicable, a bank may rely upon information set forth in such statements unless the bank knows or has reason to believe that such information is not complete or accurate, or that a settlement or amendment should have been filed and was not.

4. For purposes of furnishing information pursuant to paragraph (d), the bank may indicate the source and date of such information.

5. Where more than one beneficial owner is known to be listed for the same securities, appropriate disclosure should be made to avoid confusion.

6. Paragraph (g) does not require a description of ordinary default provisions contained in the charter, trust indentures or other governing instruments relating to securities of the bank.

Item 6—Directors

If action is to be taken with respect to election of directors, furnish the following information in tabular form to the extent practicable, with respect to each person nominated for election as a director and each other person whose term of office as a director will continue after the meeting. However, if the solicitation is made on behalf of persons other than management, the information required need only be furnished as to nominees of the persons making the solicitation.

(a) *Identification of directors.* List all directors of the bank and all persons nominated or chosen to become directors. Indicate all positions and offices with the bank held by each person named. State the age of the persons named, their terms of office, and their periods during which each such person has served. Briefly describe any arrangement or understanding between each director and any other person pursuant to which such director was selected to serve in that capacity.

Instructions. 1. Do not include any arrangements or understandings with directors of the bank acting solely in their capacities as such.

2. No nominee or person chosen to become a director who has not consented to act as such should be named in response to this item.

3. No information need be given respecting any director whose term of office as a director will not continue after the meeting to which the statement relates.

4. In connection with action to be taken concerning the election of directors, if fewer nominees are named than the number fixed by or pursuant to the governing instruments, state the reasons for this procedure and that the proxies cannot be voted for a greater number of persons than the number of nominees named.

(b) *Family relationships.* State the nature of any family relationships between any director, or person nominated or chosen by the bank to become a director.

Instructions. The term "family relationships" means any relationship by blood, marriage, or adoption, not more remote than first cousin.

(c) *Business experience.* (1) Give a brief account of the business experience during the past five years of each director or person nominated or chosen to become a director, including principal occupations and employment during that period, and the name and principal business of any corporation or other organization in which such occupations and employment were carried on.

(2) Indicate any other directorship held by each director or person chosen to become a director in any company with a class of securities registered pursuant to Section 12 of the Act.

(d) *Involvement in certain legal proceedings.* Describe any of the following events which occurred during the past five years and which are material to an evaluation of the ability or integrity of any director, or persons chosen or nominated to become a director of the bank:

(1) A petition under the Bankruptcy Act or any state insolvency law was filed by or against such person, or a receiver, fiscal agent or similar officer was appointed by a court for the business or property of such person or any partnership in which he was a general partner at or within two years before the time of such filing, or any corporation or business association of which he was an executive officer at or within two years before the time of such filing;

(2) Such person was convicted in a criminal proceeding or is a named subject of a pending criminal proceeding (excluding traffic violations and other minor offenses);

(3) Such person was the subject of any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction permanently or temporarily enjoining him from, or otherwise limiting the following activities:

(i) acting as an investment adviser, underwriter, broker or dealer in securities, or as an affiliated person, director or employee of any investment company, bank, savings and loan association or insurance company, or engaging in or continuing any conduct or practice in connection with such activity;

(ii) engaging in any type of business practice; or

(iii) engaging in any activity in connection with the purchase or sale of any security or in connection with any violation of federal or state securities laws.

(4) Such person was the subject of any order, judgment or decree, not subsequently reversed, suspended or vacated, of any federal or state authority barring suspending or otherwise limiting for more than 60 days the right of such person to engage in any activity described in subparagraph (3), above, or to be associated with persons engaged in any such activity.

(5) Such person was found by a court of competent jurisdiction in a civil action, or by a government agency, to have violated any federal or state securities law, and the judgment in such civil action or finding by the government agency has not been subsequently reversed, suspended, or vacated.

Instructions. 1. For purposes of computing the five year period referred to in this paragraph, the date of a reportable event shall be deemed the date on which the final order, judgment or decree was entered, or the date on which any rights of appeal from preliminary orders, judgments, or decrees have lapsed. With respect to bankruptcy petitions, the computation date shall be the date of filing for uncontested petitions or the date upon which approval of a contested petition became final.

2. If any event specified in this subparagraph (d) has occurred and information in regard thereto is omitted on the ground that it is not material, the bank may furnish to the Comptroller at the time of filing, as supplemental information and not as part of the statement, materials to which the omission relates, a description of the event, and a statement of the reasons for the omission of information in regard thereto.

3. The bank is permitted to explain any mitigating circumstances associated with events reported pursuant to this paragraph.

4. If the information called for by Item 6(d) is being presented in a proxy or information statement, no information need be given respecting any director whose term of office as a director will not continue after the meeting to which the statement relates.

(e) *Relationships with affiliates and others.* Describe any of the following relationships which exist:

(1) If the nominee or director has during the past five years had a principal occupation or employment with any of the bank's parents, subsidiaries or other affiliates.

(2) If the nominee or director is related to an officer of any of the bank's parents, subsidiaries or other affiliates by blood, marriage or adoption (except relationships more remote than first cousin).

(3) If the nominee or director is, or has within the last two full fiscal years been, an officer, director or employee of or owns or has within the last two fiscal years owned, directly or indirectly, in excess of 1 percent equity interest in any firm, corporation or other business or professional entity:

(i) Which has made payments to the bank or its subsidiaries for property or services during the bank's last full fiscal year in excess of 1 percent of the bank's consolidated gross revenues for its last full fiscal year;

(ii) Which proposes to make payments to the bank or its subsidiaries for property or services during the current fiscal year in excess of 1 percent of the bank's consolidated gross revenues for its full fiscal year;

(iii) To which the bank or its subsidiaries was indebted at any time during the bank's fiscal year in an aggregate amount in excess of 1 percent of the bank's total consolidated assets at the end of such fiscal year or $5,000,000, whichever is less;

(iv) To which the bank or its subsidiaries has made payments for property or services during such entity's last full fiscal year in excess of 1 percent of such entity's gross revenues for its last full fiscal year;

(v) To which the bank or its subsidiaries proposes to make payments for property or services during such entity's current fiscal year in excess of 1 percent of such entity's consolidated gross revenues for its last full fiscal year;

(vi) In order to determine whether payments made or proposed to be made exceed 1 percent of the consolidated gross revenues of any entity other than the bank for such entity's last full fiscal year, it is appropriate to rely on information provided by the nominee or director;

(vii) In calculating payments for property and services the following may be excluded:

(A) Payments where the rates or charges involved in the transaction are determined by competitive bids, or the transaction involves the rendering of services as a public utility at rates or charges fixed in conformity with law or governmental authority;

(B) Payments which arise solely from the ownership of securities of the bank and no extra or special benefit not shared on a pro rata basis by all holders of the class of securities is received;

(viii) In calculating indebtedness for purposes of subparagraph (iii) above, debt securities which have been publicly offered, admitted to trading on a national securities exchange, or quoted on the automated quotation system of a registered securities association may be excluded.

(4) That the nominee or director is a member or employee of, or is associated with a law firm which the bank retained in the last two fiscal years or proposes to retain in the current fiscal year;

(5) That the nominee or director is a control person of the bank (other than solely as a director of the bank).

(6) In addition, the bank should disclose any other relationships it is aware of between the director or nominee and bank or its management which are substantially similar in nature and scope to these relationships listed above.

Note.—In the Comptroller's view, where significant business or personal relationships exist between the director or nominee and the bank or its management including but not limited to those as to which disclosure would be required pursuant to this Item 6 (e), characterization of a director or nominee by any "label" connoting a lack of relationship to the issuer and its management may be materially misleading.

(f)(1) *Committee.* State whether or not the bank has standing audit, nominating and compensation committees of the Board of Directors, or committees performing similar functions. If the bank has such committees, however designated, identify each committee member, state the number of committee meetings held by each such committee during the last fiscal year and describe briefly the functions performed by such committees.

(2)(a) If the bank has a nominating or similar committee, state whether the committee will consider nominees recommended by shareholders and, if so;

(b) Describe the procedures to be followed by shareholders in submitting such recommendations.

(g) *Director attendance.* State the total number of meetings of the Board of Directors (including regularly scheduled and special meetings) which were held during the last full fiscal year. Name each incumbent director who during the last full fiscal year attended fewer than 75 percent of the aggregate of (1) the total number of meetings of the board of directors (held during the period for which he has been a director) and (2) the total number of meetings held by all committees of the board of which he served (during the periods that he served).

(h) *Resignation of Directors.* If a director has resigned or declined to stand for re-election to the Board of Directors since the date of the last annual meeting of shareholders because of a disagreement with the bank on any matter relating to the bank's operations, policies or practices and if the director has furnished the bank with a letter describing such disagreement and requesting that the matter be disclosed, the bank shall state the date of resignation or declination to stand for re-election and summarize the director's description of the disagreement.

If the bank believes that the description provided by the director is incorrect or incomplete it may include a brief statement presenting its views of the disagreement.

Item 7—Remuneration and Other Transactions With Management and Others

Furnish the information called for by this Item if action is to be taken with respect to (1) the election of directors, (2) any bonus, profit sharing or other remuneration plan, contract or arrangement in which any director, or officer of the bank will participate, (3) any pension or retirement plan in which any such person will participate, or (4) the granting of extension to any such person of any options, warrants, or rights to purchase any securities, other than warrants or rights issued to security holders, as such, on a pro rata basis. However, if the solicitation is made on behalf of persons other than the management, the information required need be furnished only as to nominees for election as directors and as to their associates.

(a) *Current remuneration.* Furnish the information required in the table below, in substantially the tabular form as specified, concerning all remuneration of the following persons and group for services in all capacities to the bank during the bank's last fiscal year:

(1) *Five officers or directors.* Each of the five most highly compensated officers or directors of the bank as to whom the total remuneration required to be disclosed in Columns C1 and C2, below, would exceed $50,000, naming each such person; and

(2) *All officers and directors.* All officers and directors of the bank as a group, stating the number of persons in the group without naming them.

(3) *Specified Tabular Format.*

Remuneration Table

(A)	(B)	(C)		(D)
		Cash and cash equivalent forms of remuneration		
Name of individual or number of persons in group	Capacities in which served	(C1) Salaries fees, directors fees, commissions, and bonuses	(C2) Securities or property insurance benefits or reimbursement, personal benefits	Aggregate of contingent forms of remuneration

Instructions to Item 7(a). 1. *Columns A and B. Persons subject to this item.* (a) This item applies to any person who was an officer or director of the bank at any time during the fiscal year. However, information need not be given for any portion of the period during which such person was not an officer or director of the bank, provided a statement to that effect is made. (b) The term officer is defined in § 11.2(o). (c) For the purposes of this item "bank" shall include the bank and all its subsidiaries.

2. *Column C* (a) Column C1 shall include all cash remuneration distributed or accrued in the form of salaries, fees, directors' fees, commissions and bonuses.

(b) Column C2 should include the following: (i) *Securities or property.* Where any of the specified persons or group (a) exercises any option, right or similar election in connection with any contract, agreement, plan or arrangement or (b) becomes entitled without further contingencies to retain securities or property, state the spread between the acquisition price, if any, and the fair market price of all securities or property acquired under any contract, agreement, plan or arrangement. The fair market price of any such securities or property shall be determined as of the date during the fiscal year that either of the events in (a) or (b) of this paragraph occurs, or if both events are contemplated the date of the latter event.

(ii) *Personal benefits.* (a) The value of personal benefits which are not directly related to job performance, which are furnished by the bank directly or through third parties to each of the specified persons and group, or benefits furnished by the bank to other persons which indirectly benefit the specified persons. Such personal benefits shall include the cost of any premiums or benefits paid by the bank for any life or health insurance policy or health plan of which the bank is not the sole beneficiary. Such benefits shall be valued on the basis of the aggregate actual cost to the bank. Information need not be furnished for any such benefit provided by the bank which does not discriminate in favor of officers or directors and which is available generally to all salaried employees. (b) No disclosure need be included as to any person named in the remuneration table if the aggregate amount of all personal benefits to such person did not exceed $5,000. If disclosure of such amounts is not made, a statement to that effect should be added in a footnote to the table. (c) If the bank cannot determine the actual cost of personal benefits for a specified person without unreasonable effort or expense, include a reasonable estimate of the cost of the personal benefit to the bank. If the bank cannot reasonably allocate the extent to which the benefit is personal, include the aggregate cost to the bank and estimate the percentage of cost attributable to personal use. If an estimate is made, disclose the factors upon which the estimate is based. (d) Please provide in a statement following the table a description of the bank's policies and practices with respect to providing personal benefits to officers, directors or principal shareholders. Describe the type of benefits provided and the basis for selection of the recipients.

3. *Column D.* Column D shall include remuneration of the specified persons and group in whole or in part for services rendered during the latest fiscal year (including the forms of remuneration described in paragraphs (a) through (c) below) if the distribution of such remuneration or the unconditional vesting or measurement of benefits thereunder is subject to future events.

(a) *Pension or retirement plans; annuities; employment contracts; deferred compensation plans.* (i) As to each of the specified persons and group, the amount expended for financial reporting purposes by the bank for the year which represents the contribution, payment, or accrual for the account of any such person or group under any existing pension or retirement plans, annuity contracts, deferred compensation plans, or any other similar arrangements. Such amounts should be reflected as remuneration for the fiscal year under all such plans or arrangements, including plans qualified under the Internal Revenue Code, unless in the case of a defined benefit or actuarial plan, the amount of the contribution, payment, or accrual in respect of a specified person is not and cannot readily be separately or individually calculated by the regular actuaries for the plan.

(ii) If amounts are excluded from the table pursuant to the previous provision, include a footnote to the table: (a) stating such fact; (b) disclosing the percentage which the aggregate contributions to the plan bears to the total remuneration of plan participants covered by such plan; and (c) briefly describing the remuneration covered by the plan.

(b) *Incentive and compensation plan and arrangements.* (1) With respect to stock options, stock appreciation rights plans, phantom stock plans and any other incentive or compensation plan or arrangement pursuant to which the measure of benefits is based on objective standards or on the value of securities of the bank or another person granted, awarded or entered into at any time in connection with services to the bank, include as remuneration of each of the specified persons and group any attributable amount expensed by the bank for financial reporting purposes for the fiscal year as remuneration for any such person or group.

(2) Where amounts are expensed and reported in the remuneration table, and amounts are credited in a subsequent year in connection with the same plan or arrangement for any proper reason including a decline in the market price of the securities, such credit may be reflected as a reduction of the remuneration reported in Column D. If amounts credited are reflected in the table, include a footnote stating the amount of the credit and briefly describe such treatment.

(3) The term "options" as used in this item includes all options, warrants, or rights, other than those issued to security holders as such on a pro rata basis.

(c) *Stock purchase plans; profit sharing and thrift plans.* Include the amount of any contribution, payment or accrual for the account of each of the specified persons and groups under any stock purchase, profit sharing, thrift, or similar plans which has been expensed during the fiscal year by the bank for financial reporting purposes. Amounts reflecting contributions under plans qualified under the Internal Revenue Code may not be excluded.

4. *Other permitted disclosure.* The bank may provide additional disclosure through a footnote to the table, through additional columns, or otherwise, describing the components of aggregate remuneration in such greater detail as is appropriate.

5. *Definition of "Plan."* The term "plan" as used in this item includes all plans, contracts, authorizations, or arrangements, whether or not set forth in any formal documents.

(b) *Proposed remuneration.* Briefly describe all remuneration payments proposed to be made in the future pursuant to any existing plan or arrangement to the persons and group specified in Item 7(a). As to defined benefit or actuarial plans, with respect to which amounts are not included in the table pursuant to Instruction 3(a) to Item 7(a), include a separate table showing the estimated annual benefits payable upon retirement to persons in specified remuneration and years-of-service classification.

Instruction. Information need not be furnished with respect to any group life, health, hospitalization, or medical reimbursement plans which do not discriminate in favor of officers or directors of the bank and which are available generally to all salaried employees.

(c) *Options, warrants, or rights.* Furnish the following information as to all options to purchase any securities from the bank which were granted to or exercised by the following persons since the beginning of the bank's last fiscal year, and as to all options held by such persons as of the latest practicable date: (i) each director or officer named in answer to paragraph (a)(1), naming each such person: and (ii) all directors and officers of the bank as a group, without naming them.

(1) As to options granted during the period specified state: (i) the title and aggregate amount of securities called for; (ii) the average option price per share; and (iii) if the option price was less than 100 percent of the market value of the security on the date of grant, such fact and the market price on such date shall be disclosed.

(2) As to options exercised during the period specified, state (1) the title and aggregate amount of securities purchased; (ii) the aggregate purchase price; and (iii) the aggregate market value of the securities purchased on the date of purchase.

(3) As to all unexercised options held as of the latest practicable date (state date), regardless of when such options were granted, state (i) the title and aggregate amount of securities called for, and (ii) the average option price per share.

Instructions. 1. The term "options" as used in this paragraph (c) includes all options, warrants or rights, other than those issued to security holders as such on a pro rata basis. Where the average option price per share is called for, the weighted average price per share shall be given.

2. The extension, regranting or material amendment of options shall be deemed the granting of options within the meaning of this paragraph.

3. (i) Where the total market value on the granting dates of the securities called for by all options granted during the period specified does not exceed $10,000 for any officer or director named in answer to paragraph (a)(1), or $40,000 for all officers and directors as a group, this item need not be answered with respect to options granted to such persons or group. (ii) Where the total market value on the dates of purchases of all securities purchased through the exercise of options during the period specified does not exceed $10,000 for any such period or $40,000 for such group, this item need not be answered with respect to options exercised by such person or group. (iii) Where the total market value as of the latest practicable date of the securities called for by all options held at such time does not exceed $10,000 for any such person or $40,000 for such group, this item need not be answered with respect to options held as of the specificed date by such person or group.

4. If the options relate to more than one class of securities the information shall be given separately for each such class.

(d) *Indebtedness of management.* (1) State as to each of the following specified person, herein called specified persons, who was indebted to the bank at any time since the beginning of the last full fiscal year to date: (i) the largest aggregate amount of indebtedness, including extensions of credit or overdrafts, endorsements or guarantees (in dollar amounts and as a percentage of total equity capital accounts at the time) outstanding at any time during such period; (ii) the amount thereof outstanding as of the latest practicable date; (iii) the nature of the indebtedness and of the transaction in which it was incurred; and (iv) the rate of interest paid or charged thereon:

(A) Each director or officer of the bank;

(B) Each nominee for election as director;

(C) Each security holder who is known to the bank to own on record or beneficially more than five percent of any class of the bank's voting securities ("principal security holder"); and

(D) Each associate of any such director, officer, nominee or principal security holder.

Instructions. 1. Include the name of each person whose indebtedness is described and the nature of the relationship by reason of which the information is required to be given.

2. Generally, no information need be given under this paragraph, unless any of the following are present:

(a) The extensions of credit were not made on substantially the same terms, including interest rates, collateral and repayment terms as those prevailing at the time for comparable transactions with other than the specified persons.

(b) The extensions of credit were not made in the ordinary course of business.

(c) Such extensions of credit have involved or presently involve more than a normal risk of collectibility or other unfavorable features, including the restructuring of an extension of credit, or a delinquency as to payment of interest or principal.

(d) The aggregate amount of extensions of credit outstanding at any time from the beginning of the last fiscal year to date to a person specified in (A), (B), and (C) of this paragraph together with the person's associates exceeded 10% of the equity capital accounts of the bank at that time or $5 million whichever is less. **Note.**—For purposes of this Instruction 2(d) only: (1) the information called for by paragraphs (d)(1)(iii) and (iv) of this Item need not be furnished; (2) a principal security holder shall mean each security holder known to the bank to own of record or beneficially more than five (5) percent of any class of the bank's voting securities; and (3) the name of any associates need not be furnished.

(2) If any extension of credit to the specified persons as a group exceeded 20% of the equity capital accounts of the bank at any time since the beginning of the last full fiscal year to date, disclose the maximum aggregate amount of extensions of credit to the group during the period, the aggregate amount as a percentage of the equity capital accounts of the bank and include a statement, to the extent applicable, that the bank has had, and expects to have in the future, banking transactions in the ordinary course of its business with directors, officers, principal stockholders and their associates, on substantially the same terms, including interest rates, collateral and repayment terms on extensions of credit, as those prevailing at the same time for comparable transactions with others and did not involve more than the normal risk of collectibility or present other unfavorable features.

(3) If any indebtedness required to be described arose under Section 16(b) of the Act and has not been discharged by payment, state the amount of any profit realized, that such profit will inure to the benefit of the bank or its subsidiaries and whether suit will be brought or other steps taken to recover such profit. If in the opinion of counsel a question reasonably exists as to the recoverability of such profit, it will suffice to state all facts necessary to describe the transaction, including the prices and number of shares involved.

4. Notwithstanding the foregoing, any transaction or series of transactions resulting in indebtedness to the bank in its subsidiaries which may be considered material should be disclosed.

5. If the information called for by Item 7(d) is being presented in Form F–1, § 11.41 or an offering circular filed pursuant to 12 CFR Part 16, the information called for shall be presented for the last three full fiscal years in the Form F–1 and for the last two full fiscal years in the offering circular.

6. Where a specified person is an endorser or guarantor on any extension of credit made by the bank or its subsidiaries disclosure should be made to the extent otherwise applicable.

(e) *Transactions With Management.* Describe briefly any transaction since the beginning of the bank's last full fiscal year or any presently proposed transactions, to which the bank or any of its subsidiaries was or is to be a party, in which any of the specified persons in Item 7(d) had or is to have a direct or indirect material interest, naming such person and stating his relationship to the bank, the nature of his interest in the transaction and, where practicable, the amount of such interest.

Instructions. 1. No information need be given in response to this Item 7(e) as to any remuneration or other transaction reported in response to Item 7(a), (b), (c) or (d), or as to any transaction with respect to which information may be omitted pursuant to Instruction 3(a)(i) to Item 7(a), the Instruction to Item 7(b), Instruction 3 to Item 7(c), or Instruction 2 to Item 7(d)(1).

2. No information need be given in answer to this Item 7(e) as to any transaction where:

(a) The rates or charges involved in the transaction are determined by competitive bids, or the transaction involves the rendering of services as a common or contract carrier, or public utility, at rates or charges fixed in conformity with law or governmental authority;

(b) The transaction involves services as a bank depository of funds, transfer agent, registrar, trustee under an indenture, or similar services;

(c) The amount involved in the transaction or series of similar transactions, including all periodic installments in the case of any lease or other agreement providing for periodic payments or installment, does not exceed $40,000 for the term of each transaction or series of transactions; or

(d) The interest of the specified person arises solely from the ownership of securities of the bank and the specified person receives no extra or special benefit not shared on a pro rata basis by all holders of securities of the class.

3. It should be noted that this item calls for disclosure of indirect, as well as direct, material interests in transactions. A person who has a position or relationship with a firm, corporation, or other entity, which engages in a transaction with the bank may have an indirect interest in such transaction by reason of such position or relationship. However, a person shall be deemed not to have a material indirect interest in a transaction within the meaning of this Item 7(e) where:

(a) The interest arises only (i) from such person's position as a director of another corporation or organization (other than a partnership) which is a party to the transaction, or (ii) from the direct or indirect ownership by such person and all other persons specified in subparagraphs (A) through (D) of Item 7(d)(1) above, in the aggregate, of less than a 10 percent equity interest in another person (other than a partnership) which is a party to the transaction, or (iii) from both such position and ownership;

(b) The interest arises only from such person's position as a limited partner in a partnership in which he and all other persons specified in (1) through (4) above had an interest of less than 10 percent; or

(c) The interest of such person arises solely from the holding of an equity interest (including a limited partnership interest but excluding a general partnership interest) or a creditor interest in another person which is a party to the transactions with the bank and the transaction is not material to such other person.

4. The amount of the interest of any specified person shall be computed without regard to the amount of the profit or loss

involved in the transaction. Where it is not practicable to state the approximate amount of the interest, the approximate amount involved in the transaction will be indicated.

5. In describing any transaction involving the purchase or sale of assets by or to the bank, otherwise than in the ordinary course of business, state the cost of the assets to the purchaser and, if acquired by the seller within two years prior to the transaction, the cost thereof, to the seller.

6. If the information called for by Item 7(e) is being presented in Form F-1 § 11.41 or an offering circular filed pursuant to 12 CFR Part 16, the information called for shall be presented for the last three full years in the Form F-1 and for the last two full fiscal years in the offering circular.

7. Include the name of each person whose interest in any transaction is described and the nature of the relationship by reason of which such interest is required to be described. Where it is not practicable to state the approximate amount of the interest, the approximate amount involved in the transaction shall be indicated.

8. Information shall be furnished in answer to this item with respect to transactions not excluded above which involve remuneration from the bank directly or indirectly, to any of the specified persons for services in any capacity unless the interest of such persons arises solely from the ownership individually and in the aggregate of less than 10% of any class of equity securities of another corporation furnishing the services to the bank.

9. The foregoing instructions specify certain transactions and interests as to which information may be omitted in answering this item. There may be situations where, although the foregoing instructions do not expressly authorize nondisclosure, the interest of a specified person in the particular transaction or series of transactions is not a material interest. In that case, information regarding such interest and transaction is not required to be disclosed in response to this item. The materiality of any interest or transaction is to be determined on the basis of the significance of the information to investors in light of all of the circumstances of the particular case. The importance of the interest to the person having the interest, the relationship of the parties to the transaction to each other, and the amount involved in the transaction, are among the factors to be considered in determining the significance of the information to investors.

10. Any material proceedings to which any director, officer or affiliate of the bank, any person holding in excess of five percent of the bank's outstanding stock, or any associate of any such director, officer or security holder, is a party or has an interest materially adverse to the bank or any of its subsidiaries should also be described.

(f) *Transactions with pension or similar plans.* Describe briefly any transactions since the beginning of the bank's last full fiscal year to any presently proposed transactions, to which any pension, retirement, savings or similar plan provided by the bank, or any of its parents or subsidiaries was or is to be a party, in which any person specified in Item 7(d) had or is to have a direct or indirect material interest, naming such person and stating his relationship to the bank, the nature of his interest in the transaction and, where practicable, the amount of such interest.

Instructions. 1. Instructions 2, 3, 4 and 5 to Item 7(e) shall apply to this item 7(f).

2. For the purposes of this item the term "transaction" shall mean any property purchased or sold, any extensions of credit made or outstanding or any remuneration paid during the period.

Item 8—Selection of Auditors

(a) If action is to be taken with respect to the selection or approval of auditors, or if it is proposed that particular auditors shall be recommended by any committee to select auditors for whom votes are to be cast, name the auditors and describe briefly any direct financial interest or any material indirect financial interests in the bank or any of its parents or subsidiaries, or any connection during the past 3 years with the bank or any of its parents or subsidiaries in the capacity of promoter, underwriter, voting trustee, director, officer, or employee. If the auditors to be selected are other than those which were engaged as the principal auditors for the bank's most recently filed certified financial statements, briefly summarize the circumstances and conditions surrounding the proposed change of such auditors, and state whether such change was recommended or approved by:

(1) Any audit or similar committee of the Board of Directors, if the bank has such a committee; or

(2) The Board of Directors, if the bank has no such committee.

(b) If the bank has its financial statements certified by an independent public accountant: For the fiscal year most recently completed, describe each professional service provided by the auditor and state the percentage relationship which the aggregate of the fees for all nonaudit services bear to the audit fees, and, except as provided below, state the percentage relationship which the fee for each nonaudit service bears to the audit fees. Indicate whether, before each professional service provided by the principal accountant was rendered, it was approved by, and the possible effect on the independence of the accountant was considered by (1) any audit or similar committee of the Board of Directors and (2) for any service not approved by an audit or similar committee, the Board of Directors.

Instructions. 1. For purposes of this subsection all fees for services provided in connection with the audit function (*e.g.*, reviews of quarterly reports, filings with the Board, and annual reports) may be computed as part of the audit fees. Indicate which services are reflected in the audit fees computation.

2. If the fee for any nonaudit service is less than 10 percent of the audit fees, the percentage relationship need not be disclosed.

3. Each service should be specifically described. Broad general categories such as "tax matters" or "management advisory services" are not sufficiently specific.

4. Describe the circumstances and give details of any services provided by the bank's independent accountant during the latest fiscal year that were furnished at rates or terms that were not customary.

5. Describe any existing direct or indirect understanding or agreement that places a limit on current or future years' audit fees, including fee arrangements that provide fixed limits on fees that are not subject to reconsideration if unexpected issues involving accounting or auditing are encountered. Disclosure of fee estimates is not required.

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Item 14—Mergers, Consolidations, Acquisitions and Similar Matters

* * * * *

(b) * * *

(7) * * *

(ii) Book value per share, at the date of the Balance Sheets included in the statement.

The earnings per share, dividends per share, and book value per share amounts required by subparagraphs 7(i) and 7(ii) shall be presented in tabular form where appropriate and equated to a common basis in exchange transactions;

* * * * *

11. Section 11.54, Cover Page, is amended to read as follows:

§ 11.54 Tender offer statement filed pursuant to section 14(d)(1) of the Securities Exchange Act of 1934 (form F-13)

Comptroller of the Currency

Tender Offer Form Pursuant to Section 14(d)(1) of the Securities Exchange Act of 1934—Form F-13

(Amendment No. —)

(Name of Subject Bank)

(Bidder)

(Title of Class of Securities)

CUSIP Number

(Name, Address, and Telephone Number of Person Authorized To Receive Notices and Communications on Behalf of Bidder)

The information required in the remainder of this cover page shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934 ("Act") or otherwise subject to the liabilities of that section of the Act but shall be subject to all other provisions of the Act (however, see the Note).

(1) Names of Reporting Person S.S. or I.R.S. Identification Nos. of Above Person.

(2) Check the appropriate Box if a Member of a Group (See Instructions).

(a) ☐

(b) ☐

(3) Sources of Funds (See Instructions)

(4) Check if Disclosure of Legal Proceedings is Required Pursuant to Items 2(e) or 2(f)

(5) Citizenship of Place of Organization

(6) Aggregate Amount Beneficially Owned by Each Reporting Person

(7) If the Aggregate Amount in Row (6) Excludes Certain Shares, List the Number of Excluded Shares (See Instructions)

(8) Percent of Class Represented by Amount in Row (7)

(9) Type of Reporting Person (See Instructions)

Instructions for Cover Page

(1) Names and Social Security Numbers of Reporting Persons—Furnish the full legal name of each person for whom the report is filed—*i.e.* each person required to sign the form itself—including each member of a group. Do not include the name of a person required to be identified in the report but who is not a reporting person. Reporting persons are also requested to furnish their Social Security or I.R.S. identification numbers, although disclosure of such numbers is voluntary, not mandatory (see "Special Instructions for Complying With Form F–13", below).

(2) If any of the shares beneficially owned by a reporting person are held as a member of a group and such membership is expressly affirmed please check row 2(a). If the membership in a group is disclaimed or the reporting person describes a relationship with other persons but does not affirm the existence of a group, please check row 2(b) (unless a joint filing pursuant to § 11.4(g)(2)(v) in which case it may not be necessary to check row 2(b)).

(3) Source of Funds—Classify the source of funds or other consideration to be used in making purchases as required to be disclosed pursuant to Item 4 of the schedule and insert the appropriate symbol (or symbols if more than one is necessary) in row (3):

Category of source:	Symbol
Subject bank (bank whose securities are being required)	SB
Bank	BK
Affiliate (of reporting person)	AF
Working Capital (of reporting person)	WC
Personal Funds (of reporting person)	PF
Other	OO

(4) If disclosure of legal proceedings or actions is required pursuant to either items 2(e) or 2(f) of Form F–13; row 4 should be checked.

(5) Citizenship or Place of Organization—Furnish citizenship if the named reporting person is a natural person. Otherwise, furnish the place of organization. (See Item 2 of Form F–13.)

(6), (8) Aggregate Amount Beneficially Owned by Each Reporting Person, etc.—Rows (6) and (8) are to be completed in accordance with the Instructions to Item 6 of Form F–13. All percentages are to be rounded off to nearest tenth (one place after decimal point).

(10) Type of Reporting Person—Please classify each "reporting person" according to the following breakdown and place the appropriate symbol (or symbols, *i.e.*, if more than one is applicable, insert all applicable symbols) on the form:

Category:	Symbol
Broker Dealer	BD
Bank	BK
Insurance Company	IC
Investment Company	IV
Investment Adviser	IA
Employee Benefit Plan, Pension Fund, or Endowment Fund	EP
Parent Holding Company	HC
Group Member	GM
Corporation	CO
Partnership	PN
Individual	IN
Other	OO

Note.—Filing persons may, in order to avoid unnecessary duplication, answer items on the form by appropriate cross reference to an item or items on the cover page(s). This approach may be used only where the cover page item or items provide all the disclosure required by the scheduled item. Moreover, such a use of a cover page item will result in the item becoming a part of the schedule and accordingly being considered as "filed" for purposes of Section 18 of the Securities Exchange Act or otherwise subject to the liabilities of that section of that Act.

Special Instructions for Complying With Form F–13

Under Sections 14(d) and 23 of the Securities Exchange Act of 1934 and the rules and regulations thereunder the Comptroller of the Currency is authorized to solicit the information requirement to be supplied by this form by certain security holders of certain banks.

Disclosure of the information specified in this form is mandatory, except for Social Security and I.R.S. Identification numbers the disclosure of which is voluntary. The information will be used for the primary purpose of determining and disclosing the holdings of certain beneficial owners of certain equity shareholders. This statement will be made a matter of public record. Therefore, any information given will be available for inspection by any member of the public.

Failure to disclose the information requested by this schedule, except for Social Security or I.R.S. identification numbers, may result in civil or criminal action against the person involved for violation of the Federal securities laws and rules promulgated thereunder.

Instructions. Four copies of this statement, including all exhibits should be filed with the Comptroller of the Currency.

General Instructions

* * * * *

Dated: November 26, 1979.

John G. Heimann,

Comptroller of the Currency.

[FR Doc. 79–37247 Filed 12–3–79; 8:45 am]

BILLING CODE 4810–33–M

FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Docket No. R–0255]

Supervison of Foreign Banking Organizations and Edge Corporations by Federal Reserve Banks

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule: Correction.

SUMMARY: This document corrects a previous **Federal Register** document (FR Doc. 79–34405) beginning at page 64398 of the issue for Wednesday, November 7, 1979. The previous document concerned the supervision of foreign banking organizations and Edge Corporations by Federal Reserve Banks.

EFFECTIVE DATE: October 24, 1979.

FOR FURTHER INFORMATION CONTACT: C. Keefe Hurley, Senior Counsel (202/452–3269), or Michael L. Kadish, Attorney (202/452–3428), Legal Division, Board of Governors of the Federal Reserve System.

SUPPLEMENTARY INFORMATION: In the third column of page 64398, paragraph "1." of *Part 225—Bank Holding Companies and Change in Bank Control* is corrected to read as follows:

1. By revising § 225.1(c) to read as follows:

§ 225.1 Authority, scope, and definitions.

* * * * *

(c) *Federal Reserve Bank.* The term "Federal Reserve Bank" as used in this Part with respect to action by, on behalf of, or directed to be taken by a bank holding company or other organization shall mean either the Federal Reserve Bank of the Federal Reserve district in which the operations of the bank holding company or other organization are principally conducted, as measured by total deposits held or controlled by it in subsidiary banks on the date on which it became, or is to become, a bank holding company, or such Reserve Bank as the Board may designate. With respect to notices filed and other actions taken under the Control Act, the term refers to the Federal Reserve Bank for the institution to be acquired, as determined by the preceding sentence in the case of bank holding companies and by section 9 of the Federal Reserve Act in the case of State member banks. In the case of a foreign banking organization that is not a bank holding company but which has one or more branches, agencies, or commerical lending companies located in any State of the United States or the District of Columbia, "Federal Reserve Bank" shall

mean, unless otherwise determined by the Board, the Reserve Bank of the district in which its banking assets are the largest as of the later of January 1, 1980, or the date that it establishes its first branch, agency or commercial lending company.

Board of Governors of the Federal Reserve System, November 26, 1979.

Theodore E. Allison,

Secretary of the Board.

[FR Doc. 79-37194 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

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12 CFR Part 226

[Reg. Z; FC-0164]

Truth in Lending; Final Official Staff Interpretation

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final official staff interpretation.

SUMMARY: The Board is publishing in final form official staff interpretation FC-0164 of Regulation Z, Truth in Lending, regarding the applicability of the identification requirement of § 226.6(d) to open-end credit plans involving multiple creditors. The agency is taking this action after reviewing the comments received upon republication of the interpretation.

DATE: Effective December 4, 1979.

FOR FURTHER INFORMATION CONTACT: Maureen P. English, Section Chief, Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, (202) 452-3867.

SUPPLEMENTARY INFORMATION: (1) In FC-0164, Board staff stated that § 226.6(d) of Regulation Z does not require each creditor to be identified on the § 226.7(a) or (b) disclosures for open-end credit plans involving more than one creditor.

(2) FC-0164 was published in the **Federal Register** on July 18, 1979, with an effective date of August 17, 1979. In response to a request for public comment submitted in accordance with § 226.1(d)(3) of Regulation Z, the effective date was suspended and the interpretation was republished for comment on August 30, 1979.

(3) The request for republication suggested that the identification provision of § 226.6(d) applies to both open-end and other than open-end credit transactions and that the position taken in FC-0164 will encourage the replacement of other than open-end credit with open-end credit.

All of the comments received upon republication of FC-0164 supported its reissuance as originally published. As many of the commenters pointed out, neither the Truth in Lending Act nor Regulation Z requires identification of the creditor where there is only one creditor. In light of that fact, the staff does not believe that § 226.6(d) should be read to require that each creditor be identified in a multiple creditor transaction. Also contributing to the staff's conclusion is the fact that the periodic statement must reflect an address for the customer to use for account inquiries. Moreover, the staff does not believe that the position taken in FC-0164 significantly influences a creditor's decision regarding the type of credit program it intends to offer. Rather, the staff believes that such a determination is dictated by factors present in the marketplace.

Consequently, after fully considering the arguments contained in the request for republication and those contained in the comments, the staff continues to believe that FC-0164 correctly interprets Regulation Z.

(4) Official Staff Interpretation FC-0164 which follows remains unchanged from the version published in the **Federal Register** on August 30, 1979. It is effective immediately.

(5) Authority: 15 U.S.C. 1640(f).

12 CFR Part 226, FC-0164

§ 226.6(d) Application of § 226.6(d) to § 226.7(a) and (b) disclosures. (Modifies Letter 597 and FC-0042).

§ 226.7 (a) Application of § 226.6(d) to § 226.7 (a) and (b) disclosures. (Modifies Letter 597 and FC-0042).

§ 226.7(b) Application of § 226.6(d) to § 226.7 (a) and (b) disclosures. (Modifies Letter 597 and FC-0042).

November 27, 1979.

This is in response to your letter of * * *, in which you request an official staff interpretation of § 226.6(d) of Regulation Z. Section 226.6(d) prescribes general Truth in Lending disclosure requirements and responsibilities when "there is more than one creditor * * * in a transaction." You are concerned with the application of § 226.6(d) to the disclosures required for open end credit plans by §§ 226.7 (a) and (b) of Regulation Z.

Your question arises in relation to open end credit card accounts for which both a card issuing bank and its agent bank are creditors under Regulation Z. You indicate that currently both the card issuing bank and the agent bank are identified as creditors on the initial disclosures provided to customers pursuant to § 226.7(a) and on the periodic statements required by § 226.7(b). You ask whether § 226.6(d) requires this identification.

Section 226.6(d) provides:

If there is more than one creditor or lessor in a transaction, *each creditor or lessor shall be clearly identified* and shall be responsible for making only those disclosures required by this Part which are within his knowledge and the purview of his relationship with the customer or lessee. If two or more creditors or lessors make a joint disclosure, *each creditor or lessor shall be clearly identified.* The disclosures required under paragraphs (b) and (c) of § 226.8 shall be made by the seller if he extends or arranges for the extension of credit. Otherwise disclosures shall be made as required under paragraphs (b) and (d) of § 226.8 or paragraph (b) of § 226.15. (Emphasis added.)

The staff is of the opinion that, although § 226.6(d) does not explicitly differentiate between open end credit and credit other than open end, not all of the requirements of that section apply to open end credit plans. For example, the requirements set forth in the last two sentences of § 226.6(d) specifying disclosures to be made under § 226.8 for credit transactions other than open end involving more than one creditor or under § 226.15 for consumer lease transactions involving more than one lessor clearly have no applicability in the case of open end credit. Additionally, the staff believes that since neither § 226.7(a) nor § 226.7(b) requires identification of the creditor of an open end plan in which there is only one creditor, § 226.6(d) does not require that each creditor be identified in connection with the § 226.7 (a) or (b) disclosures for open end plans in which there is more than one creditor.

Although in connection with the disclosures required by §§ 226.7 (a) and (b) there need be no identification of the creditors of an open end account in which there is more than one creditor, each such creditor is responsible under § 226.6(d) for making all required disclosures which are within the knowledge of that creditor and the purview of its relationship with a customer. Such creditors may, of course, make joint disclosures. Furthermore, one or more of the creditors of an open end account may be identified in connection with the disclosures required by § 226.7(a) and/or § 226.7(b) as additional information in accordance with § 226.6(c) of Regulation Z.

Public Information Letter 597 indicates, and Official Staff Interpretation FC-0042 could be read to imply, that § 226.6(d) requires identification of each creditor of an open end credit plan in which there is more than one creditor. Upon reconsideration, however, the staff believes that the opinions expressed in this letter constitute the correct interpretation of the requirements of the regulation. Therefore, Public Information Letter 597 and Official Staff Interpretation FC-0042 are hereby modified to coincide with the views expressed herein.

This is an official staff interpretation of Regulation Z issued after republication for comment in accordance with § 226.1(d)(2) of the regulation. It will become effective December 4, 1979.

Sincerely,

Nathaniel E. Butler,

Associate Director.

Board of Governors of the Federal Reserve System, November 28, 1979.

Theodore E. Allison,

Secretary of the Board.

[FR Doc. 79-37140 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

FARM CREDIT ADMINISTRATION

12 CFR Parts 613, 614, and 616

Eligibility and Scope of Financing; Loan Policies and Operations; Coordination

AGENCY: Farm Credit Administration.

ACTION: Final rule.

SUMMARY: The Farm Credit Administration, by its Federal Farm Credit Board, took final action to amend its regulations concerning the lending operations of the institutions of the Farm Credit System. The amendments (1) remove certain restrictions on farm-related business financing, (2) clarify that the Federal land banks may pay interest on future payment funds received from borrowers, and (3) modify current policies and appraisal standards for security offered in connection with loans.

EFFECTIVE DATE: December 4, 1979.

FOR FURTHER INFORMATION CONTACT: Sanford A. Belden, Deputy Governor, Office of Administration, Farm Credit Administration, 490 L'Enfant Plaza SW., Washington, D.C. 20578 (202-755-2181).

SUPPLEMENTARY INFORMATION: By notice published in the Federal Register on June 21, 1979, interested persons were afforded the opportunity to file written comments or suggestions on the proposed amendments.

The amendments to the regulations relating to farm-related businesses delete (1) The requirement that a business to be eligible to borrow from a Federal land bank or production credit association must perform "on farm" services, and (2) the limitation that the banks and associations may finance only those assets and activities of the business which are directly related to services performed on farms. In addition, concurrence of the district bank for cooperatives will no longer be required for loans made by the Federal land banks and production credit associations to businesses in competition with cooperatives. As amended, the regulations permit the Federal land banks and production credit associations to provide full financing to businesses which furnish farmers and ranchers custom-type services which are directly related to their on-farm operating needs.

A number of comments were received with respect to these proposed amendments. While they came from different persons or organizations, many of them were similar in nature. One of the common comments is that the proposed regulation would work to the detriment of the so-called "family farm." These comments in part were motivated by the belief that the revised regulation would break new ground in that it would permit the financing of large feedlots, an operation which some of the commentators believe would be injurious to the interests of the small or family type farm.

A primary purpose of the regulation is to assist the smaller farmers who may not have the resources for the kind of capital investment needed for performing many services which are critical to agriculture today. For example, the regulation would permit the financing of farm-related businesses which perform such "off the farm" services as hauling of milk and other agricultural commodities from the farm to market, custom feed mixing operations, large animal veterinary services, dehydration and cubing or pelletizing of hay, and the drying of other farm commodities, such as peanuts. These are types of services which the ordinary small farmer frequently cannot afford or does not desire to perform himself, but which may be crucial to his on-farm operating needs. It is believed clearly in the interests of such farmers to have these facilities made available and to have financing for them available from the Farm Credit institutions.

It is true that the regulation would, under some circumstances, permit financing of feedlots which might "feed out" cattle as an extension of the farmer's own on-farm operations. Again, even this service could be significant to smaller farmers who might elect not to perform this aspect of preparing the cattle for market. Further, under carefully circumscribed circumstances, the Farm Credit System has for some time been financing certain aspects of feedlot operations. To this extent, the change in the regulation will not constitute an entirely new departure in System financing. Since the Federal Farm Credit Board was persuaded that, on balance, the change in the regulation would achieve the objective of assisting the smaller farmer, it adopted the regulation as proposed.

Another of the common comments was that the Farm Credit Act of 1971 did not authorize the financing of farm-related business whose services were provided other than on the farm. Neither the literal language of the statute nor its legislative history compel this conclusion. While the Farm Credit Administration, in implementing the Act, narrowed the authority by providing an "on-farm" requirement with respect to the services to be furnished by farm-related businesses, this was an administrative decision, rather than a statutory restriction. The statute provides only that farm-related businesses, to obtain System financing, must furnish farm-related services directly related to the on-farm operating needs of farmers and ranchers. It does not require that the services be performed on the farm. The revised regulation reflects the statutory intent in that it would require that farm-related businesses, to be eligible for financing by System institutions, provide services which are directly related to the on-farm operating needs of farmers and ranchers.

The amendment relating to the payment of interest by the Federal land banks on future payment funds received from borrowers reflects a long-standing interpretation of the regulations. The Federal land banks are permitted by the regulations to accept from borrowers advance conditional payments to be applied against loan payments becoming due in the future. The regulations have been interpreted as allowing interest to be paid on these funds in an amount not to exceed the interest on the related loan which would have not otherwise accrued if the payments had been applied upon receipt against the loan. As amended, the regulations will specifically authorize the payment of interest on the funds at a rate not to exceed the loan rate for as long as the payments remain unapplied. Several comments were received on this proposed regulation. Most were favorable. One comment, however, suggested that the rate of interest allowable on these advance conditional loan payments be limited to the rate allowable on saving deposits in member banks of the Federal Reserve System. Inasmuch as these payments are made by borrowers for application against future loan payments, the Federal Board considered the rate on the related loan to be a more equitable limitation than the suggested limitation. This is because the borrower continues to be liable for interest on the total indebtedness at the loan rate for as long as the payment remains unapplied against the loan. Therefore, the regulation was adopted as proposed.

The amendments relating to policies and appraisal standards for loan security (1) provide for bank board policies to assure that non-agricultural assets are not given undue consideration in the final loan decision, (2) simplify the appraisal standards for collateral offered as security for loans, and (3) require that security for Federal land bank loans be interests in real estate constituting agricultural property, farm-related business property, or rural housing as appropriate to the type of loan involved. Several comments were received on the proposed amendments. All were favorable. Some, however, suggested various editorial changes in the proposed regulation. As a result of these comments, certain technical changes have been made in the regulations as proposed.

Chapter VI of Title 12 of the Code of Federal Regulations is amended to read as follows:

PART 613—ELIGIBILITY AND SCOPE OF FINANCING

1. Section 613.3050 is revised as follows:

§ 613.3050 Farm-related business.

(a) *Definition.* A farm-related business is a person engaged in furnishing to farmers or ranchers custom-type farm-related services directly related to their on-farm operating needs.

(b) *Eligibility.* (1) To be eligible to borrow, a person shall establish as part of his application for credit his qualifications as a farm-related business.

(2) Loans shall not be made to commercial businesses which purchase farm products from or sell inputs to farmers or ranchers unless substantially all of such inputs handled are used incident to the services provided.

(c) *Scope of financing.* Federal land banks may make loans to farm-related businesses for necessary sites, capital structures and equipment and initial working capital for such services. Production credit associations may make loans to farm-related businesses for any working capital, equipment, and operating needs incident to the operation of farm-related businesses. Such financing is subject to the provisions of Section 616.6040.

PART 614—LOAN POLICIES AND OPERATIONS

2. Section 614.4090 is revised as follows:

§ 614.4090 Federal land banks.

The banks are authorized to make and participate with other Federal land banks in long-term real estate mortgage loans in rural areas for a term of not less than 5 years or more than 40 years. Subject to limitations applicable to making long-term real estate mortgage loans, the banks are authorized to make continuing commitments to land and to extend financial assistance of a similar nature. Policies as prescribed by the bank's board shall be used in making loans, continuing commitments for loans, and in extending other financial assistance. Borrowers shall be permitted to make advance payments on their loans or, under agreement with the banks, make advance conditional payments to be applied on future maturities or to be available for return to the borrower for purposes for which the bank would increase its existing loans. Banks may pay interest on advance conditional payments for the time the funds are held unapplied at a rate not to exceed the rate charged on the related loan.

3. Section 614.4160 is amended by revising paragraphs (b) and (c) to read as follows:

§ 614.4160 Lending objective.

(a) * * *

(b) It is also the objective of the Farm Credit System to provide a full range of credit services to farmer cooperatives to assist them in increasing the income of their members as patrons. The type of farmer cooperative operation, quality of management, and basic financial factors shall be carefully evaluated as to their effect upon the long-range benefit to members. Bank boards shall establish policies, and banks for cooperatives shall develop procedures for administration of quality standards that fully consider the needs of, support by, and service performed for members, and risk protection afforded the lender.

(c) Subject to FCA approval, bank boards shall adopt policies adequate to provide the direction it desires management to follow in administering credit and lending standards to ensure attainment of the System's objectives. Particular direction should be provided which ensures that nonagricultural assets owned by applicants or included in collateral appraisals are not given undue weight in the final loan decision. These policies should convey the thrust that loans made under the eligibility provision of Sections 613.3020 and 613.3030 are predominantly agricultural or aquatic loans. Bank management shall prescribe operating procedures to administer effectively board policies, including provision that proper weight be given the infinite combination of person, property, and purpose which can exist. Guidelines shall be included which provide for identification of that portion of mixed value (agricultural and nonagricultural) assets which may be considered agricultural for lending purposes.

4. Section 614.4220 is amended by deleting the introductory paragraph, and by revising paragraphs (a) and (b) to read as follows:

§ 614.4220 General.

(a) Primary real estate security shall be valued on the basis of appraised value, and primary chattel security or additional security shall be valued on the basis of recovery value. Bank boards shall develop policies, subject to FCA approval, to assure that the appraised value of nonagricultural assets, i.e., mineral deposits, commercial buildings, and improvements, are properly identified in the appraisal report.

(b) *Appraised Value.* Appraised value shall be the basis for valuing primary real estate and is the reasonably supported market value. Market value is defined as the amount which a property will bring if a reasonable time is allowed to find a purchaser and if both seller and prospective buyer are fully informed, neither being under abnormal pressure.

(1) The above definition contemplates the consummation of a sale and the passing of full title from seller to buyer under the following conditions:

(i) Buyer and seller are free of undue stimulus and are motivated by no more than the reactions of typical owners.

(ii) Both parties are well informed or well advised and act prudently each for what he considers his own best interest.

(iii) A reasonable time is allowed to test the market.

(iv) Payment is made in cash or in accordance with financing terms generally available in the community for this type of property.

(2) The market value established is for collateral purposes and is supported by the rationale of the total market over a reasonable period of time and is for customary and current legal use of the property. It excludes single purpose or limited highest and best use sales and these based on speculative assumptions. A reasonable period of time would generally necessitate giving consideration to the full range of sales over at least the previous 6 months.

There is a difference between market price and market value. Market value represents the rationale of buyers collectively within the area while market price indicates what an individual property may have sold for. Comparable sales supporting market value should meet the true definition of market value or reflect proper

adjustment to the defined market value base.

* * * * *

5. Section 614.4230 is amended by revising paragraph (a) to read as follows:

§ 614.4230 Federal land banks.

(a) Primary security for a Federal land bank loan shall consist of a first lien on interest in real estate comprising agricultural property, an eligible farm-related business, or an eligible rural residence, whichever is appropriate for the type of loan being made. The real estate interest must be a mortgageable interest under deeds or leases which reasonably may be considered adequate to afford the security of a first lien upon the rights and interest on which the collateral value is predicated. Collateral closely aligned with, an integral part of, and normally sold with real estate may be included in the appraised value of the primary security. Values shall be determined within approved aprraisal standards.

* * * * *

PART 616—COORDINATION

6. Section 616.6040 is revised to read as follows:

§ 616.6040 Farm-related business.

The district policies as to farm-related businesses shall assure that these lending activities do not conflict with the objectives and responsibilities of any institution of the System. The policies may permit loans by production credit associations and Federal land banks to small cooperatives furnishing eligible farm-related services with concurrence by the bank for cooperatives.

(Secs. 5.9, 5.12, 5.18, 85 Stat. 619, 620, 621).

Donald E. Wilkinson,

Governor.

[FR Doc. 79-37318 Filed 12-3-79; 8:45 am]

BILLING CODE 6705-01-M

CIVIL AERONAUTICS BOARD

14 CFR Part 297

[ER-1159; Docket No. 35568]

Final Rule To Liberalize Regulation of Foreign Indirect Cargo Carriers

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: The Board is adopting a simple registration procedure to grant operating authority to foreign air freight forwarders and foreign cooperative shippers associations. This action is being taken on the Board's initiative to give foreign air freight forwarders equal competitive opportunities with U.S. air freight forwarders, which were recently deregulated. In addition, the Economic and Organization Regulations are being modified to conform to the new rule.

DATES: Adopted: November 28, 1979. Effective: January 3, 1980, except for §§ 297.20 and 297.40 which require GAO review. The Board will publish a notice of GAO's decision.

FOR FURTHER INFORMATION, CONTACT: Joseph Di Bella, Bureau of International Aviation, Legal Division, 1825 Connecticut Avenue NW., Washington, D.C. 20428, (202) 673-5035.

SUPPLEMENTARY INFORMATION: On May 17, 1979, the Board proposed to adopt a new Part 297 of its Economic Regulations, to govern operations by foreign air freight forwarders and foreign cooperative shippers associations (EDR-378, ODR-18, 44 FR 30694, May 29, 1979). The proposed regulation included a simple registration procedure in place of the previous hearing proceedings under section 402 of the Federal Aviation Act of 1958, as amended ("Act"); elimination of the need to file tariffs; exemption from the duty to provide just and reasonable rates; simplification of reporting and waybill requirements; elimination of public liability and cargo liability insurance requirements (except for a duty to disclose the extent of cargo liability limits, and of liability insurance coverage, if any); and permission for foreign freight forwarders to act as agents of either shippers or direct air carriers. These provisions parallel the deregulation of U.S. air freight forwarders in the revisions to Part 296 (ER-1094, 44 FR 6634, January 31, 1979). The only major difference is that additional procedures would be made available to deal with foreign policy issues that might be raised by a foreign air freight forwarder application, such as ownership and control, or reciprocal treatment of U.S. carriers by foreign governments. The expansion of the Board's exemption power in the Airline Deregulation Act of 1978 explicitly permits us to extend to foreign forwarders the changes that have already been made for U.S. forwarders.

Part 297 was proposed in order to eliminate unnecessary regulatory obstacles to entry by foreign air freight forwarders, to equalize the degree of regulatory oversight vis-a-vis domestic air freight forwarders, and to bring the benefits of increased competition to the shipping public. Foreign air freight forwarders have been at a disadvantage in having to obtain a foreign air carrier permit, which usually takes 5 months or more, before they can begin operations to and from the United States, while U.S. carriers serving the same markets need only register with the Board to begin operations. This regulation will allow foreign forwarders to enter a market with virtually the same ease as their U.S. counterparts, and it will formally relieve them of some of the regulatory restrictions that might inhibit vigorous competition between all forwarders. Some of those restrictions have already been removed by exemption, such as the duty to file tariffs.[1] Those that are still in effect are the vestiges of an earlier regulatory scheme that relied more on government regulations than on market forces to determine what prices and services would be offered. For instance, the statutory requirement that carriers charge just and reasonable rates sprang from a lack of confidence in the ability of the competitive market to assure reasonable rates in earlier times. If allowed to remain effective, such a requirement would be an invitation to litigation, perhaps leading to rates established by courts instead of by market forces. Since January, 1979, U.S. freight forwarders have been relieved of these restrictions, and the early results of free competition between them have been encouraging. By equalizing the positions of domestic and foreign forwarders, we will extend these gains and enhance the competition in the international freight forwarding industry, to the ultimate benefit of the shipping public.

Comments were filed by The Flying Tiger Line Inc. (FTL); the International Airforwarder and Agents Association (IAAA); and the law firms of Martin, Whitfield, Smith and Bebchick (Martin) and Bernstein and MacCarthy (Bernstein). Reply comments were filed by Trans International Air Lines, Inc. (TIA) and IAAA. No one objects to adoption of Part 297 in principle, but several persons suggest modifications to the proposed rule.

FTL suggests that simplified show cause procedures be made mandatory for the processing of foreign air freight forwarder applications or, in the alternative, that the names of foreign forwarders requesting Part 297 authority be published, to give U.S. carriers notice and an opportunity to reply. The carrier argues that this is necessary to insure that the Board adequately considers the extent to which an applicant's country of citizenship imposes restrictions upon the operations of U.S. cargo carriers in that country. TIA rejects the notion of mandatory show-cause procedures as

[1] Order 79-3-51, March 8, 1979.

being unnecessarily cumbersome, but supports the proposal that the Board publish a brief notice of foreign indirect cargo carrier applications, with an identification of the applicant's nationality, in the Board's Weekly Summary of Filings, and that a four-week period be provided for objections. IAAA also opposes use of show-cause, on the grounds that foreign governments seldom restrict the operations of indirect U.S. cargo carriers; that discriminatory treatment of direct U.S. carriers such as FTL does not justify U.S. retaliation against indirect foreign air carriers; and that the show-cause procedure, even if limited to foreign policy issues as suggested by FTL, would be time-consuming and burdensome.

We have decided to reject FTL's proposal for mandatory show-cause procedures because it would defeat the purpose of Part 297, which is to reduce unnecessary paperwork and "regulatory lag". As we explained in EDR-378, almost all foreign indirect cargo carrier applications are currently processed by show cause, usually without objection. Nonetheless, an average of five months is normally consumed in writing the two orders and waiting for comments, and a significant amount of staff resources is occupied despite the ministerial nature of the task. Moreover, this does not take into account the time and expense that an applicant must undergo in fashioning a show-cause petition and supplying the requisite information. Since applications that raise serious issues are the exception rather than the rule, it follows that, as a general rule, foreign air freight forwarder applications should be processed under a simple registration procedure, and approved under exemption authority. For those applications that are controversial, we have provided in § 297.22 a variety of procedural options that may be utilized according to the nature of the policy issues that must be resolved.

FTL's alternative proposal—publication of the names and nationalities of persons applying for foreign air freight forwarding authority, and a comment period—has merit, and is being adopted. While we had originally intended that all applications would be listed in the Board's Weekly Summary of Filings, and that the 60-day processing period (§ 297.20) would provide time for preparation of objections, we will formalize the notice and comment period to reduce confusion and insure that comments are received in time for the staff to analyze and act upon them, if necessary. TIA's suggestion of 4 weeks for comments is reasonable, and is being adopted. *See* § 297.21.

IAAA is concerned that a large amount of information that currently must accompany foreign air carrier permit applications under Part 211 would automatically be required if the Board decided to institute a 402 proceeding under § 297.21(e). This is not necessarily true. If a 402 proceeding were initiated, the Board would delineate the issues to be decided and the information to be supplied by the applicant. As Part 211 only applies to non-Part 297 carriers, *i.e.*, foreign carriers that are not indirect cargo air carriers, the information request in Appendix A to Part 211 would not apply, even inadvertently. We are amending § 211.1 to make it clear that foreign air freight forwarders and foreign cooperative shippers associations are not subject to Part 211.

Martin argues that foreign indirect cargo carriers should not be required to identify their nationality in all advertisements, tickets, stationery, or public documents (proposed § 297.30). Martin states that such a condition is inconsistent with court decisions that prohibit discrimination against aliens; that it should not apply to a U.S. corporation that is foreign-owned; that it is not relevant to quality of service or financial responsibility; that other measures, such as bonding, insurance, or indemnity requirements, can be imposed to insure financial responsibility; that foreign identification is an indirect and ineffective means of informing shippers that a foreign air freight forwarder may not provide domestic forwarding services; and that nationality identification might cause a loss of business from shippers that would prefer to deal with American companies. Martin argues that a U.S. subsidiary of a foreign owner should not be considered a foreign national. However, Martin recognizes that were its unnamed client, in whose behalf it has commented in this docket, to be acquired by foreign interests, its Part 296 authority would be invalidated, and authority as a foreign air freight forwarder would have to be obtained. Both Board policy and section 101(16) of the Act establish that the nationality of a carrier is determined by its ultimate ownership, not its situs of incorporation. *See* Kuehne & Nagel d/b/a Kuehne & Nagel Air Freight, Inc., Foreign Permit 50 C.A.B. 672, 676 & n.1, served May 21, 1969. In its reply, IAAA states that a foreign identification requirement would be no more appropriate for foreign air freight forwarders than it would be for "the Wilkinson razor blade company, Mercedes Benz, or any other foreign company, especially in these days of deregulation." No person supports retention of this requirement.

We have decided not to adopt the foreign identification provision. Our original intention was to provide shippers with information that might be relevant to financial accountability or the scope of services of a foreign air freight forwarder. Upon further consideration, we believe that disclosure of foreign ownership in the advertising and documents serves no regulatory purpose important enough to warrant the burden on the carriers. The requirement that foreign air freight forwarders identify agents in the United States for service of process, and the waiver of sovereign immunity (§ 297.23), will insure their accountability in United States' courts. Furthermore, the carriers generally have assets in this country which are available for enforcement of any judgments against them. Shippers deal with air carriers on a regular basis, and should be well informed on the reputation of an air freight forwarder for financial accountability and the quality of its service, as well as whether it is a foreign or U.S. air freight forwarder.

Finally, we were concerned that shippers be informed of the fact that foreign air freight forwarders may not, under section 1108(b) of the Act, engage in cabotage, *i.e.*, forwarding between points within the United States. However, the foreign identification provision would be only an indirect means of preventing domestic forwarding, as it would require that shippers be aware of section 1108(b). We think we may reasonably rely upon the Board's enforcement powers, as well as the natural policing inclination of the foreign freight forwarders' domestic counterparts. Should abuses occur, we have ample power under the Act to deal with them, on either an individual or blanket basis.

Subsequent to publication of EDR-378, the Board amended Part 211 to eliminate the requirement that foreign air carrier permit applications be sent through diplomatic channels before being submitted to the Board. ER-1132, 44 FR 40494, July 11, 1979. Bernstein suggests that this change in procedure be recognized in Part 297 for foreign air freight forwarder applications, but IAAA proposes that it be applied only to Part 297 registrations by forwarders already holding section 402 permits. IAAA argues that new applications should be sent through diplomatic channels to ensure that the applicant's country of citizenship supports it. We see no reason to discriminate between

classes of registrants, and have decided to conform Part 297 to the amendments to Part 211. Section 297.20(b) has been modified to provide that registrations should be forwarded directly to the Board, without transmission through diplomatic channels. To deal with the question of sponsorship raised by IAAA, a section has been added to registration form 297A where an applicant will be required to provide the signature and identity of a responsible official of the applicant's home government who will attest that the necessary authority has been obtained from that government to operate to and from the United States as an air freight forwarder.

We are modifying § 297.24(b) to make it clear exactly when a registrant must resubmit Form 297A to disclose a change in ownership. Form 297A requires listing of all persons owning or holding beneficial ownership of 10 percent or more of the registrant's stock. Whenever any person listed no longer holds 10 percent, or a person not listed holds 10 percent or more, Form 297A must be resubmitted as an application for amendment of the registration. The existing authority shall remain valid pending Board action on the amendment, but registrants should be aware that acquisition of ownership interest by persons who are not citizens of the country of citizenship of the registrant may cause invalidation of the registration.

Except as discussed above, the proposed changes were not opposed by the commenters, and the rule is being adopted as proposed. These rules are being made effective 30 days after publication, except for § 297.20 (Filing for Registration) and § 297.40 (Financial and Operating Report), which will be submitted to the General Accounting Office (GAO) for review under the Federal Reports Act (44 U.S.C. 3512). GAO will conduct its clearance review to ensure that a minimal burden is imposed upon registrants, and that the information requested is otherwise consistent with the Federal Reports Act. However, carriers may submit registration applications immediately upon adoption of this rule, pending GAO approval. The 60-day review period under § 297.20 will begin running on the date of receipt of a registration form, unless GAO subsequently requires substantial change in the registration procedure, in which case re-registration may be required. The Board will publish a notice of GAO's decision as soon as it is received.

Termination of Existing Permit Authority

Important Note.—The Board plans to issue an order terminating existing permit authority under section 402 for indirect foreign air transportation of property subject to Presidential review under section 801 of the Act. The order, if not disapproved, would become effective approximately 120 days after publication of this rule. Foreign air freight forwarders holding current permit authority should therefore apply for registration under this rule by January 28, 1980 to avoid a gap in authority after their permit authority has been terminated.

By Order 79–3–51, March 8, 1979, the Board provided existing foreign air freight forwarders with a temporary exemption from section 403 of the Act, so as to relieve them from the obligation to file tariffs pending completion of this rulemaking. As all existing 402 permits for indirect foreign air carriers of property will be terminated approximately 120 days from publication of this rule, the exemption in Order 79–3–51 will expire on the same day that the order cancelling the 402 permits becomes effective.

Accordingly, a new Part 297 is added to the Board's Economic Regulations (14 CFR Part 297) to read as follows:

PART 297—FOREIGN AIR FREIGHT FORWARDERS AND FOREIGN COOPERATIVE SHIPPERS ASSOCIATIONS

Subpart A—General

Sec.

297.1 Purpose.
297.2 Applicability.
297.3 Definitions.
297.4 Joint loading.
297.5 Foreign air freight forwarder as agent.
297.6 Foreign cooperative shippers association as agent of shippers.

Subpart B—Exemption for Foreign Indirect Air Transportation of Property

297.10 Exemption from the Act.
297.11 Disclaimer of jurisdiction.

Subpart C—Registration for Foreign Air Freight Forwarders and Foreign Cooperative Shippers Associations

297.20 Filing for registration.
297.21 Objections to registration application.
297.22 Procedure on receipt of registration application.
297.23 Waiver of sovereign immunity.
297.24 Notification to the board of change in operations.
297.25 Cancellation or conditioning of registration.

Subpart D—General Rules for Foreign Indirect Air Carriers

297.30 Public disclosure of cargo liability insurance.

Sec.

297.31 Preparation of airwaybills and manifests.
297.32 Prohibition against receipt of commissions.

Subpart E—Reporting Requirements

297.40 Financial and operating report.

Subpart F—Violations

297.50 Enforcement.

Authority.—Sec. 204, 416 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 771, as amended by 92 Stat. 1731, 1732; (49 U.S.C. 1324, 1386).

Subpart A—General

§ 297.1 Purpose.

This part establishes registration procedures and operating rules for foreign air carriers that engage indirectly in air transportation of property from points within the United States to points outside of the United States. It also exempts these carriers from certain provisions of the Act, and establishes simplified reports for them.

§ 297.2 Applicability.

This part applies to foreign air transportation of property by foreign indirect air carriers outbound from the United States. It also applies to applications for registration as a foreign indirect air carrier of property.

§ 297.3 Definitions.

For purpose of this part:

(a) "Foreign air freight forwarder" means a foreign indirect air carrier that is responsible for the transportation of property from the point of receipt to point of destination, and utilizes for the whole or any part of such transportation the services of a direct air carrier or its agent, of another foreign air freight forwarder, or of an air freight forwarder registered under Part 296.

(b) "Foreign cooperative shippers association" means a bona fide association of shippers operating as a foreign indirect air carrier on a nonprofit basis that undertakes to ship property by air for the account of such association or its members, and utilizes for the whole or any part of such transportation the services of a direct air carrier or its agent, of a foreign air freight forwarder, or of an air freight forwarder registered under Part 296.

(c) "Direct air carrier" means an air carrier or foreign air carrier directly engaged in the operation of aircraft under a certificate, regulation, order, or permit issued by the Board.

(d) "Foreign indirect air carrier" means any person, not a citizen of the United States, who undertakes

indirectly to engage in foreign air transportation of property.[1]

§ 297.4 Joint loading.

Nothing in this part shall preclude joint loading, meaning the pooling of shipments and their delivery to a direct air carrier for transportation as one shipment, under an agreement between two or more indirect air carriers or foreign indirect air carriers.

§ 297.5 Foreign air freight forwarder as agent.

A foreign air freight forwarder may act as agent of a shipper, or of a direct air carrier that has authorized such agency, if it expressly reserves the option to do so when the shipment is accepted. A foreign air freight forwarder shall not act as the agent of any direct air carrier with respect to shipments accepted for forwarding.

§ 297.6 Foreign cooperative shippers association as agent of shippers.

A foreign cooperative shippers association may act as agent of a shipper, if it expressly reserves the option to do so when the shipment is accepted.

Subpart B—Exemption for Foreign Indirect Air Transportation of Property

§ 297.10 Exemption from the Act.

Foreign indirect air carriers with an effective registration under this part are exempted from the following sections or subsections of the Act:

(a) Section 402 (Permits);

(b) Section 403 (Tariffs), except section 403(b)(2); and

(c) Section 404(a)(2) (Carrier's Duty to establish just and reasonable rates, etc.).

§ 297.11 Disclaimer of jurisdiction.

The Board declines to exercise its jurisdiction over foreign indirect air carriers of property with respect to shipments that originate in a foreign country. The Board reserves the right to exercise its jurisdiction over any foreign indirect air carrier of property at any time it finds that such action is in the public interest.

[1] Section 101(16) of the Act defines a "citizen of the United States" as:

(a) an individual who is a citizen of the United States or one of its possessions, or

(b) a partnership of which each member is such an individual, or

(c) a corporation or association created or organized under the laws of the United States or of any State, Territory, or possession of the United States, of which the president and two-thirds or more of the board of directors and other managing officers thereof are such individuals and in which at least 75 percentum of the voting interest is owned or controlled by persons who are citizens of the United States or of one of its possessions.

Subpart C—Registration for Foreign Air Freight Forwarders and Foreign Cooperative Shippers Associations

§ 297.20 Filing for registration.

(a) Not later than 60 days before the start of operations as a foreign indirect air carrier, every foreign air freight forwarder and foreign cooperative shippers association shall apply for registration with the Board, unless upon a showing of good cause, the Director, Bureau of International Aviation, allows application at a later time.

(b) Application shall consist of filing with the Board's Bureau of International Aviation, Regulatory Affairs Division, two copies of completed Form 297A (obtainable from the Civil Aeronautics Board, Publications Services Division, Washington, D.C. 20428). Substantial ownership and effective control of an applicant must reside in citizens of the country indicated in the registration application as authorizing operations to and from the United States.

§ 297.21 Objections to registration application.

Persons objecting to registration by a foreign air freight forwarder or foreign cooperative shippers association shall file their objections with the Bureau of International Aviation, Regulatory Affairs Division, within 28 days of the filing date of the registration forms. The Board will list the names and nationality of all persons applying for registration in its Weekly Summary of Filings.

§ 297.22 Procedure on receipt of registration application.

After review of a registration form filed under § 297.20, the Board will take one or more of the following actions:

(a) Indicate by stamp on CAB Form 297A the effective date of registration, and return to the carrier the duplicate copy of Form 297A as evidence of registration with the Board under this part;

(b) Reject an application for registration for failure to comply with this part;

(c) Request additional information from the applicant;

(d) Issue an order subjecting a carrier's exercise of authority under this part to such terms, conditions, or limitations as may be required by the public interest; or

(e) Institute a proceeding under section 402 of the Act.

§ 297.23 Waiver of sovereign immunity.

By accepting an approved registration form under this part, a carrier waives any right it may possess to assert any defense of sovereign immunity from suit in any action or proceeding instituted against the carrier in any court or other tribunal in the United States based upon any claim arising out of operations by the carrier under this part.

§ 297.24 Notification to the Board of change of operations.

(a) Not later than 30 days before any change in its name or address or any temporary or permanent cessation of operations, each foreign indirect air carrier shall notify the Board's Bureau of International Aviation, Regulatory Affairs Division, of the change by resubmitting CAB Form 297A.

(b) The registrant shall apply for an amendment of its registration not later than 30 days after any person listed on its existing registration as owning or holding beneficial ownership of 10 percent or more of the registrant's stock no longer has an interest of 10 percent or more, or after any person not so listed becomes an owner or holder of 10 percent or more. Application for amendment shall be made by resubmitting CAB Form 297A, but the existing registration shall remain valid pending Board action on the amendment.

§ 297.25 Cancellation or conditioning of registration.

The registration of a foreign indirect air carrier may be canceled or subjected to additional terms, conditions, or limitations if:

(a) It files with the Board a written notice that it is discontinuing foreign indirect air carrier activities;

(b) It fails to perform air transportation services as authorized;

(c) It fails to file the reports required by this part;

(d) A substantial ownership interest is acquired by persons who are not citizens of the country of citizenship of the registrant; or

(e) The Board finds that it is in the public interest to do so.

Subpart D—General Rules for Foreign Indirect Air Carriers

§ 297.30 Public disclosure of cargo liability insurance.

Every foreign air freight forwarder shall give notice in writing to the shipper, when any shipment is accepted, of the limits of its cargo liability insurance, or of the absence of such insurance, and the limits of its liability, if any. The notice shall be included clearly and conspicuously on all of its rate sheets and airwaybills, and on any other documentation that is given to a shipper at the time of acceptance of the shipment.

§ 297.31 Preparation of airwaybills and manifests.

(a) Each registered foreign indirect air carrier shall prepare an accurate airwaybill describing completely all services rendered to or on behalf of the shipper, including the conditions under which the contract will be completed, in its capacity as a foreign indirect air carrier. A copy of the airwaybill shall be given to the consignor and to the consignee.

(b) Each registered foreign indirect air carrier shall prepare an accurate manifest showing every individual shipment included in each shipment consigned for transportation to a direct air carrier.

(c) A waiver of paragraph (a) of this section may be granted by the Board upon a written application by the foreign indirect air carrier not less than 30 days before the shipment to which it relates is transported, if the waiver is in the public interest, and is warranted by special or unusual circumstances.

§ 297.32 Prohibition against receipt of commissions.

No foreign air freight forwarder, acting in that capacity, shall accept directly or indirectly any payment of a commission from a direct carrier or its agent.

Subpart E—Reporting Requirements

§ 297.40 Financial and operating report.

(a) Each foreign indirect air carrier shall file with the Board a Financial and Operating Report (CAB Form 296R) on or before February 15 of each year, addressed to Reports Control, Data Systems Management Division, Office of Comptroller.

(b) Blank copies of CAB Form 296R will be supplied annually by the Civil Aeronautics Board.

(c) In the spaces provided, each foreign indirect air carrier shall report the gross air freight forwarding revenues, gross air freight forwarding expenses, net income (loss) from forwarding operations, and the number of shipments and number of tons of air freight received from customers as an indirect carrier. Foreign cooperative shippers associations need not report revenue or expense data.

Subpart F—Violations

§ 297.50 Enforcement.

In case of any violation of any of the provisions of the Act, or this part, or any other rule, regulation or order issued under the Act, the violator may be subject to a proceeding under sections 1002 and 1007 of the Act before the Board or a U.S. District Court, as the case may be, to compel to compliance; or to civil penalties under the provisions of section 901(a) of the Act; or in the case of willful violation, to criminal penalties under the provisions of section 902(a) of the Act; or other lawful sanctions including cancellation of registration.

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

BILLING CODE 6320-01-M

CAB Form 297A
(1-79)

REGISTRATION OR AMENDMENTS UNDER PART 297
OF THE ECONOMIC REGULATIONS OF THE
CIVIL AERONAUTICS BOARD

INSTRUCTIONS: This form must be submitted in duplicate to Regulatory Affairs Division, B-58, Bureau of International Aviation, Civil Aeronautics Board, Washington, D.C. 20428. Date of filing for the purposes of the Board's regulations is deemed to be the date the forms are received by the Board.

FOR USE BY CAB ONLY

1. Name and Mailing Address of Registrant in the United States:

NOTE: Name should include any other names under which business will be conducted. If registering a name change, show new name(s) here, and previously registered name(s) in block 10.a on reverse.

2. Address of principal place of business in the United States (if different from above) and registrant's Area Code and Telephone Number:

3. Indicate country of citizenship. List below the names and citizenship of each person owning or holding beneficial ownership of 10 percent or more of the applicant's stock.

Applicant's Country of Citizenship

Name	Citizenship

4. Name and address of designated agent residing within the United States for service of process.

5. Is this filing registrant's

☐ Initial Registration

☐ Amendment to reflect changes since previous filing (Please explain on reverse)

NOTE: Carriers already holding permit authority should check "Initial Registration"

6. Check type or types of service registrant intends to perform upon commencement of operations:

☐ Foreign Air Freight Forwarder

☐ Foreign Cooperative Shippers Association

7. If this is an initial registration, give proposed date of commencement of operations:

8. Authorization from applicant's country of citizenship.

I certify that the applicant has received authority from the Government of _____ to operate to and from the United States as an air freight forwarder or a cooperative shippers association.

Signature	Title or Position	Department of Government
_____	_____	_____

9. Certification

I certify that the information contained in this application, and in the attachments hereto, is complete and accurate to the best of my knowledge.

Signature: _____

Date: _____ Name (please type) _____

Place: _____ Title: _____ (see note)

NOTE: Application must be signed by a responsible officer, such as the President, Vice President, Secretary or Treasurer of a corporation or association, or partner or owner of other non-corporate applicants.

10. (For use in reporting any changes or amendments to information previously filed).

a. Previously registered name and/or address:

b. Description of any other changes or amendments:

[FR Doc. 79-37295 Filed 12-3-79; 8:45 am]
BILLING CODE 6320-01-C

14 CFR Part 207

[ER-1160; Docket No. 35568; Amdt. No. 23 to Part 207]

Final Rule To Liberalize Regulation of Foreign Indirect Cargo Carriers

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This amendment to the Board's charter regulations conforms to a new 14 CFR Part 297 adopted today. The Board's new Part, designated ER-1159, Part 297, provides for a simple registration procedure to grant operating authority to foreign air freight forwarders and foreign cooperative shippers associations.

DATES:

Adopted: November 28, 1979.
Effective: January 3, 1980.

FOR FURTHER INFORMATION, CONTACT: Josepah Di Bella, Bureau of International Aviation, Legal Division, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428 (202) 673-5035.

For the reasons stated in ER-1159, issued simultaneously, the Board is amending its charter regulations to include air freight forwarding by carriers possessing authority under the new Part 297.

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 207, *Charter Trips and Special Services*, as follows:

Paragraphs (a)(2)(iii) and (a)(3)(v) of § 207.11 are amended to read:

§ 207.11 Charter flight limitations.

(a) Charter flights (trips) in air transportation shall be limited to the following:

* * * * *

(2) * * *

(iii) By an air freight forwarder or cooperative shippers association registered under Part 296 of this subchapter; with respect to flights from the United States in foreign air transportation, by a foreign air freight forwarder or a foreign cooperative shippers association holding effective Board authority; or, with respect to flights to the United States in foreign air transportation, by any foreign air freight forwarder or foreign cooperative shippers association.

* * * * *

(3) * * *

(v) By an air freight forwarder or cooperative shippers association registered under Part 296 of this subchapter; with respect to flights from the United States in foreign air transporation, by a foreign air freight forwarder or a foreign cooperative shippers association holding effective Board authority; or, with respect to flights to the United States in foreign air transportation, by any foreign air freight forwarder or foreign cooperative shippers association.

* * * * *

(Sec. 204, 416 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 771, as amended by 92 Stat. 1731, 1732 (49 U.S.C. 1324, 1386))

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37296 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

14 CFR Part 208

[ER-1161; Docket No. 35568, Amdt. No. 23 to Part 208]

Final Rule To Liberalize Regulation of Foreign Indirect Cargo Carriers

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This amendment to the Board's regulations governing supplemental air transportation conforms to a new 14 CFR Part 297 adopted today. The Board's new Part, designated ER-1159, Part 297, provides for a simple registration procedure to grant operating authority to foreign air freight forwarders and foreign cooperative shippers associations.

DATES:

Adopted: November 28, 1979.
Effective: January 3, 1980.

FOR FURTHER INFORMATION, CONTACT: Joseph Di Bella, Bureau of International Aviation, Legal Divison, 1825 Connecticut Avenue NW., Washington, D.C. 20428 (202) 673-5035.

For the reasons stated in ER-1159, issued simultaneously, the Board is amending its charter regulations to include air freight forwarding by carriers possessing authority under the new Part 297.

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 208, *Terms, Conditions, and Limitations of Certificates to Engage in Supplemental Air Transportation*, as follows:

Paragraphs (a)(2)(v) and (a)(3)(v) of § 208.6 are amended to read:

§ 208.6 Charter flight limitations.

(a) Charter flights in air transportation performed by supplemental air carriers shall be limited to the following:

* * * * *

(2) * * *

(v) By an air freight forwarder or cooperative shippers association registered under Part 296 of this subchapter; with respect to flights from the United States in foreign air transportation, by a foreign air freight forwarder or a foreign cooperative shippers association holding effective Board authority; or, with respect to flights to the United States in foreign air transportation, by any foreign air freight forwarder or foreign cooperative shippers association.

* * * * *

(3) * * *

(v) By an air freight forwarder or cooperative shippers association registered under Part 296 of this subchapter; with respect to flights from the United States in foreign air transportation, by a foreign air freight forwarder or a foreign cooperative shippers association holding effective Board authority; or, with respect to flights to the United States in foreign air transportation, by any foreign air freight forwarder or foreign cooperative shippers association.

* * * * *

(Sec. 204, 416 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 771, as amended by 92 Stat. 1731, 1732 (49 U.S.C. 1324, 1386))

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37297 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

14 CFR Part 211

[ER-1162; Docket No. 35568; Amdt. No. 8 to Part 211]

Final Rule To Liberalize Regulation of Foreign Indirect Cargo Carriers

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This amendment to the Board's regulations concerning applications by foreign air carriers conforms to a new 14 CFR Part 297 adopted today. The Board's new Part, designated ER-1159, Part 297, provides for a simple registration procedure to grant operating authority to foreign air freight forwarders and foreign cooperative shippers associations.

DATES:

Adopted: November 28, 1979.
Effective: January 3, 1980.

FOR FURTHER INFORMATION, CONTACT: Joseph Di Bella, Bureau of International Aviation, Legal Division, 1825 Connecticut Avenue, NW., Washington, D.C. 20428 (202) 673-5035.

For the reasons stated in ER-1159, issued simultaneously, the Board is

amending its regulations concerning applications by foreign air carriers to exclude foreign air freight forwarders, who will apply hereafter under new Part 297.

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 211, *Applications for Permits to Foreign Air Carriers*, as follows:

Section 211.1 is amended by adding a sentence at the end to read:

§ 211.1 Formal requirements.

* * * Foreign indirect air carriers of property under Part 297 of this chapter are not required to submit applications under this part.

(Sec. 204, 416 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 771, as amended by 92 Stat. 1731, 1732 (49 U.S.C. 1324, 1386))

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37298 Filed 12-3-79; 8:45 am]

BILLING CODE: 6320-01-M

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14 CFR Part 212

[ER-1163; Docket No. 35568; Amdt. No. 32 to Part 212]

Final Rule To Liberalize Regulation of Foreign Indirect Cargo Carriers

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This amendment to the Board's charter regulations conforms to a new 14 CFR Part 297 adopted today. The Board's new Part, designated ER-1159, Part 297, provides for a simple registration procedure to grant operating authority to foreign air freight forwarders and foreign cooperative shippers associations.

DATES:

Adopted: November 28, 1979.

Effective: January 3, 1980.

FOR FURTHER INFORMATION, CONTACT: Joseph Di Bella, Bureau of International Aviation, Legal Division, 1825 Connecticut Avenue, NW., Washington, D.C. 20428 (202) 673-5035.

For the reasons stated in ER-1159, issued simultaneously, the Board is amending its charter regulations to include air freight forwarding by carriers possessing authority under the new Part 297.

Accordingly, the Civil Aeronautics Board amended 14 CFR Part 212, *Charter Trips by Foreign Air Carriers*, as follows:

Paragraphs (a)(1)(iii) and (a)(2)(v) of § 212.8 are amended to read:

§ 212.8 Charter flight limitations.

(a) Charter flights (trips) shall be limited to the following:

* * * * *

(1) * * *

(iii) By an air freight forwarder or cooperative shippers association registered under Part 296 of this subchapter; with respect to flights from the United States in foreign air transportation, by a foreign air freight forwarder or a foreign cooperative shippers association holding effective Board authority; or, with respect to flights to the United States in foreign air transportation, by any foreign air freight forwarder or foreign cooperative shippers association.

* * * * *

(2) * * *

(v) By an air freight forwarder or cooperative shippers association registered under Part 296 of this subchapter; with respect to flights from the United States in foreign air transportation, by a foreign air freight forwarder or a foreign cooperative shippers association holding effective Board authority; or, with respect to flights to the United States in foreign air transportation, by any foreign air freight forwarder or foreign cooperative shippers association.

* * * * *

(Sec. 204, 416 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 771, as amended by 92 Stat. 1731, 1732 (49 U.S.C. 1324, 1386))

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37299 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

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14 CFR Part 215

[ER-1164; Docket No. 35568; Amdt. No. 2 to Part 215]

Final Rule To Liberalize Regulation of Foreign Indirect Cargo Carriers

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This amendment to the Board's regulations concerning name changes by air carriers and foreign air carriers conforms to a new 14 CFR Part 297 adopted today. The Board's new Part, designated ER-1159, Part 297, provides for a simple registration procedure to grant operating authority to foreign air freight forwarders and foreign cooperative shippers associations.

DATES:

Adopted: November 28, 1979.

Effective: January 3, 1980.

FOR FURTHER INFORMATION, CONTACT: Joseph Di Bella, Bureau of International Aviation, Legal Division, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, (202) 673-5035.

For the reasons stated in ER-1159, issued simultaneously, the Board is amending its regulations concerning name changes by air carriers and foreign air carriers to exclude indirect foreign air carriers of property, who will hereafter use the procedures in new Part 297 for name changes.

Accordingly, the Civil Aeronautics Board amended 14 CRF Part 215, *Names of Air Carriers and Foreign Air Carriers*, as follows:

Section 215.1 is amended to read:

§ 215.1 Applicability.

This part applies to all direct air carriers and all foreign air carriers, except air taxi operators and indirect foreign air carriers of property.

(Sec. 204, 416 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 771, as amended by 92 Stat. 1731, 1732 (49 U.S.C. 1324, 1386))

By the Civil Aeronautics Board.

Phyllis T. Kaylor

Secretary.

[FR Doc. 79-37300 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

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14 CFR Part 296

[ER-1165; Docket No. 35568; Amdt. No. 3 to Part 296]

Final Rule To Liberalize Regulation of Foreign Indirect Cargo Carriers

AGENCY: Civil Aeronautics Board.

ACTION: Final Rule.

SUMMARY: This amendment to the Board's regulations concerning air freight forwarders and cooperative shippers associations conforms to a new 14 CFR Part 297 adopted today. The Board's new Part, designated ER-1159, Part 297, provides for a simple registration procedure to grant operating authority to foreign air freight forwarders and foreign cooperative shippers associations.

DATES:

Adopted: November 28, 1979.

Effective: January 3, 1980.

FOR FURTHER INFORMATION, CONTACT: Joseph Di Bella, Bureau of International Aviation, Legal Division, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428, (202) 673-5035.

For the reasons stated in ER-1159, issued simultaneously, the Board is amending the air freight forwarder

regulations to transfer the financial and operating report requirements for foreign air freight forwarders to the new Part 297.

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 296, *Air Freight Forwarders and Cooperative Shippers Associations*, as follows:

Paragraph (a) of § 296.40 is amended to delete the reference to foreign air freight forwarders so that the paragraph reads:

§ 296.40 Financial and operating report.

(a) Each air freight forwarder and cooperative shippers association shall file with the Board a Financial and Operating Report (CAB Form 296R) (Obtainable from Publications Services Section, CAB, Washington, D.C. 20428) on or before February 15 of each year, addressed to Reports Control, Data Systems Management Division, Office of the Comptroller.

* * * * *

(Sec. 204, 416 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 771, as amended by 92 Stat. 1731, 1732 (49 U.S.C. 1324, 1386))

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37301 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

14 CFR Part 385

[Reg. OR-159; Docket No. 35568; Amdt. No. 92 to Part 385]

Final Rule To Liberalize Regulation of Foreign Indirect Cargo Carriers

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMARY: This amendment to the Board's regulations concerning delegations of authority conforms to a new 14 CFR Part 297 adopted today. The Board's new Part, designated ER-1159, Part 297, provides for a simple registration procedure to grant operating authority to foreign air freight forwarders and foreign cooperative shippers associations.

DATES:

Adopted: November 28, 1979.

Effective: January 3, 1980.

FOR FURTHER INFORMATION, CONTACT: Joseph Di Bella, Bureau of International Aviation, Legal Division, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428, (202) 673-5035.

For the reasons stated in ER-1159, issued simultaneously, the Board is amending its organizational regulations to delegate authority to the Director, Bureau of International Aviation, to approve, disapprove, or cancel registrations by foreign air freight forwarders, or to waive reporting requirements applicable to foreign air freight forwarders, under new Part 297.

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 385, *Delegations and Review of Action Under Delegation; Nonhearing Matters*, as follows:

A new paragraph (v) is added to § 385.26 to read:

§ 385.26 Delegation to the Director, Bureau of International Aviation.

The Board delegates to the Director, Bureau of International Aviation, authority to:

* * * * *

(v)(1) Approve or disapprove applications for registration filed under Part 297 of this chapter (Economic Regulations), or require that a registrant under Part 297 submit additional information.

(2) Cancel the registration of any foreign air freight fowarder or foreign cooperative shippers association that files a written notice with the Board indicating the discontinuance of common carrier activities.

(3) Grant or deny requests by foreign air freight forwarders or foreign cooperative shippers associations for permission to deviate from the documentation requirements of § 297.32 of this chapter (Economic Regulations). Such requests will be granted upon a showing that the record retention system of the forwarder permits ready access to information otherwise required on a manifest; that the name of the person determining rates and charges, together with the commodity rate applied, appears on the airwaybill; that the forwarder will provide copies of airwaybills to the consignor or consignee when either so requests; and that the recordkeeping operations of the forwarder otherwise comport with the policy set forth in Order E-19074 of December 7, 1962.

(Sec. 204, 416 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 771, as amended by 92 Stat. 1731, 1732; (49 U.S.C. 1324, 1386))

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37302 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 271 and 274

[Docket No. RM79-68; Order No. 42-A]

Final Rules Amending Regulations on New Natural Gas and Certain Natural Gas Produced From the Outer Continental Shelf

AGENCY: Federal Energy Regulatory Commission.

ACTION: Order Amending Final and Interim Regulations and Denying Motion for Reconsideration and Granting in Part and Denying in Part Petitions for Rehearing of Order 42.

SUMMARY: This regulation amends the final regulations implementing section 102 of the Natural Gas Policy Act of 1978 which sets ceiling prices for new natural gas and certain natural gas produced from the outer continental shelf. This regulation also amends the filing requirements to reflect the changes made in the final regulations.

EFFECTIVE DATE: November 29, 1979.

FOR FURTHER INFORMATION CONTACT: Scott Koves, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, (202) 357-8317.

[Order No. 42-A]

Order Denying Motion for Reconsideration and Granting in Part and Denying in Part Petitions for Rehearing of Order No. 42

Issued: November 29, 1979.

I. Background

On August 14, 1979, the Federal Energy Regulatory Commission (Commission) issued Order No. 42 in Docket No. RM79-68.[1] Applications for rehearing of that order were filed on September 13 and 14, 1979 by several parties [2] (Petitioners), pursuant to § 286.102 of the Commission's regulations. On October 10, 1979, Indicated Producers filed a Motion for Reconsideration of Order No. 42.

Order No. 42 issued Final Regulations for Subpart B of Part 271 of the

[1] Published on August 17, 1979, at 44 FR 48180.

[2] True Oil Company; Harvey E. Yates Company and the Independent Petroleum Association of New Mexico; Texas Oil & Gas Corp., Amoco Production Company; Houston Oil & Minerals Corp., Goldking Production Company, Texas Production Company, Pinto, Inc., Ecee, Inc., and Cliffs Drilling Company; and Tenneco Oil Company, Pennzoil Company, Texas Gulf, Inc., General American Oil Company of Texas. Energy Consumers and Producers Association filed comments on September 4, 1979, which we will consider herein.

Commission's regulations which implements section 102 of the Natural Gas Policy Act of 1978, 15 U.S.C. 3301, *et seq.* (NGPA). Section 102 of the NGPA applies to the first sale of new natural gas. Order No. 42 revised the Commission's interim regulations under the NGPA issued December 1, 1978, in Docket No. RM79–3 [3] and issued Part 271, Subpart B as final regulations. On October 15, 1979, the Commission issued an order granting rehearing to permit further consideration of the issues raised in the petitions for rehearing.

II. Specifications of Error

A. NGPA section 102(c)(1)(C)(ii)(II)—the Behind-the-Pipe Exclusion

Section 102(c)(1)(C) of the NGPA applies to gas produced from "new onshore reservoirs" which are generally defined as onshore reservoirs from which natural gas was not produced in commercial quantities before April 20, 1977. Under the Behind-the-Pipe exclusion, if an old well penetrated the subject reservoir and produced oil or gas in commercial quantities prior to April 20, 1977, the penetrated reservoir is disqualified if gas from that reservoir "could have been produced in commercial quantities" through such old well prior to April 20, 1977.

In Order No. 42, for the reasons discussed, we decided to apply a physical capability test in determining whether gas "could have been produced in commercial quantities" from the subject reservoir. The test only inquires into the capability of the reservoir to produce. Such a physical capability test disregards costs of production and marketing.

Order No. 42 rejected use of an economic test for determining whether gas could have been produced from the reservoir in commercial quantities. Petitioners made various arguments in favor of applying an economic test. Chief among these were the following: (a) The Commission ignored the plain words of the statute by giving no effect to the phrase "in commercial quantities." (b) The Commission inappropriately applied the explanation in the Statement of Managers [4] (page 79) to both components of the phrase "could have been produced"—"in commercial quantities" because the analysis referred only to the phrase "could have been produced." (c) The Commission's interpretation contradicts customary usage of the term "commercial." (d) The legislative history of the NGPA supports the view that Congress intended that an economic test be used to determine whether gas could have been produced in commercial quantities. (e) The Commission's interpretation of the Behind-the-Pipe Exclusion frustrates Congress' policy permitting incentive prices in order to encourage production of previously uneconomical reserves.

We agree that the statutory language, "could have been produced in commercial quantities" must be interpreted and applied in its entirety. A physical capability test should be used for "could have been produced"; an economic test should be used for "in commercial quantities." Therefore, the Commission agrees that it must use both a physical capability test and an economic test in determining whether the reservoir is disqualified by the Behind-the-Pipe Exclusion.[5]

None of the subject applications for rehearing articulated a specific economic test. However, several Petitioners argued that the rebuttable presumption in section 102(c)(3) [6] should be applied in determining whether gas "could have been produced in commercial quantities". Under such a rule, there would be a rebuttable presumption that the Behind-the-Pipe Exclusion would not apply unless actual sales and deliveries had been made from the subject reservoir, prior to April 20, 1977. Thus, the burden of proving the lack of capability to produce in commercial quantities would be shifted to protestants or the jurisdictional agency because the protestants or agency would have to prove such capability existed.

We reject this suggestion. The rebuttable presumption prescribed in section 102(c)(3) applies only to the question of whether gas *has* been produced in commercial quantities, not whether it *could* have been produced. Imposing a rebuttable presumption which would require only that actual sales had not been made prior to April 20, 1977, would all but eliminate the Behind-the-Pipe Exclusion, and would impose an unreasonable administrative burden on jurisdictional agencies by improperly shifting the burden of proof to them in all cases.[7]

One Petitioner suggests that the gas should not be disqualified under the Behind-the-Pipe Exclusion if there were no marketing facilities, such as a gathering system, on April 20, 1977. We do not agree that the absence of marketing facilities is dispositive. While the Statement of Managers, at page 79 directed the application of a physical capability test in determining whether a reservoir could have been produced, that test is to be applied only with respect to the *reservoir's* physical capability to produce and not to whether "actual production capability existed". In other words, as stated by the conferees, "if the pipe were perforated, or if the necessary additional facilities were installed at the appropriate place, [the reservoir] *could have produced* natural gas." (Emphasis added). Therefore, the absence of marketing facilities does not automatically dispose of the issue of whether the reservoir could have been produced in commercial quantities. However, the costs of installing additional necessary facilities will be recognized in considering whether such production would have been in commercial quantities.

We are adopting an economic test which we believe to be comprehensive, yet administratively feasible. However, we do not wish to impose this test and require the submission of economic data where there is very little likelihood that gas could have been produced in commercial quantities from the subject reservoir as of April 20, 1977. Therefore, we will require application of this test only if the potentially disqualifying well—that is, an old well which penetrated the subject reservoir before April 20, 1977, and produced oil or gas in commercial quantities before that date—does not meet both of the following conditions:

(1) No sales and deliveries of natural gas were made prior to April 20, 1977, through the potentially disqualifying well.

(2) No sales and deliveries of natural gas from the subject reservoir were made through the potentially disqualifying well on or after April 20, 1977, and prior to November 9, 1978.

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[3] Published on December 1, 1978, at 43 FR 56448, *et seq.*

[4] Joint Explanatory Statement of the Committee on Conference, Natural Gas Policy Act of 1978, P.L. 95–621, S. Rep. No. 95–1126, August 16, 1978.

[5] In recognition of this, the Commission issued a final order in Docket No. GP79–27 on September 28, 1979 which acknowledged that both a physical capability test and an economic test should be applied to the § 102(c)(1)(C) determination made by the State of North Dakota on the Gulf Oil Corp. State 1–18–3D, Martin Weber Weber 1–18–1C, Marinenko 1–32–1A, Glovatsky 1–17–4A, for the Little Knife Madison Reservoir. In that case, the sourness of the gas and the remoteness of the well was considered as evidence of the non-commerciality of the reserves in question prior to April 20, 1977.

[6] Among other things, section 102(c)(3) provides that, for purposes of section 102(c)(1)(C), a rebuttable presumption exists that production from a reservoir in commercial quantities has not occurred if natural gas has not been sold and delivered from such reservoir before April 20, 1977.

[7] We do believe that certain rebuttable presumptions are reasonable in these cases. (See discussion *infra.*) However, the section 102(c)(3) rebuttable presumption is not one of them.

If both of these conditions are met, we will not require proof under an economic test because we will presume that the subject reservoir could not have been produced in commercial quantities through the potentially disqualifying well before April 20, 1977. This rebuttable presumption is in new paragraph (f)(1) of the special rule in § 271.204 and is incorporated in the filing requirements in § 274.202(d)(2)(ii)(D)(II).

The presumption is based on two components. The first recognizes that, if gas was not being produced and sold prior to April 20, 1977, from a potentially disqualifying well that penetrated the subject reservoir, then marketing facilities (gathering lines, processing facilities, and so forth) probably were not in existence as of that date and would have had to be installed at a considerable incremental cost.[8]

The second component of the presumption is based on the assumption that if no sales actually commenced from the subject reservoir within a reasonable time after April 20, 1977, from a potentially disqualifying well that penetrated that reservoir prior to April 20, 1977, then the subject reservoir probably was not commercial as of April 20, 1977. We have employed the date of enactment of the NGPA (November 9, 1978) as the cut-off date for this period. The generally higher ceiling prices permitted by the NGPA in many cases rendered marketable gas reserves which up until that time were not commercial.

We have incorporated this presumption into the reporting requirements in § 274.203 by limiting the reporting obligations of new paragraph (d)(2)(ii)(D) to those applicants who are unable to meet the presumption. This should reduce the number of applicants that may be required to submit further evidence as to the applicability of the Behind-the-Pipe Exclusion.

However, in the event that the rebuttable presumption of non-commerciality does not apply, then we believe it is reasonable to require the applicant to submit economic evidence that is substantially more convincing than would otherwise be required. Under these circumstances, the applicant must submit evidence that clearly demonstrates that the gas could not have been produced in commercial quantities from such reservoir through such old well before April 20, 1977. The new paragraph (d)(2)(ii)(D) to § 274.202 incorporates this requirement.

However, the Commission also recognizes that section 102(c)(1)(C), like section 102(d), involves a reservoir determination. Therefore, the determination that a reservoir is a new onshore reservoir need be made only once and can apply to all wells producing from the reservoir. Furthermore, if it is necessary to apply an economic test, only one applicant need present such economic data. Thus, new § 274.202(d)(2)(ii)(D)(I) provides that if a final eligibility determination has been made determining that the subject reservoir qualifies as a new onshore reservoir, subsequent applicants need not meet the evidentiary showing required by new clause (ii)(D)(II) of § 274.202(d)(2) in order to demonstrate that the reservoir from which they are producing is not disqualified as a new onshore reservoir under the Behind-the-Pipe Exclusion. Once the applicant shows that such a final eligibility determination has been made, the applicant need only show that the well for which he seeks a determination is in fact producing from the reservoir that was previously determined to be a new onshore reservoir and that the Withheld Gas Exclusion, which is determined on a well-by-well basis, does not apply. Correspondingly, if a jurisdictional agency gives adequate notice and opportunity to participate in a proceeding and if one applicant receives a negative determination due to the fact that the reservoir has been disqualified because it was produced in commercial quantities prior to April 20, 1977, or because the Behind-the-Pipe Exclusion applied to the reservoir, and that determination has become final under § 273.102, all subsequent application relative to wells producing from the subject reservoir would also be disqualified under section 102(c)(1)(C).

The Commission believes that use of the rebuttable presumption will reduce the number of applicants who must file data to prove that a reservoir meets the economic test in § 274.202(d)(2)(ii)(D)(II) to a manageable number.

The economic test, stated in § 271.201, provides that a reservoir could have produced in commercial quantities if the sale of the production from the reservoir through the potentially disqualifying well could generate revenues (net of royalty) equal to or greater than the sum of (i) 1.6 times the minimum incremental costs (properly allocable to such production of installing post-April 20, 1977 facilities required to market such production, plus (ii) the minimum incremental expenses (properly allocable to such production) reasonably required to operate such facilities. All costs, expenses, and revenues are to be determined as of April 20, 1977.

In order to avoid the unmanageable administrative task of engaging in numerous proceedings dealing with the issue of appropriate return, we have made certain reasonable assumptions to derive this rule of thumb formula which reflects a minimum reasonable return. Based upon examination of the prime lending rate of 6.25 percent [9] as of April 20, 1977; the federal tax rate of 48 percent as of that date; and the after-tax return of less than 6.25 percent [10] on safe investments in the money market as of April 20, 1977, the Commission has determined 6.25 percent to be the appropriate after-tax rate of return. The rule of thumb formula approximately reflects an after-tax rate of return of 6.25% in the average case by multiplying incremental capital costs by a constant of 1.6.[11]

In accordance with the economic test, if the sale of the gas would have recouped the required costs, expenses and return, then the reservoir "could have been produced in commercial quantities" prior to April 20, 1977, and the Behind-the-Pipe Exclusion applies. In that case, gas from the reservoir would not qualify for the section 102 new onshore reservoir price. We are amending our regulations by adding a new paragraph (f)(1) to § 271.204 which incorporates the economic test set forth herein in the definition of the phrase "could have been produced in commercial quantities", and by adding a new paragraph (d)(2)(ii)(D)(II) to § 274.202 of the filing requirements.

The key components of this test are estimates of reserves, costs, and the market price of the gas. The following formula is to be used in applying the economic test: [(market price available as of April 20, 1977) × (reserves net of royalty producible from the subject reservoir through the potentially disqualifying wells)] − [(incremental operating expenses) + (1.6 × incremental capital costs)]. If the result is negative, then the exclusion does not apply. In order to maintain a relatively simple economic test we shall assume that escalations in the additional capital costs and operating expenses would be offset by escalations in the price applicable to the sale. Furthermore, we

[8] This component focuses on gas produced from reservoirs other than the subject reservoir because, if gas was produced and sold from the subject reservoir prior to April 20, 1977, the reservoir was "produced in commercial quantities before April 20, 1977," and, according to section 102(c)(1)(C)(i) is disqualified as a new onshore reservoir.

[9] Federal Reserve Bulletin, No. 5, Vol. 63, May 1977, page A26, Table 1.34.

[10] Federal Reserve Bulletin, No. 5, Vol. 63, May 1977, page A27, Table 1.36.

[11] See Appendix A for further explanation.

will assume that the effects of the time value of money will likewise be offset. Therefore, all costs, expenses, and revenues will be viewed as of one time frame, April 20, 1977. We are making these and other assumptions because we cannot justify requiring extensive special relief-type proceedings to determine whether or not the Behind-the-Pipe Exclusion applies for each of what may be a substantial number of onshore reservoirs.

According to the test in § 274.202(d)(2)(ii)(D)(II): if the sale of production from the subject reservoir (net of royalty) through any well that produced crude oil or natural gas in commercial quantities prior to April 20, or natural gas in commercial quantities prior to April 20, 1977, at the *"market price reasonably available as of April 20, 1977"*, could not have generated revenues sufficient to equal or exceed the sum of 1.6 times the *"minimum incremental costs properly allocable to such production of installing cost-efficient facilities not in existence as of April 20, 1977"*, reasonably required to market such production, plus the *"minimum incremental expenses properly allocable to such production reasonably required to operate such facilities"*, then the Behind-the-Pipe Exclusion will not apply. (Emphasis added.) Application of the test requires the understanding of the following terms:

(1) The "market price reasonably available as of April 20, 1977" means the price reasonably likely to have been paid for the gas on that date. This might be shown, for example, by offers actually made to purchase the gas at a certain price or by the prices being paid for gas of similar quality on April 20, 1977, in the area of the sale.

(2) The phrase "minimum incremental costs" means the lowest additional capital costs, *i.e.*, non-recurring expenditures, for facilities.

(3) "Properly allocable to such production" means that if, for example, a gathering line would have been required to be built to gather the subject reserves but also would have been used to gather reserves known prior to April 20, 1977, and produced from other reservoirs through other wells, some reasonable allocation of the costs of that gathering line would have to be made. In addition, if oil or gas liquids (such as butane) would have been produced in conjunction with the subject reserves, then a reasonable allocation of costs to the separate products should also be made.

(4) "Cost-efficient facilities" means the most economical facilities reasonably required to sell the subject reserves. For example, if, all other things considered equal, the producer had the choice of building a 1 mile gathering line to sell the reserves to pipeline A or building a 20 mile gathering line to sell to pipeline B, the 1 mile line would probably be the "cost-efficient facility". If the producer had the choice of installing a 4-inch gathering line and a 150 hp compressor or a 2-inch gathering line and a 50 hp compressor and the 2-inch gathering line and 50 hp compressor would have provided sufficient capacity for delivery, the 2-inch gathering line and 50 hp compressor probably would be the "cost-efficient facility." However, there may be cases where the cost-efficient facilities would have a capacity larger than that required to sell only the subject reserves. For example, if other reserves could have been attached to the same gathering line and other delivery facilities required to market the subject reserves, consideration of economies of scale might dictate considering the cost of facilities with a larger capacity and allocating such cost to the subject reserves on the basis of, for example, the percentage of daily throughput through the system.

(5) The phrase "facilities not in existence as of April 20, 1977" means that only costs of additional facilities that were required to market gas but were not already installed as of April 20, 1977, are to be considered. For example, if a gathering line was already built as of April 20, 1977, none of the costs of that line would be considered in the test. If, however, the line was only partially completed and processing facilities were still required to be installed as of April 20, 1977, then the cost to complete the gathering line plus the cost to install the processing facilities would be considered. The "sunk costs" of that portion of the gathering facilities already installed as of April 20, 1977, would not be considered.

(6) The "minimum incremental expenses, properly allocable to such production, reasonably required to operate such facilities" means the lowest, most reasonable estimate of the total operating expenses, *i.e.*, recurring costs such as maintenance expenditures, that would be paid over time relative to producing and marketing reserves from the subject reservoir through the potentially disqualifying well. However, as in the case of capital costs, operating expenses must be allocated if the facilities used to market the subject reserves are also used to market other reserves. An example may clarify what is intended. Even though the capital costs invested in a gathering line in existence on April 20, 1977, are "sunk costs" and therefore irrelevant to the economic test, the expenses of operating that line incurred on or *after* April 20, 1977, are relevant. The total of those expenses should be subtracted from revenues in establishing whether the test is met. However, if the line would be used to gather other reserves in addition to the subject reserves, the total operating expenses must be allocated to the subject reserves on some reasonable basis; for example, the percentage of average throughput might be used for that purpose.

We have formulated two examples located in Appendix B to this order to further clarify how the economic test should be applied in practice.

We believe that this economic test accomplishes the congressional intent of section 102 of the NGPA. Not only did Congress wish to encourage the production of previously non-commercial reserves by allowing an incentive price but Congress also wished to deny this incentive price to production withheld from the marketplace for purposes of price speculation, *i.e.*, cases where an incentive price should not be necessary to encourage production of the reserves. This intent underlies the Behind-the-Pipe and Withheld Gas Exclusions. The Commission believes that the economic test adopted herein for the Behind-the-Pipe Exclusion will encourage production of reserves which were not commercial prior to April 20, 1977; *i.e.*, reserves the sale of which could not generate revenues at least equal to the incremental costs and expenses of marketing the gas plus a minimum reasonable return. Furthermore, the Commission believes an economic test which would allow a return higher than such minimum return as well as a recovery of sunk costs would contravene the intent underlying the Behind-the-Pipe Exclusion because it might permit the section 102 maximum lawful price to be applied to gas previously withheld from production in order to speculate on greater profits than could have been generated if the reserves had been sold at prices available on April 20, 1977.

The test employs factors used in making the common business decision of whether to expend additional money on a given project or to apply it elsewhere. Only incremental expenditures and incremental revenues are relevant in deciding whether to expand additional money on the project. Expenditures incurred prior to the date of the decision are irrelevant to that decision. The economic test for the

Behind-the-Pipe Exclusion fixes that decisional date as April 20, 1977. Consequently, the only costs to be considered are those incremental costs which were necessary as of April 20, 1977, in order to produce natural gas from the reservoir in commercial quantities.

B. Section 271.204(c)—Definition of "Commercially Producible" as Used in Section 102(d) of the NGPA

Section 271.204(c) of the Commission's Regulations defines the term "commercially producible" which is found in section 102(d)(2)(B)(iii) of the NGPA. Section 102(d) of the NGPA generally provides that gas produced from old OCS leases from reservoirs discovered on or after July 27, 1976, may qualify for the section 102 price. A reservoir will be considered as having been discoverd before July 27, 1976, if it was penetrated by a well prior to July 27, 1976, and the results of at least one of three possible groups of tests (described in section 102(d)(2)(B)) demonstrate that production from the reservoir was potentially economic as of the time of the tests. If a production test, or production capability evidence, meeting the requirements of OCS Order No. 4, demonstrates that the well was "capable of producing in paying quantities," the reservoir is disqualified. If induction-electric logs, sidewall cores and other test data indicate that, at the time of the test, the reservoir was "commercially producible," then, again, the reservoir is disqualified.

Section 271.204(b) defines "capable of producing in paying quantities" in terms of whether the eventual sale of the reserves would have generated sufficient revenues to recover out-of-pocket operating costs. This is the standard consistently applied by the United States Geological Survey (USGS). However, § 271.204(c) ties the definition of "commercially producible" to the definition of "production in commercial quantities" which is based on whether there have been actual sales and deliveries or the gas has been retained for beneficial economic use.

One Petitioner suggests that the definition of "commercially producible" should not be linked to the definition of "production in commercial quantities" in § 270.102(b)(4). Upon reconsideration of this issue, we agree. The term "commercially producible" in clause (iii) of NGPA section 102(d)(2)(B) is actually linked to the same types of tests and evidence that are the subject of the paying quantities standard in clauses (i) and (ii) of section 102(d)(2)(B). All three clauses are designed to determine if a reservoir was discovered prior to July 27, 1976. We do not believe that one economic test should be applied to determine the capability of a reservoir to produce in paying quantities, and another to determine if the same reservoir would be commercially producible if both are to be used to determine the same thing—the date of discovery of the reservoir. Accordingly, we shall amend § 271.204(c) to require the same out-of-pocket cost test for the commercially producible standard which we applied in § 271.204(b) for the paying quantities standard. We also have amended the reporting requirements at § 274.203(e)(3) to refer to "commercially producible."

One Petitioner and Indicated Producers assert that § 271.204(c) ignores when the determination of "commercially producible" is to be made, *i.e.*, when the results of such tests became available. They suggest that § 271.204(c) should be amended so that an economic test is based on the tests and evidence available before July 27, 1976, and that the economic test itself should take into account all costs which would have been required to be incurred after the date of such tests to produce and market the gas, including, for example, the costs of additional platforms and pipelines.

We disagree with the Indicated Producers suggestions, and therefore shall deny Indicated Producers' Motion for Reconsideration. First, the § 271.204(c) definition of "commercially producible" does not eliminate the requirement otherwise found in the third clause of section 102(d)(2)(B) that the "commercially producible" determination is to be made as of the time the tests were made or evidence was obtained. Second, as to the issue of the type of economic test to be applied, we believe Congress clearly intended to adopt the criteria by which the USGS makes an OCS reservoir determination. Those criteria include the application of the out-of-pocket cost analysis already described in § 271.204(b).[12]

C. Notice

One Petitioner asserts that the Commission failed to give adequate notice and opportunity to participate in Docket No. RM79-68 because its Final Regulations issued in Order No. 42 go beyond mere clarification or interpretation of the Behind-the-Pipe Exclusion.

We disagree. First, Order No. 42 was the culmination of a rulemaking process involving the issuance of interim regulations on December 1, 1979, followed by public hearings and a lengthy comment period ending January 29, 1979. During that comment period the proper interpretation of all parts of section 102 was raised for public comment and the Petitioner had adequate opportuntiy to recommend as it now suggests, that an economic test should be applied with respect to the Behind-the-Pipe Exclusion. Moreover, Petitioner's claim is moot because under this order we have promulgated an economic test for the phrase "could have been produced in commercial quantities", in the Behind-the-Pipe Exclusion. This was what the Petitioner had requested.

D. Section 102(c)(1)(B)—New Onshore Wells

One Petitioner suggests that we erred in our answer to a question involving new recompletions by restricting the application of the section 102 price to only gas produced from "new wells." In Order No. 42, we stated:

> Another comment suggested that new recompletions, either by plug back or re-entry, should qualify for the section 102 price. Although it is more economical in some instances to recompete a well than to drill a new well, the statutory language limits the section 102 price, *inter alia*, to wells spudded on or after February 19, 1977 or wells drilled to an increased depth of at least 1000 feet on or after February 19, 1977. [Mimeo at page 3]

We did not intend this statement to be read as requiring the drilling of a "new well" in order to qualify gas from a new OCS lease, a new onshore reservoir, or a new OCS reservoir on old OCS lease for the section 102 price. A well must be a "new well" only if its is to qualify as a "new onshore well" under section 102(c)(1)(B).

III. Public Procedures and Effective Dates

For the reasons discussed in Order No. 42 (issued August 14, 1979), the amendments to § 271.204(a) and (b) of Subpart B of Part 271 were issued as final regulations and were immediately effective as to jurisdictional agency determinations which had not become final (as determined in § 275.202) as of August 13, 1979.

Our order today: amends paragraph (c) and adds a new paragraph (f) to § 271.204; makes several changes to the interim regulations in § 274.202; and makes a conforming amendment to the interim regulations in § 274.203(e)(3).

The amendment to paragraph (c) of § 271.204 and the conforming modification to § 274.203(e)(3), were made in response to comments made in Indicated Producer's motion for reconsideration as well as the petitions for rehearing of Order No. 42. The effect

[12] See the public file on Docket No. RM79-68.

of the amendments is to conform our regulations to existing USGS standards of review. Accordingly, it is in the public interest to issue the amendments to the final regulations in § 271.204(c) and the interim regulations in § 274.203(e)(3) effective immediately with regard to jurisdictional agency determinations which have not become final under § 275.202 as of the day before the date of issuance of this order.

The amendments which apply a new economic test to determinations which involve the Behind-the-Pipe Exclusion (and associated reporting requirements), were made in response to comments we have received to date. We shall therefore issue these as final regulations and shall not request further public comments. We believe that complying with the 30-day publication requirement of section 553(d) of the Administrative Procedure Act is impractical in this case and contrary to the public interest since numerous jurisdicational agency determinations dealing with the Behind-the-Pipe Exclusion are pending and uncertainty exists respecting the application of the Behind-the-Pipe Exclusion. Therefore, new paragrph (f) in § 271.204 is issued as a final rule and new clauses (C) and (D) of § 274.202(d)(2)(ii) are issued as interim rules, effective immediately for all applications for which a jurisdictional agency determination has not been made as of the day before the date of issuance of this order. In the case of determinations already received by the Commission for which the 45 day period under § 275.202(a) has not expired, or if applicable, the 120 day period under § 275.202(e), we shall provide applicants the opportunity to supplement their applications in accordance with the amended regulations, in which case we may remand the determinations to the jurisdictional agencies for their reconsideration.

The Commission orders:

(A) The Petitions for Rehearing reference above filed in Docket No. RM79–68 are granted in part and denied in part as is more fully detailed in the text above.

(b) The motion for reconsideration filed by Indicated Producers is denied.

(c) Parts 271 and 274 of the Commission's regulations are amended as set forth below to be effective as set forth above.

(Natural Gas Act, as amended, 15 U.S.C. 717 *et seq.*; Department of Energy Organization Act, 42 U.S.C. 7107, *et seq.*; E.O. 12009, 42 F.R. 46267; Natural Gas Policy Act of 1978, 15 U.S.C. §§ 3301–3432.)

In consideration of the foregoing, the final rules in Part 271 and the interim rules in Part 274 of Subchapter H, Chapter I, Title 18, Code of Federal Regulations are amended as set forth below, effective as set forth above.

By the Commission.

Kenneth F. Plumb,

Secretary.

PART 271—CEILING PRICES

1. Section 271.204 is amended by deleting paragraph (c) and substituting the following in lieu thereof:

§ 271.204 Special rules.

* * * * *

(c) *Commercially producible.* For purposes of section 102(d)(2)(B)(iii) of the NGPA, a reservoir is commercially producible if a well completed therein can reasonably be expected to produce natural gas in quantities sufficient to yield revenues in excess of operating costs. For the purposes of this paragraph, operating costs include those out-of-pocket cash expenses necessary to operate and maintain a well.

2. Section 271.204 is further amended by adding new paragraph (f) to read as follows:

(f) *Could have been produced in commercial quantities.* For purposes of determining under section 102(c)(1)(C)(ii)(II) of the NGPA, whether natural gas from a reservoir could have been produced in commercial quantities thru an old well which penetrated such reservoir before April 20, 1977:

(1) A rebuttable presumption exists that a reservoir could not have been produced in commercial quantities prior to April 20, 1977, through such old well if:

(i) No sales and deliveries of natural gas were made prior to April 20, 1977, through such well; and,

(ii) No sales and deliveries of natural gas from the subject reservoir were made through such well on or after April 20, 1977, and before November 9, 1978.

(2) If such rebuttable presumption is not met, then the first seller must clearly demonstrate that the sale of the production from such reservoir through such old well at the market price reasonably available as of April 20, 1977, could not reasonably have generated revenues (net of royalty) equal to or greater than the sum of (i) 1.6 times the minimum incremental costs (properly allocable to such production) of installing cost-efficient facilities (not in existence as of April 20, 1977) reasonably required to market such production, plus (ii) the minimum incremental expenses (properly allocable to such production) reasonably required to operate such facilities. All costs, expenses, and revenues shall be determined as of April 20, 1977.

PART 274—DETERMINATIONS BY JURISDICTIONAL AGENCIES

3. Section 274.202 of the Commission's Interim Regulations is amended in paragraph (d)(2)(ii) by redesignating clause (ii)(C) as (ii)(E) and clause (ii)(D) as (ii)(F) and by inserting new clauses (ii)(C) and (ii)(D) to read as follows:

§ 274.202 New natural gas.

* * * * *

(d) *New onshore reservoir.*

* * * * *

(2)

* * * * *

(ii)

* * * * *

(C) If the question in clause (ii)(B) is answered in the negative, were any sales and deliveries of natural gas made from any other reservoir through any old well described in clause (ii)(A) prior to April 20, 1977, and were any sales and deliveries of natural gas made from the subject reservoir through such old well on or after April 20, 1977, and before November 9, 1978?

(D) If the applicant is unable to answer both questions in clause (ii)(C) in the negative, he must demonstrate that the Behind-the-Pipe Exclusion in section 102(c)(1)(C)(ii) of the NGPA does not apply by submitting the following:

(I) Proof that a final eligibility determination has been made that the subject reservoir is a new onshore reservoir by identifying such determination by the jurisdictional agency and FERC Docket number and the API well numbers, or,

(II) Evidence clearly demonstrating that the sale of production from the subject reservoir (net of royalty) through any well described in paragraph (d)(2)(ii)(A) at the market price reasonably available as of April 20, 1977 could not have generated revenues sufficient to equal or exceed the sum of (*i*) 1.6 times the minimum incremental costs properly allocable to such production of installing cost-efficient facilities not in existence as of April 20, 1977, reasonably required to market such production, plus (*ii*) the minimum incremental expenses properly allocable to such production reasonably required to operate such facilities. All costs, expenses and revenues shall be determined as of April 20, 1977. The applicant shall also provide an explanation of the basis of all estimates accompanied by substantiating workpapers and such other evidence necessary to substantiate fully the

conclusion that the Behind-the-Pipe Exclusion does not apply.

§ 274.203 [Amended]

4. Section 274.203 is amended in paragraph (e)(3) by deleting, "capable of producing in commercial quantities" and substituting "commercially producible" in lieu thereof.

Appendix A

The Commission has established a rule-of-thumb formula which employs a 1.6 multiplier in all cases as a surrogate for a more detailed return analysis conducted on a case-by-case basis. Such case-by-case analyses would create too great an administrative burden to be feasible. The constant of 1.6 was derived from an average annual investment analysis which assumed an investment of $500,000, a Federal income tax (FIT) rate of 48 percent [1] and a required after-tax rate of return of 6.25 percent. The analysis also employed a 15-year depletion period as well as the sum-of-the-year digits method of depreciation. Fifteen years was chosen as a reasonable approximation of the average depletion period, based on the depletion period used in Opinion No. 770.[2]

The sum-of-the-years digits method of depreciation was used because the Commission believes that it best approximates the results of the unit of production method of depreciation employed in industry. That method is representative of actual delivery from a reservoir. Normally, the reservoir is produced at a high rate in early years and declines in production on an exponential basis in later years.

The result of the analysis indicates that the resulting amount of return and FIT is $310,496, approximately 60 percent of the assumed investment of $500,000. Therefore, in the average case, increasing the incremental costs by 60 percent (*i.e.*, multiplying by a constant of 1.6) will produce an after-tax return of approximately 6.25 percent.

[1] State income taxes were not provided for because of differing tax structures in the various states.

[2] *Mimeo.* at page 68 (issued July 27, 1976 in Docket No. RM75-14).

Calculation of Return Allowance and Federal Income Taxes

Assumptions

1. 15 year productive life.
2. After tax return allowance: 6.25%.
3. 1977 statutory tax rate: 48%.
4. Employed sum-of-the-year digits method of depreciation.
5. No salvage value.
6. Estimated incremental capital costs: $500,000.

	Beginning of year investment	Depreciation	End of year investment	Average investment
Year:				
1	$500,000	$62,500	$437,500	$468,750
2	437,500	58,333	379,167	408,334
3	379,167	54,167	325,000	352,083
4	325,000	50,000	275,000	300,000
5	275,000	45,833	229,167	252,084
6	229,167	41,667	187,500	208,334
7	187,500	37,500	150,000	168,750
8	150,000	33,333	116,667	133,334
9	116,667	29,167	87,500	102,083
10	87,500	25,000	62,500	75,000
11	62,500	20,833	41,667	52,084
12	41,667	16,667	25,000	33,333
13	25,000	12,500	12,500	18,750
14	12,500	8,333	4,167	8,334
15	4,167	4,167	0	2,083
Totals		500,000		2,583,336

Average Annual Investment=$2,583,336÷15 years=$172,222.
Return Allowance=($172,222×0.0625)×15 years=$161,458.
Federal Income Taxes=$161,458×.48/52=$148,038.
Return plus Federal Income Tax ($310,496) is approximately 0.62 times the initial investment.

Appendix B

Two examples should help clarify how the test is to be applied.

Hypothetical No. 1—Assume that, as of April 20, 1977, the applicant was flaring casinghead gas produced in conjunction with commercial oil production through an old well (subject well) from the subject reservoir. Gas was flared due to the absence of a required gas gathering line as of that date. Several months later, the producer builds the gathering line and commences sales and deliveries of the casinghead gas produced from the subject reservoir through the subject well (subject reserves) as well as gas he produced from other wells in the same locality as the subject well using the newly built gathering line. Assume that the record reflects that the most economical gathering system would be comprised of a 4-inch line and a 150 hp compressor capable of efficiently handling the throughput from all wells in the same locality rather than a 2-inch line and 50 hp compressor that would have been required to carry only the subject reserves. Also assume that the record reflects that, as of April 20, 1977, the producer had the choice of (1) building a 1-mile long, 4-inch gathering line at a total capital cost of $40,000 plus $10,000 total estimated future operating expenses to sell the subject reserves to pipeline A and receive $1.45 per Mcf for the gas, or (2) to build a 20-mile long, 4-inch gathering pipe at a total capital cost of $500,000 plus $75,000 total estimated future operating expenses to sell to pipeline B and receive the same $1.45 price. Assume 50,000 Mcf [1] of "subject reserves" producible through the subject old well based on the producing history of the reservoir and another 50,000 Mcf of other reserves know to exist as of April 20, 1977, that would be expected to be attached to the same gathering line.

Clearly the facilities in the first alternative would involve the most economical, and therefore "cost-efficient", facilities for marketing the subject reserves given that in both alternatives the gas will receive the same price. Fewer facilities at a lower total cost are involved. The economic test would, therefore, focus on the first alternative. At that point in the inquiry any reasonable method of allocating the costs and expenses to the subject reserves could be applied. For example, the ratio of subject reserves to total reserves or the ratio of daily throughput could be used to allocate costs and expenses. Assume that the record reflects a reasonable allocation procedure that results in $20,000 capital costs and $5,000 operating expenses allocable to the subject reserves.

The test, as described in § 271.204(f)(1) and § 274.202(d)(2)(ii)(D)(II) using a formula format, is applied as follows: [(market price available on April 20, 1977) × (total reserves net of royalty producible through the subject well from the subject reservoir in Mcf)] − [((1.6) × ("the minimum incremental costs, properly allocable to such production, of installing cost-efficient facilities not in existence as of April 20, 1977, reasonably required to market such production")) + ("the minimum incremental expenses, properly allocable to such production, reasonably required to operate such facilities")]. If the result is negative, then the exclusion does not apply.

Inserting the data of the correct hypothetical facilities into the formula, produces the following results:

[($1.45/Mcf) × (50,000 Mcf)] − [((1.6) × ($20,000)) + ($5,000)] = [$72,500] − [$37,000] = $35,500

[1] Measured at 14.73 psia, 60° F, and BTU content of 1,000 Btu/cf.

Because the project could have recovered more than the required costs, expenses and return, the "could have been produced in commercial quantities" test is met, the Behind-the-Pipe Exclusion applies, and the reservoir is disqualified as a new onshore reservoir.

Hypothetical #2—Assume that, as of April 20, 1977, an old gas well (subject well) was producing gas from a lower zone, which gas was being sold, and the upper "Behind-the-Pipe" zone (the subject reservoir) was in a non-producing status at that time. The record reflects that the estimated cost to recomplete into the subject reservoir at such later time as the lower zone is depleted would be $2,000 when estimated as of April 20, 1977. Future total operating expenses properly allocable to the subject reserves are estimated to be $5,000. The market price, as of April 20, 1977, was $1.45 (based on the price being received for production from the lower zone) and 50,000 Mcf [2] of reserves were estimated to be producible from the subject reservoir through the subject well (subject reserves). However, the applicant also submits evidence that the gathering system used to market the gas from the subject well was built at a cost of $150,000 in 1976. He also offers proof that the cost of a new well to commence actual production and sales from the subject reservoir prior to April 20, 1977 would have been in excess of $100,000.

The record facts should be analyzed as follows. The only capital cost relevant for consideration is the $2,000 cost of a prospective recompletion. The $150,000 expenditure was a sunk cost as of April 20, 1977. That expenditure is irrelevant to the economic considerations facing the producer on April 20, 1977, *i.e.*, whether the price he could receive for producing the subject reserves would make it worth his spending an additional $2,000 to recomplete into that zone sometime in the near future. The $100,000 estimated cost of a new well is also irrelevant because the test concerns only the commerciality of producing gas from the subject reservoir *through the subject old well* assuming that, *when the zone is eventually completed in,* the price would be limited to the market price available on April 20, 1977. The test does not inquire into alternative ways of commencing actual production and sales prior to April 20, 1977.[3] Accordingly, only $2,000 of additional costs would be required to commence sales of gas produced from the subject reservoir *through the subject old well.* The formula would be applied as follows:

$[(\$1.45/\text{Mcf}) \times (50{,}000\ \text{Mcf})] - [((1.6) \times (\$2{,}000)] + (\$5{,}000)] = [\$72{,}500] - [\$8{,}200] = \$64{,}300$

[2] Measured at 14.73 psia, 60° F, and a Btu content of 1000 Btu/cf.

[3] As we noted earlier, the physical capability aspect of the "could have been produced in commercial quantities" test only relates to the physical capability of the reservoir to produce if and when it is completed in and all sale facilities are in place.

Again, because the applicant could have recovered the required costs, expenses and return, his reservoir is disqualified.

[FR Doc. 79-37310 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 178

[Docket No. 79F-0331]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Certain Adjuvants and Production Aids

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the food additive regulations to provide for the safe use of rice bran wax as a release agent in processing plastic packaging materials intended for food-contact applications. This action is in response to a petition from H&C Industries, Inc., Torrance, CA.

DATES: Effective December 4, 1979; objections by January 3, 1980.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: A notice published in the **Federal Register** of October 2, 1979 (44 FR 56744) announced that a food additive petition (FAP 9B3430) had been filed by H&C Industries, Inc., Del Amo Executive Plaza, 3848 Carson St., Torrance, CA 90503, proposing that the food additive regulations be amended to provide for the safe use of rice bran wax as a release agent in processing plastic packaging materials intended for food-contact use.

Having evaluated data in the petition and other relevant materials, FDA concludes that the food additive regulations should be amended to include the petitioned additive as set forth below.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), § 178.3860 is amended in paragraph (b) by alphabetically inserting a new item in the list of substances to read as follows:

§ 178.3860 Release agents.

* * * * *

(b) * * *

List of substances and limitations.

* * * * *

Rice bran wax—For use only in plastics intended for contact with dry foods identified as Type VIII in Table 1 of § 176.170(c) of this chapter, at levels not in excess of 1.0 percent by weight of the polymer.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before January 3, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date: This regulation becomes effective December 4, 1979.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)))

Dated: November 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-37136 Filed 12-3-79; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 548

[Docket No. 79N-0239]

Certifiable Peptide Antibiotic Drugs for Animal Use; Bacitracin, Neomycin, Polymyxin, Hydrocortisone Sterile Ophthalmic Ointment

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The animal drug regulations are amended to reflect approval of a new animal drug application (NADA) filed by Burroughs Wellcome Co., providing for the safe and effective use of a sterile ophthalmic ointment for the treatment of certain forms of conjunctivitis in dogs and cats.

EFFECTIVE DATE: December 4, 1979.

FOR FURTHER INFORMATION CONTACT: Bob Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Burroughs Wellcome Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709, filed an NADA (65-476) providing for the safe and effective use of a sterile ophthalmic ointment containing in each gram, 400 units of bacitracin zinc, 5 milligrams of neomycin sulfate, 5,000 units of polymyxin B sulfate, and 10 milligrams of hydrocortisone acetate. The drug, used for treating dogs and cats for certain acute and chronic forms of conjunctivitis when caused by susceptible organisms, is identical to one currently in the regulations (21 CFR 548.314(b)). These drugs are limited to use by or on the order of a licensed veterinarian.

In accordance with the regulations promulgated under the Freedom of Information Act (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application is available for public examination at the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m, Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), (n), 82 Stat. 347, 350-351 (21 U.S.C. 360b(i), (n))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), § 548.314b *Bacitracin zinc, polymyxin B sulfate, neomycin sulfate, hydrocortisone acetate ophthalmic ointment* is amended in paragraph (c)(2) by adding before the number "025463" the phrase "000081 and."

Effective Date. This regulation is effective December 4, 1979.

(Sec. 512(i), (n), 82 Stat. 347, 350-351 (21 U.S.C. 360b(i), (n)).)

Dated: November 26, 1979.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 79-36992 Filed 12-3-79; 8:45 am]

BILLING CODE 4110-03-M

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 535

Iranian Assets Control Regulations; Authorization of Certain Judicial Proceedings Regarding Property of Iran or Iranian Entities

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Foreign Assets Control is amending the Iranian Assets Control Regulations. The purpose of the amendment is to add new paragraph (d) to § 535.504. That section authorizes certain judicial proceedings with respect to property of Iran or Iranian entities. The need for the amendment is to exclude from that authorization any pre-judgment attachment of certain types of property of Iran and Iranian entities brought into the United States under specific license from the Office of Foreign Assets Control. The effect of the amendment is that attachments are not authorized with respect to such specifically licensed Iranian property.

EFFECTIVE DATE: November 29, 1979.

FOR FURTHER INFORMATION CONTACT: Dennis M. O'Connell, Chief Counsel, Office of Foreign Assets Control, Department of the Treasury, Washington, D.C. 20220, (202) 376-0236.

SUPPLEMENTARY INFORMATION: Since the regulations involve a foreign affairs function, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, requiring notice of proposed rulemaking, opportunity for public participation and delay in effective date are inapplicable.

31 CFR Part 535 is amended by the addition of paragraph (d) to § 535.504, as follows:

§ 535.504 Certain judicial proceedings with respect to property of Iran or Iranian entities.

* * * * *

(d) Property transferred into or held in the United States by Iran or an Iranian entity under a specific license which by its terms withdraws the authorization for pre-judgment attachment with respect to such property is excluded from the privileges of paragraph (a) of this section.

(Secs. 201-207, 91 Stat. 1626; (50 U.S.C. 1701-1706); E.O. No. 12170, 44 FR 65729)

Dated: November 29, 1979.

Stanley L. Sommerfield,

Director.

Approved:

Richard J. Davis,

Assistant Secretary.

[FR Doc. 79-37159 Filed 12-3-79; 8:45 am]

BILLING CODE 4810-25-M

DEPARTMENT OF DEFENSE

Corps of Engineers, Department of the Army

33 CFR Part 207

Navigation Regulations; Navigation Lock, Chicago River, Ill.

AGENCY: U.S. Army Corps of Engineers, DoD.

ACTION: Final rule; correction.

SUMMARY: In the Federal Register dated November 27, 1979 (FR Doc. 79-36489, 44 FR 67657) the Heading, "Lake Washington Ship Canal, Washington" incorrectly appears. The heading is changed to read "Navigation Lock, Chicago River, Illinois."

DATE: Effective on November 28, 1979.

ADDRESS: HQDA, DAEN-CWO-N, Washington, D.C. 20314.

FOR FURTHER INFORMATION CONTACT: Mr. Ralph T. Eppard, (202) 272-0200.

(40 Stat 266; 33 U.S.C. 1)

Dated: November 28, 1979.

Richard M. Edwards,

Assistant Chief, Construction—Operations Division, Directorate of Civil Works.

[FR Doc. 79-37142 Filed 12-3-79; 8:45 am]

BILLING CODE 3710-92-M

Proposed Rules

Federal Register
Vol. 44, No. 234
Tuesday, December 4, 1979

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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Ch. I

Improving Government Regulations; Semiannual Agenda of Regulations

AGENCY: Office of Personnel Management.

ACTION: Semiannual Agenda of Regulations.

SUMMARY: The following Office of Personnel Management regulations are scheduled for review or development during the six month period from January 1, 1980, through June 30, 1980. As a service to users, we have also included a compilation of significant regulations published from June 1, 1979, through October 31, 1979. (Excepted service appointing authorities are not included.)

FOR FURTHER INFORMATION CONTACT: Beverly M. Jones, Issuance System Manager, Office of Planning and Evaluation, 202/254–7086.

Office of Personnel Management.

Beverly M. Jones,

Issuance System Manager.

Part 1 of Semiannual Agenda

[Regulations issued from June 1 through Oct. 31, 1979]

5 CFR Part and title	Date of publication	Type of action	Effective or comment date
Improving Government Regulations Semi-Annual Agenda of Regulations.	June 1, 1979	Agenda	
890—Federal Employees Health Benefits Program; Benefits for Members of Medically Underserved Populations.	June 5, 1979	Proposed	Aug. 16, 1979 (for comments).
294—Availability of Official Information	June 8, 1979	Final	June 8, 1979.
720—Affirmative Employment Program	June 8, 1979	Final	June 8, 1979.
831, 870, 871, and 890—Retention of Benefits Upon Employment by Initial Tribal Organization.	June 12, 1979	Proposed	Aug. 13, 1979 (for comments).
317—Appointment, Reassignment, Transfer and Development in the Senior Executive Service.	June 15, 1979	Amendment to Interim	June 15, 1979 (Aug. 14 for comments).
353—Restoration to Duty	June 19, 1979	Proposed	Aug. 20, 1979 (for comments).
315—Career and Career-Conditional Employment June	June 26, 1979	Proposed	Aug. 27, 1979 (for comments).
735—Public Access to Financial Disclosure Reports	June 29, 1979	Notice	
214—Senior Executive Service (minimum number of career reserve positions).	June 29, 1979	Final	July 1, 1979.
713 and 720—Equal Opportunity Affirmative Employment Programs	June 29, 1979	Final	June 29, 1979.
831, 870, 871, 890, and 891—Retirement; Federal Employees Group Life Insurance, Health Benefits Program; Retired Federal Employees Health Benefits Program; Reconsideration Procedures.	June 29, 1979	Interim	June 29, 1979 (Aug. 28 for comments).
711—Labor-Management Relations Program; transfer of functions to Federal Labor Relations Authority.	July 6, 1979	Final	June 29, 1979.
871—Life insurance, optional; cancellation of declination for Postal Service employees.	July 10, 1979	Proposed	Sept. 10, 1979 (for comments).
595—Physicians' comparability allowances	July 13, 1979	Final	July 13, 1979.
213—Nepotism, children of civil service employees and uniform services; summer job appointments (excepted service).	July 13, 1979	Proposed	Sept. 11, 1979 (for comments).
338—Nepotism; children of civil service employees and uniform services; summer job appointments; qualification requirements (competitive service).	July 13, 1979	Proposed	Sept. 11, 1979 (for comments).
620—Alternative work schedules experiment; interim master plan	July 20, 1979	Interim	July 20, 1979; Sept. 17, 1979 (for comments).
890—Health benefits, Federal employees' Health plans, discontinued; contingency reserves disposition.	July 20, 1979	Final	July 20, 1979.
733—Political participation by Federal employees in local elections; designations: Manassas, VA.	July 20, 1979	Proposed	Sept. 18, 1979 (for comments).
295—Sunshine Act meetings; removal of obsolete CFR Part	July 20, 1979	Final	June 29, 1979.
752—Adverse Actions; Statutory and Regulatory Requirements under the Senior Executive Service.	July 31, 1979	Interim	July 31, 1979; Oct. 1, 1979 (for comments).
315—Career and Career-conditional employment	July 31, 1979	Final	Aug. 11, 1979.
315, 316, 410, 550, and 831—Disabled veterans, Temporary appointments, training programs, etc.	July 31, 1979	Final	July 31, 1979.
315—Probationary periods for new managers and supervisors; establishment.	July 31, 1979	Final	Aug. 11, 1979.
359—Senior executive service, removal, reinstatement and guaranteed placement.	July 31, 1979	Interim	July 31, 1979; Oct. 1, 1979 (for comments).

Part 1 of Semiannual Agenda—Continued

[Regulations issued from June 1 through Oct. 31, 1979]

5 CFR Part and title	Date of publication	Type of action	Effective or comment date
210—Agencies, actions, employees and positions; coded exemption lists; removal.	Aug. 3, 1979	Final	July 30, 1979.
432—Reduction in grade and removal based on unacceptable performance.	Aug. 3, 1979	Final	Aug. 3, 1979.
430—Performance appraisal	Aug. 3, 1979	Final	July 24, 1979.
771—Agency administrative grievance system	Aug. 3, 1979	Proposed	Sept. 4, 1979 (for comments).
Recreation/Creative Arts Therapy; minimum educational requirement	Aug. 3, 1979	Notice	Aug. 3, 1979.
772—CSRA: Appeals; technical correction; deletion of CFR part	Aug. 7, 1979	Final	June 30, 1979.
630—CSRA: Absence and leave; exception for individuals under appointment to The Senior Executive Service.	Aug. 7, 1979	Proposed	Oct. 9, 1979 (for comments).
752—Adverse actions	Aug. 10, 1979	Final	Aug. 10, 1979.
534—Pay under other systems	Aug. 10, 1979	Interim	Aug. 10, 1979; Oct. 9, 1979 (for comments).
1001—Conduct standards: Financial reporting requirements	Aug. 14, 1979	Final	Aug. 14, 1979.
1—Nomenclature and editorial changes in CFR	Aug. 14, 1979	Final	June 29, 1979.
733—Political participation by Federal employees in local elections; designations: Stafford County, VA.	Aug. 14, 1979	Proposed	Oct. 15, 1979 (for comments).
Regions, name changes	Aug. 14, 1979	Notice	Aug. 1, 1979.
720—Equal employment opportunity and affirmative employment programs; transfer of functions; corrections.	Aug. 17, 1979	Final; correction	June 29, 1979.
451—Incentive awards	Aug. 17, 1979	Proposed	Sept. 17, 1979 (for comments).
330—Recruitment, selection, and placement: Vacancies in competitive service; notification requirement.	Aug. 24, 1979	Final	Aug. 24, 1979.
831—Retirement: Law enforcement officers and firefighters; special retirement coverage.	Aug. 24, 1979	Proposed	Oct. 23, 1979 (for comments).
45 CFR Part 801—Voting Rights Program: Appendix A: Mississippi	Aug. 31, 1979	Final	Aug. 3, 1979.
308—Volunteer Service	Aug. 31, 1979	Final	Aug. 31, 1979.
540—Merit Pay System	Sept. 7, 1979	Final	Sept. 7, 1979.
337 and 410—Examining system; training; grade and pay retention provisions.	Sept. 7, 1979	Proposed	Nov. 6, 1979 (for comments).
334—Temporary assignment of employees between executive agencies and States, etc.	Sept. 18, 1979	Proposed	Oct. 18, 1979 (for comments as corrected).
213, 230, 301, 310, 315, 351, 511, 534, 550, 572, 630, and 930—Authority delegations to agencies to take certain actions without prior OPM approval.	Sept. 21, 1979	Final	Sept. 21, 1979.
831—Senior Executive Service; exclusions from coverage	Sept. 21, 1979	Interim	Sept. 21, 1979 (Nov. 20, for comments).
334—Temporary assignment of employees between executive agencies and States.	Sept. 21, 1979	Correction	
213, 230, 250, 300, 302, 315, 316, 351, 410, 531, and 591—Civil Service Reform; personnel management authority; removal of OPM prior approval, and blanket basis and agency-by-agency written agreement basis delegations.	Sept. 25, 1979	Final	Sept. 25, 1979.
737—Ethics in government; post employment conflict of interest; designation of senior employees.	Sept. 25, 1979	Interim	Sept. 25, 1979 (Oct. 30 for comments).
45 CFR Part 801—Voting rights program; nomenclature and editorial changes.	Sept. 28, 1979	Final	Sept. 28, 1979.
353—Restoration to duty of injured employees; delegation of one-year limitation.	Oct. 2, 1979	Final	Oct. 2, 1979.
340 and 890—Part-time Employment; Federal Employees Health Benefits Program.	Oct. 5, 1979	Final	Oct. 5, 1979.
451—Incentive Awards	Oct. 12, 1979	Final	Oct. 12, 1979.
581—Processing Government Orders Issued against the United States for Child Support or Alimony.	Oct. 19, 1979	Proposed	Dec. 18, 1979.
315—Career and Career—Conditional Appointment: former Peace Corps personnel.	Oct. 23, 1979	Interim	Oct. 1, 1979 (Dec. 20 for comments).

Part 2 of Semiannual Agenda

[Regulations scheduled for review or development, Jan. 1 through June 30, 1980]

CFR or other authority	Title	Brief description	Knowledgeable official
5 CFR Parts 1 through 9	Civil Service Rules	In conjunction with an extensive revision of Executive Order 9830 (2-24-47) concerning Federal Personnel Administration, a proposal is being considered to eliminate the Civil Service Rules. This project may necessitate a number of regulatory revisions during the next 6-12 months. The proposal will be coordinated with Departments and agencies covered by the current rules.	Anne Kirby, (202) 632-6898.
5 CFR 213.3202 (d) through (g)	Excepted Schedules—Schedule B	Provides appointing authorities for students to enter career-related work-study programs leading to non-competitive conversion under Executive Order 12015. Interim regulations expected to be issued for comment January 1980.	James R. Poole, (202) 632-5678.
5 CFR Part 214	Senior Executive Service positions	New Part to cover definitions of general and career-reserved positions as well as career type positions in the excepted service for the purpose of determining appointment in the Senior Executive Service. This will be issued in final.	Neal Harwood, (202) 632-4695.

Part 2 of Semiannual Agenda—Continued

[Regulations scheduled for review or development, Jan. 1 through June 30, 1980]

CFR or other authority	Title	Brief description	Knowledgeable official
5 CFR Part 293	Personnel Records and Files	After input from agencies and OPM offices, add a Subpart D to this Part that will prescribe procedures for the maintenance of employee performance appraisal records.	William H. Lynch, (202) 254-9790, (202) 254-9793.
5 CFR Part 294	Availability of Official Information	Will be revised to reflect current judicial interpretations of the provisions of the Freedom of Information Act (5 U.S.C. 552). Proposed rule expected to be published by May 1980.	William C. Duffy, (202) 632-4596.
5 CFR Part 305	Executive Assignment System	Revision of existing regulations to reflect changes in the Executive Assignment System resulting from the establishment of the Senior Executive Service.	Ann Ugelow, (202) 632-6820.
5 CFR Part 307	Veterans Readjustment Appointments	Transfer of existing regs to Part 720	Don Smith, (202) 254-3058.
5 CFR 316.302	Term Employment	Transfer of existing regs on term appointments for Veterans to Part 720.	Don Smith, (202) 254-3058.
5 CFR 316.402	Temporary Limited Employment	Transfer of existing regs on temporary limited appointments for Veterans to Part 720.	Don Smith, (202) 254-3058.
5 CFR Part 315	Career and Career Conditional Employment Industrial Staffing plan.	New approach to staffing career positions in installations with fluctuating workloads. Based on the results of a two-year test in 10 Commerce and DOD activities.	Ed McHugh, (202) 632-6817.
5 CFR 315.607	Noncompetitive Appointment of former Peace Corps Personnel.	As described	Maribeth Zankowski, (202) 632-6817.
5 CFR Part 317	Appointment, Reassignment, Transfer and Development in the Senior Executive Service.	Some of this new Part was published March 30, 1979 as an Interim Regulation. This covered initial conversion to the Senior Executive Service. Additional subparts will be issued in final.	Ann Ugelow, (202) 632-6820.
5 CFR Part 335	Term Promotion	To delegate by agreement to agencies authority to make term promotion listing up to five years in two limited situations.	Maribeth Zankowski, (202) 632-6817.
5 CFR 337.102	Evaluating Qualifications for Employees Who are in Retained Grade.	New regulation to implement grade and pay retention provisions of CSRA. Explains how qualifications are to be evaluated for employees subject to grade retention and after such eligibility expires. Final by early 1980.	Lynn Waldorf, (202) 632-4473.
5 CFR Part 340 (Pub. L. 95-437)	Federal Employee Part-Time Employment Act of 1978.	OPM's internal regulations to implement 5 U.S.C. 3401 will be published for a 60-day public comment period, by January 1, 1980. Final regulations will be published in OPM Administrative Manual Supplement 20-1, Chapter 340.	Cynthia Simpson, (202) 632-7484.
5 CFR Part 351	Reducting in Force	Final regulations covering retention credit for performance appraisals issued under Subpart 430 B, and tenure groups for managers and supervisors serving probation.	Ted Dow or Tom Glennon, (202) 632-6817.
5 CFR 352.801	Reemployment Rights—Subpart H, For Employee Separated for Specified Periods of Service with American Institute of Taiwan.	Requires reemployment of Federal employees separated for specified periods of service with the American Institute of Taiwan. Interim regulations expected to be issued for comment, 1979.	Maribeth Zankowski, (202) 632-6817.
5 CFR Part 359	Senior Executive Service: Removal during probation; removal after probation for performance reasons; and guaranteed placement.	This new Part to 5 CFR implements Subchapter V of Chapter 35 of title 5 as amended by the Civil Service Reform Act of 1978. To be issued in final.	Ann Ugelow, (202) 632-6820.
5 CFR 410.501	Determining sources of training	Regulation relating to agencies' determinations to use a Government or non-Government training facility.	Michael Miller, (202) 632-5684.
5 CFR 410.502	Selection of non-Government facilities for training.	Amend the regulations to ensure that training officials have a role in acquiring training from non-Government facilities.	Frank Masterson, (202) 632-5684.
5 CFR 410.503	General Prohibitions, Training, Through Non-Government Facilities.	New regulation to implement grade and pay retention provisions of CSRA. Adds exceptions to constraints when employee subject to grade retention. Final by early 1980.	Lynn Waldorf, (202) 632-4473.
Pub. L. 95-454, Civil Service Reform Act, Title VI, Sec. 601.	Personnel Research Programs and Demonstration Projects.	Final regulations which add new Part 470 to implement programs for conducting research and demonstration projects. Status. Draft regulations published late in 1979. Final regulations should be issued by Mar. 15, 1980.	Donald Hill, (202) 632-6077.
5 CFR 511.601 through 511.703	Appeals; Effective dates of Position classification Actions on Decisions.	Revisions to regulations to match the contents to OPM terminology as well as incorporate recent changes. Currently undergoing final approval and should be published in the FEDERAL REGISTER as final regulations by Dec. 1, 1979.	Frank T. Catenaccio, (202) 632-7744.
5 CFR Part 534	Pay under other systems	Pay regulations for the Senior Executive Serivce. Some material will be issued in final.	Jack Vincent, (202) 632-6820.
5 CFR Part 531, Subpart B and 5 CFR Part 539.	Determining Rate of Basic Pay; Conversions between Pay Systems.	Revised Regulations to improve pay-setting policies when employees change pay systems. Development continuing.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 531, Subpart C	Pay Adjustments for Supervisors	Revised regulations on pay adjustments for GS supervisors of wage employees. Development continuing.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 531, Subpart D	Within Grade Increases	Revised regulations to simplify and clarify procedures and standards for granting quality increases and withholding within-grade increases. Proposed regulations to be published in early 1980.	Craig B. Pettibone, (202) 632-4682.

Part 2 of Semiannual Agenda—Continued

[Regulations scheduled for review or development, Jan. 1 through June 30, 1980]

CFR or other authority	Title	Brief description	Knowledgeable official
5 CFR Part 532	Pay Under Prevailing Rate Systems	Comprehensive new regulations for Federal Wage System. Development continuing.	Windsor Eagan, (202) 632-5454.
5 CFR Part 536	Grade and Pay Retention	Final regulations to implement Title VIII of the Civil Service Reform Act of 1978. (Interim regulations published Mar. 2, 1979.) Development continuing.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 550, Subpart C	Allotments and Assignments for Federal Employees.	Revised regulations to increase delegation of appropriate flexibility to agencies. Development continuing.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 550, Subpart H	Back Pay	Revised regulations to implement section 702 of the Civil Service Reform Act of 1978. Proposed regulations to be published in early 1980.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 550, Subpart J	Adjustments of Work Schedules for Religious Observances.	Final regulations to implement Title IV of the Federal Employees Flexible and Compressed Work Schedules Act of 1978. (Interim regulations already issued.) Development continuing.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 550, Subpart K	Installment Deductions for Indebtedness Because of Erroneous Payment.	Regulations to revise former OMB regulations on installment deductions. Development continuing.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 551	Pay Administration under the Fair Labor Standards Act.	Regulations to implement the Fair Labor Standards Act in the Federal Government. Development continuing.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 591, Subpart A	Uniforms and Uniform Allowances	Regulations to revise OMB regulations on uniform and uniform allowances for Federal employees. Development continuing.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 620	Alternative Work Schedules Experimental Program.	Regulations to implement the Federal Employees Flexible and Compressed Work Schedules Act of 1978. Proposed regulations published May 22, 1979. Final regulations to be published late 1979/early 1980.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 630, Subpart C	Annual Leave	Revised regulations to implement section 410 of the Civil Service Reform Act of 1978, concerning annual leave accumulation for the Senior Executive Service. Proposed regulations published Aug. 7, 1979. Final regulations to be published in late 1979/early 1980.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 720, Subpart C	Federal Women's Program	Proposed regs to implement expected revision of E.O. 9830 establishing legal basis for the program and to reinforce OPM's authority in this area following Reorganization Plan No. 1 (Oct. 1, 1979).	A. Diane Graham or Diane Herrmann, (202) 632-6870.
5 CFR Part 720, Subpart D	Hispanic Employment Program	Proposed regs to implement expected revision of E.O. 9830 establishing legal basis for the program and to reinforce OPM's authority in this area following Reorganization Plan No. 1 (Oct. 1, 1979).	A. Diane Graham or Roceliz Velez, (202) 632-6800.
5 CFR Part 720 Subpart E	Selective Placement Program	Proposed regs to implement expected revision of E.O. 9830 and to reinforce OPM's authority in this area following Reorganization Plan No. 1 (Oct. 1, 1979).	A. Diane Graham or Hedwig Oswald, (202) 632-4437.
5 CFR Part 720, Subpart F	Upward Mobility Program	Proposed regs to implement expected revision of E.O. 9830 establishing legal basis for the program and to reinforce OPM's authority in this area following Reorganization Plan No. 1 (Oct. 1, 1979).	A. Diane Graham or Curtestine Boardley, (202) 632-6256.
5 CFR Part 720, Subpart G	Veterans Employment Programs	Receipt of existing regs from Part 307 and Part 316 to coincide with the VEP's placement within the organizational structure of OPM (Oct. 1, 1979).	A. Diane Graham or Donald Smith, (202) 254-3058.
5 CFR Part 731	Suitability	Authorities, disqualification standards, rating actions, and appeals rights. Will be revised to reflect (1) the recent reorganization of the former CSC, (2) the OPM's policy of increased delegation of its decision-making authorities to agencies. Completion of proposed regulations tentatively scheduled for Jan. 1, 1980.	Bob Hubbard (202) 632-6152.
5 CFR Part 732	Security and Related Determinations	Reemployment eligibility and action by the OPM. Completion of proposed revision tentatively scheduled for Jan. 1, 1980.	Bob Hubbard, (202) 632-6152.
Executive Order 11222, May 6, 1965	Standards of Ethical Conduct for Government Officers and Employees.	Revision of Executive Order 11222 affecting Standards of Conduct. Proposed rules expected June 1, 1980.	David Reich, (202) 632-7642.
5 CFR Part 735	Employee Responsibilities and Conduct	Revision of Form 278 and Form 278A public financial disclosure requirements set forth in the Ethics in Government Act of 1978—revision expected Jan. 31, 1980.	David Reich, (202) 632-7642.
5 CFR Part 735	Employee Responsibilities and Conduct	Proposed regulations revising 5 CFR Part 735 re standards of conduct published for public comment. Expected June 30, 1980.	David Reich, (202) 632-7642.
5 CFR Part 737	Post Employment Conflict of Interest	Final regulations concerning post employment conflict of interest restrictions as set forth in the Ethics in Government Act of 1978. Expected by Jan. 15, 1980.	Gary Davis, (202) 632-7642.
5 CFR Part 752	Regulatory Requirements for taking adverse actions under the Senior Executive Service.	Amends Part 752 to implement new Subchapter V of Chapter 75 of title 5, U.S.C. To be issued in final.	Ann Ugelow, (202) 632-6820.
5 CFR 831.903 and 831.904	Early Retirement Coverage for Law Enforcement and Firefighter Personnel Serving in Administrative Positions.	Proposed rules to delete the regulatory requirement that early retirement coverage attaches to an officer or firefighter only if experience is a basic qualification for filling the position. Still pending.	Craig B. Pettibone, (202) 632-4682.
5 CFR 870.202; 5 CFR 890.102	Regular Life Insurance; Exclusions; FEHBP: Coverage.	Clarification of exclusions from coverage of employees whose employment is of uncertain duration. Still pending.	Craig B. Pettibone, (202) 632-4682.
5 CFR 870.501; 5 CFR 871.501	Conversion of Regular Life Insurance Coverage; Conversion of Optional Life Insurance Coverage.	Proposed rules authorizing OPM to order extension of time limit for conversion to private contract where timely conversion was prevented due to administrative error. Still pending.	Craig B. Pettibone, (202) 632-4682.
5 CFR 890.401	Conversion of Health Benefits Coverage		Craig B. Pettibone, (202) 632-4682.
5 CFR 871.205 and 871.401	Optional Life Insurance; Cancellation of Declination for Certain Postal Employees.	Proposed rules providing for automatic cancellation of declination of optional life insurance when an employee enters the Postal Career Executive Service were published July 10, 1979. Final regulations are still pending.	Craig B. Pettibone, (202) 632-4682.

Part 2 of Semiannual Agenda—Continued

[Regulations scheduled for review or development, Jan. 1 through June 30, 1980]

CFR or other authority	Title	Brief description	Knowledgeable official
Pub. L. 93-350	Transfer of Law Enforcement Officers and Firefighters from Basic to Supervisory Positions.	Interim regulations to implement provisions of Pub. L. 93-350 which deem a law enforcement officer or firefighter who transferred from a basic to a supervisory and/or administrative 5 U.S.C. 8336(c) position. Proposed regulations published August 24, 1979.	Craig B. Pettibone, (202) 632-4682.
Pub. L. 93-638	Retention of Retirement, Health Benefits, and Life Insurance Coverages by Employees of the Indian Tribal Organizations.	Proposed rules to implement provisions of Pub. L. 93-638 which permit certain Federal employees transferring to tribal organization employment without a break in service to retain coverages under the CSR, FEHB, and FEGLI programs. Published June 12, 1979.	Craig B. Pettibone, (202) 632-4682.
Pub. L. 95-368	FEHB for Members of Medically Underserved Populations.	Proposed rules to implement recent amendment to FEHB law. Published June 5, 1979.	Craig B. Pettibone, (202) 632-4682.
Pub. L. 95-256	Elimination of Age 70 Mandatory Retirement	New revised proposed rules to implement recent amendments to the CSR law. Still pending.	Craig B. Pettibone, (202) 632-4682.
5 CFR Part 831.107; 5 CFR Part 831, Subpart L; 5 CFR Part 831, Subpart M.	Retirement; Administration and General Provisions; Disability Retirement on Application of an Agency and Disability Retirement Appeals; Collection and Claims Against Annuity.	Reorganization of the CSC requires revision of all retirement and insurance regulations having to do with appeals, since appeals are now handled by MSPB. Provisions defining appealable decisions, reconsideration of decisions, and permitting correction of errors remain the responsibility of the OPM. Proposed regulations published June 29, 1979.	Craig B. Pettibone, (202) 632-4682.
5 CFR 870.205	Regular Life Insurance; Coverage, Appeals.		Craig B. Pettibone, (202) 632-4682.
5 CFR 871.206	Optional Life Insurance; Coverage; Appeals.		Craig B. Pettibone, (202) 632-4682.
5 CFR 890.103	Federal Employees Health Benefits Program; Employee Appeals, Corrections and Adjustments.		Craig B. Pettibone, (202) 632-4682.
5 CFR 890.104	FEHBP; Legal Actions		Craig B. Pettibone, (202) 632-4682.
5 CFR 891.105	Retired Federal Employees Health Benefits; Appeals.		Craig B. Pettibone, (202) 632-4682.
5 CFR 890.301(h)	FEHB; Registration and Enrollment on Becoming Eligible for Medicare.	Proposed regulations were published May 18, 1979 to permit enrollees to change to low option 31 days before becoming eligible for Medicare benefits. Final regulations are still pending.	Craig B. Pettibone, (202) 632-4682.
5 CFR 890.303(d)	FEHB; Continuation of Enrollment	Proposed regulations to provide continued health benefits coverage for certain survivor annuitants.	Craig B. Pettibone, (202) 632-4682.

[FR Doc. 79-36232 Filed 12-3-79; 8:45 am]

BILLING CODE 6325-01-M

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization and Conservation Service

7 CFR Part 726

Proclamation of National Marketing Quotas for Burley Tobacco

AGENCY: Agricultural Stabilization and Conservation Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Secretary of Agriculture is preparing to proclaim national marketing quotas for burley tobacco for the 1980–81, 1981–82, and 1982–83 marketing years. This announcement must be made by February 1, 1980. You are invited to submit written comments and other information with respect to the determination of the quotas and related matters.

DATES: Written comments must be received by January 17, 1980 in order to be sure of consideration.

ADDRESSES: Send comments to the Director, Price Support and Loan Division, ASCS, U.S. Department of Agriculture, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT: Robert L. Tarczy, ASCS, (202) 447–6733.

SUPPLEMENTARY INFORMATION: The Agricultural Adjustment Act of 1938, as amended (referred to herein as the "Act") requires the Secretary to (1) proclaim quotas for the 1980–81, 1981–82, and 1982–83 marketing years, (2) determine and announce the amount of the national marketing quota for the 1980–81 marketing year, and (3) conduct a referendum of farmers engaged in the 1979 production of burley tobacco to determine whether they favor or oppose quotas for the 1980–81, 1981–82, and 1982–83 marketing years.

Section 319(b) of the Act provides that this action shall be taken on or before February 1, 1980. The referendum must be conducted within 30 days after the proclamation.

Section 319(c) of the Act provides that the national marketing quota determined under this section for burley tobacco for any marketing year shall be the amount produced in the United States which the Secretary estimates will be utilized in the United States and will be exported during such marketing year, adjusted upward or downward in such amount as the Secretary, in his descretion, determines is desirable for the purpose of maintaining an adequate

supply or for effecting an orderly reduction of supplies to the reserve supply level. Any such downward adjustment shall not exceed 5 per centum of such estimated utilization and exports. For each marketing year for which marketing quotas are in effect under this section, the Secretary in his discretion may established a reserve (hereinafter referred to as the "national reserve") from the national marketing quota in an amount not in excess of 1 per centum of the national marketing quota to be available for making corrections and adjusting inequities in farm marketing quotas, and for establishing marketing quotas for new farms (that is, farms for which farms marketing quotas are not otherwise established). A reserve of 780,000 pounds was established for the 1979–80 marketing year (44 FR 7114).

Section 301(b) of the Act defines "Reserve supply level" as normal supply plus 5 percent. "Normal supply" is defined as a normal year's domestic consumption and exports, plus 175 percent of a normal year's domestic consumption and 65 percent of a normal year's exports as an allowance for a normal carry-over. A "Normal year's domestic consumption" is defined as the yearly average quantity produced in the United States during the ten marketing years immediately preceding the marketing year in which such consumption is determined, adjusted for current trends in such consumption. A "Normal year's exports" is defined as the yearly average quantity produced in the United States which was exported form the United States during the ten marketing years immediately preceding the marketing year in which such exports are determined, adjusted for current trends in such exports. The reserve supply level used in determining the national marketing quota for the 1979–80 marketing year was 1,643 million pounds, calculated from a normal year's domestic consumption of 500 million pounds and a normal year's exports of 115 million pounds (44 FR 7114). The proposed reserve supply level for use in determining the national marketing quota for the 1980–81 marketing year is 1,597 million pounds, calculated from a normal year's domestic consumption of 475 million pounds and a normal year's exports of 130 million pounds.

Section 301(b) of the Act defines "total supply" as the carry over at the beginning of the marketing year (October 1) plus the estimated production in the United States during the calendar year in which the marketing year begins. The total supply for the 1979–80 marketing year is 1,783 million pounds based on carryover of 1,226 million pounds and estimated production of 557 million pounds.

The amount of the national marketing quota for the 1979–80 marketing year is 615 million pounds based upon total utilization of 615 million pounds with no adjustments necessary to maintain or reduce supplies (44 FR 7114). For the 1980–81 marketing year, utilization in the United States is estimated to be about 470 million pounds and exports are estimated to be about 130 million pounds. The total supply for the 1979–80 marketing year is 186 million pounds greater than the proposed reserve supply level, but the amount of the adjustment desirable for maintaining adequate supplies or for effecting an orderly reduction of supplies to the reserve supply level is still being considered.

Section 319(e) of the Act provides, in part, that each farm marketing quota shall be deterimed by multiplying the previous year's farm marketing quota by a national factor obtained by dividing the national marketing quota determined under subsection 319(c) (less the national reserve) by the sum of the farm marketing quotas for the immediately preceding year for all farms for which burley tobacco marketing quotas will be determined: *Provided*, That such national factor shall not be less than 95 per centum.

Section 319(i) of the Act provides, in part, that if the Secretary, in his discretion, determines it is desirable to encourage additional marketings of any grades of burley tobacco during any marketing year to insure traditional marketing patterns to meet the normal demands of export and domestic markets, he may authorize the marketing of such grades without the payment of penalty or deduction from subsequent quotas to the extent of 5 per centum of the farm marketing quota for the farm on which the tobacco was produced, and such marketings shall be eligible for price support.

Section 319(h) of the Act provides that effective with the marketing year beginning October 1, 1976, no marketing quota, other than a new farm marketing quota, shall be established for a farm on which no barley tobacco was planted or considered planted in any of the five years immediately preceding the year for which farm marketing quotas are being established.

Proposed Rule

The subjects and issues involved in the proposed determinations with respect to burley tobacco for the 1980–81 marketing year are:

1. The amount of national marketing quota.
2. The amount of the reserve supply level.
3. The amount of the national reserve.
4. Whether the Secretary should implement the provision in section 319(i) of the Act to encourage additional marketings of any grades to insure traditional marketing patterns.
5. The date or period of the referendum on quotas for the 1980–81, 1981–82, and 1982–83 marketing years for burley tobacco and whether the referendum should be conducted at polling places rather than by mail ballot (31 FR 12011).

The national factor is not considered an issue in these determinations because it results from a mathematical computation under section 319(e) of the Act.

All written submissions will be made available for public inspection from 8:15 a.m. to 4:45 p.m. Monday through Friday, in Room 3741—South Building, 14th and Independence Avenue, SW., Washington, D.C.

This amendment has not been classified "significant" and is being published under emergency procedures, as authorized by Executive Order 12044 and Secretary's Memorandum 1955, without a full 60-day comment period. It has been determined by Jerome F. Sitter, Director, Price Support and Loan Division that an emergency situation exists which warrants less than a full 60-day comment period on this proposal because quotas for this kind of tobacco must be announced by February 1, 1980.

A draft Impact Analysis is available from Robert L. Tarczy, Price Support and Loan Division, Room 3741—South Building, P.O. Box 2415, Washington, D.C. 20013.

Signed at Washington, D.C., on November 29, 1979.

John E. Gibbs,

Acting Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 79-37305 Filed 12-3-79; 8:45 am]

BILLING CODE 3410-05-M

Commodity Credit Corporation

7 CFR Parts 1421, 1446

1980 Peanut Program; Proposed Determinations Regarding a Loan and Purchase Program for the 1980 Crop of Peanuts

AGENCY: Commodity Credit Corporation, U.S. Department of Agriculture.

ACTION: Proposed rule.

SUMMARY: The Secretary of Agriculture proposes to make determinations and

issue regulations concerning a loan and purchase program, sales policy, and other related matters, for the 1980 crop of peanuts. The loan and purchase program is authorized by the Agricultural Act of 1949, as amended (hereinafter referred to as the "Act").

The program is intended to stabilize market prices and to protect producers, handlers, processors and consumers. This notice invites comments on these proposed determinations.

DATES: Written comments must be received on or before February 4, 1980 in order to be sure of consideration.

ADDRESS: Send comments to Director, Price Support and Loan Division, ASCS, U.S. Department of Agriculture, Room 3741-South Building, P.O. Box 2415, Washington, D.C. 20013.

FOR FURTHER INFORMATION CONTACT: Gypsy Banks, ASCS, (202) 447–6733.

SUPPLEMENTARY INFORMATION: The following determinations are required to be made by the Secretary in accordance with the provisions of subsection 108(a) of the Agricultural Act of 1949, as added by the Food and Agriculture Act of 1977:

1. *The national level of support for 1980 crop quota peanuts.* The Act provides that the Secretary shall make price support available to producers through loans, purchases, or other operations on quota peanuts at such levels as he finds appropriate, but not less than $420 per ton. In determining price support levels, subsection 108(a) of the Act directs the Secretary to take into consideration: (a) Any change in the index of prices paid by farmers for production items, interest, taxes, and wage rates during the period January 1 through December 31, 1979, inclusive, and (b) the eight factors specified in section 401(b) of the Act, namely, the supply of the commodity in relation to the demand therefore, the levels at which other commodities are being supported, the availability of funds, the perishability of the commodity, the importance of the commodity to agriculture and the national economy, the ability to dispose of stocks acquired through a support operation, the need for offsetting temporary losses of export markets, and the ability and willingness of producers to keep supplies in line with demand.

2. *The national level of support for 1980 crop additional peanuts.* The Act provides that the Secretary shall make price support available to producers through loans, purchases, or other operations on "additional peanuts," which are defined as any peanuts which are marketed from a farm and which are in excess of the marketings of quota peanuts from such farm for the marketing year but not in excess of the actual production from the farm acreage allotment. This subsection requires that the loan rate for 1980 crop additional peanuts shall be announced not later than February 15, 1980, and that in determining this rate the Secretary shall take into consideration the demand for peanut oil and peanut meal, expected prices of other vegetable oils and protein meals, and the demand for peanuts in foreign markets.

Sales policy

The Department also invites comments on a sales policy for additional loan peanuts acquired under the 1980 program and sold for export for edible use.

Section 359(j) of the Agricultural Adjustment Act of 1938, contained in the Food and Agriculture Act of 1977, provides that additional peanuts received under loan may be sold for domestic edible use at not less than all costs incurred with respect to the peanuts sold, plus: (1) 100 percent of the quota loan value if sold and paid for during the harvest season and upon delivery by the producer, or (2) 105 percent of the quota loan value if sold after delivery but before December 31 of the marketing year, or (3) 107 percent of the quota loan value if sold later than December 31 of the marketing year. In addition to these restrictions on sales of additional peanuts, for domestic edible use, Section 407 of the Agricultural Act of 1949 provides that when giving consideration to establishing sales policy, the Commodity Credit Corporation should give consideration to price, terms, and conditions which will not discourage or deter manufacturers, processors and dealers from acquiring and carrying normal inventories of the current crop. The Corporation shall not sell any basic agricultural commodity or storable nonbasic commodity at less than 5 percentum above current support price for such commodity plus reasonable carrying charges. These restrictions do not apply to the sales of peanuts and oilseeds for the extraction of oil or sales for export.

Proposed Rule

The Secretary of Agriculture proposes to make determinations and issue regulations with regard to the following for 1980-crop peanuts:

(a) The national level of support for quota peanuts.

(b) The national level of support for additional peanuts.

(c) Sales policy for additional peanuts received under loan or acquired by the Commodity Credit Corporation under the 1980 program, and sold for export for edible use.

Before making any determinations, consideration will be given to any relevant data, views, recommendations, or alternative proposals which are submitted in writing to the Director of the Price Support and Loan Division, ASCS–USDA.

All written submissions made pursuant to this notice will be made available for inspection from 8:15 a.m. to 4:45 p.m. Monday through Friday, in Room 3741, South Building.

Note.—This proposal has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations", and has been classified "significant". An approved draft impact analysis is available from Gypsy Banks, ASCS, (202) 447–6733.

Signed at Washington, D.C., on November 27, 1979.

John E. Gibbs,

Acting, Executive Vice President Commodity Credit Corporation.

[FR Doc. 79–37101 Filed 12–3–79; 8:45 am]

BILLING CODE 3410–05–M

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7 CFR 1446

General Regulations Governing 1979 and Subsequent Crops; Peanut Warehouse Storage Loans and Handler Operations

AGENCY: Commodity Credit Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: These proposed regulations provide that: (1) The final date for disposing of contract additional peanuts shall be extended to November 30 following the calendar year in which the crop is grown if certain conditions are met; (2) the final date for scheduling supervision for farmers stock peanuts shall be July 31 following the calendar year in which the crop was grown unless prior approval of a later date is given; and (3) a reduction in marketing penalties may be granted for handlers for marketing violations which were made unintentionally or unknowingly. Reduction of penalty provisions shall also apply to 1978 crop peanuts. The purpose of this rule is to insure that all handlers are treated fairly when requesting extention of the final date for exportation of peanuts and to provide some relief to handlers who have made unintentional marketing errors.

DATE: Comments must be received by February 4, 1980 to be assured of consideration.

These proposed regulations will be effective for the 1979 and subsequent

crops, with one exception: the proposed new paragraph (d) for Section 1446.8 will be effective for the 1978 and subsequent crops.

ADDRESS: Mail comments to the Director, Price Support and Loan Division, ASCS, U.S. Department of Agriculture, 3741 South Building, P.O. Box 2415, Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Dalton J. Ustynik, (ASCS) (202) 447–6733.

SUPPLEMENTARY INFORMATION: The final date for disposition of contract additional peanuts is established at August 31 or such later date as may be authorized by the association. Problems have arisen in cases where handlers have lost export buyers and must obtain extensions of the final date. In some instances foreign buyers have elected to use U.S. cold storage facilities and domestic handlers must agree to this condition in sales contracts. Problems have also arisen in cases where handlers have not submitted adequate justification to the association when requesting extension of the final date for exportation. This proposed regulation will ensure that the final date for exportation will be extended in all cases where the handler submits the required documentation. This proposed regulation also provides that the final date for scheduling supervision for farmers stock peanuts shall be during the normal marketing year but not later than July 31 following the calendar year in which the crop was grown, unless prior approval of a later date is authorized by the Association.

Public Law 96–31 approved July 7, 1979, provides the Secretary of Agriculture with authority to reduce marketing quota penalties for peanuts if the Secretary determines that the marketings subject to the penalty were done unintentionally ur unknowingly and that a reduction in the amount of penalty would not impair the effective operation of the price support program for peanuts. It is proposed to reduce penalties on an individual basis if a determination is made that the marketings by a handler which were subject to the penalty were done unintentionally or unknowingly and that a reduction in the amount of the penalty would not impair the effective operation of the price support program for peanuts. It is also proposed to set the reduced penalty rate at 40 percent of the basic quota support rate for the crop year in which the peanuts were produced. These reduced penalties shall also apply to 1978 crop peanuts. The penalty rate shall remain at 120 percent of the basic quota support in any case where a handler marketed a larger quantity or higher grades than could reasonably be produced from the quantity of peanuts having the grade kernel content and quality of quota farmers stock peanuts purchased by the handler for domestic edible use during the applicable marketing year if the handler did not purchase any additional peanuts during the crop year.

Proposed Rule

It is proposed that, effective for the 1979 and subsequent crops of peanuts, that the regulations at 7 CFR Part 1464 be amended to read as follows:

1. Section 1446.8 is amended by revising the introductory paragraph, and by adding new paragraphs (c), (d), and (e) to read as set forth below:

§ 1446.8 Compliance by handlers of contract additional peanuts.

All contract additional peanuts acquired by a handler shall be disposed of by domestic crushing or export to an eligible country. All handler's records shall be subject to a review by CCC or other representatives of the Secretary, to determine compliance with the provision of this subpart. Refusal to make such handler's records available to authorized representatives of the Secretary or the failure of such records submitted to establish such disposition by the handler shall constitute prima facie evidence of non-compliance with this subpart. Reviews shall be made by the association in accordance with guidelines established by CCC. The association shall not take any administrative actions concerning program violations prior to notification by the Director, Producers Associations Division, ASCS.

* * * * *

(c) *Disposition.* Handlers shall dispose of all contract additional peanuts by August 31, (the final date for exportation or crushing), following the calendar year in which the crop was grown, except that this final date shall be extended to November 30 of that year by CCC if the handler, by August 31, complies as follows:

(1) Furnishes information to the Association showing that the contract additional peanuts have been milled and positive lot identified;

(2) furnishes the Association the name and location of storing facilities of the contract additional peanuts;

(3) Provides a written statement of agreement to the Association to pay any supervision costs incurred on the contract additional peanuts after August 31;

(4) Provides a written statement of agreement to the Association that such contract additional peanuts will not be substituted and used in the domestic edible and related markets.

(d) *Penalty rate for unintentional marketing errors.* (1) *Penalty rate.* The penalty rate for unintentional errors for the 1978 and subsequent crops shall be 40 percent of the basic quota support rate for the crop year in which the peanuts were produced. The penalty rate shall remain at 120 percent of the basic quota support in any case where the handler marketed a larger quantity or higher grades than could reasonably be produced from the quantity of peanuts having the grade kernel content and quality of quota farmers stock peanuts purchased by the handler for domestic edible use during the applicable marketing year if the handler did not purchase any additional peanuts during the crop year.

(2) *Requests for reduction of penalty.* Handlers requesting a reduction of the marketing quota penalty shall file a written report immediately following discovery of the marketing error with the Producers Associations Division, Agricultural Stabilization and Conservation Service, P.O. Box 2415, Washington, D.C. 20250. The report shall contain the following information:

(i) A full explanation of the error and circumstances which caused the marketing error;

(ii) Any corrective measures taken by the handler when the error was discovered; and

(iii) A full explanation stating why a reduction of the marketing quota penalty would not impair the effective operation of the peanut price support program. CCC reserves the right to ask for any necessary additional information.

(3) *Action on request for reduction of penalty.* The Deputy Administrator, Commodity Operations, will issue a final determination on requests for reduction of marketing quota penalties, for errors by handlers. Each case shall be considered separately on its individual circumstances.

(e) *Peanuts on which penalty is due.* If the marketing of contract additional peanuts for which a penalty is to be assessed was done unintentionally or unknowingly by a handler, the penalty shall be assessed at the reduced rate provided for in § 1446.8(d)(1) upon a final determination by the Deputy Administrator, Commodity Operations, that the error in marketing of such peanuts was done unintentionally or unknowingly and that a reduction in the amount of the penalty would not impair the effective operation of the price support program for peanuts. The provisions of this paragraph shall be applicable only to handlers who made a

good faith effort to comply fully with the terms and conditions of the program.

2. Section 1446.9 is amended by revising paragraphs (d), (i), (j)(5) through (j)(5)(iv), and paragraph (j)(6) to read as follows:

§ 1446.9 Supervision and handling of contract additional peanuts

* * * * *

(d) *Replacements.* The identical additional farmer stock peanuts contracted shall be handled in accordance with this section except that with prior notification and approval of the association, farmer stock quota peanuts of the same crop, type, quality, and area may be used to replace, such additional peanuts. The identical additional milled peanuts shelled under supervision of the association shall be disposed of in accordance with this section, except that with prior notification and approval of the association, such peanuts may be used to replace, in domestic use, quota peanuts of the same crop, type, area, and screen size, which have been exported. The quota peanuts exported, for which replacement is requested, must have been positive lot identified and otherwise handled as additional peanuts. Additional peanuts may be used in domestic edible and related uses with prior notification and approval of the association and upon presentation of the association of an irrevocable letter of credit in an amount not less than 120 percent of the quota support rate on any portion of the lot for which replacement has not been approved. Such letter of credit shall be issued in a form and by a bank acceptable to CCC. The handler shall deliver to the asociation satisfactory evidence that a like amount of quota peanuts of appropriate screen sizes have been exported in accordance with these regulations. Such evidence must be submitted no later than 30 days after the final date for exportation. If satisfactory evidence is not presented by such date, the association will draw against the letter of credit the full amout of the marketing quota penalty applicable to the quantity of peanuts on which an accounting was not made.

* * * * *

(i) *Final dates for scheduling supervision.* Additional contract farmers stock peanuts shall be scheduled for supervision by the association during the normal marketing period but not later than July 31 following the calendar year in which the crop is grown, unless prior approval of a later date is authorized by the association.

(j) * * *

* * * * *

(5) *Evidence of export.* The handler shall furnish the association with the following documentary evidence of exportation of peanuts or peanut products not later than 30 days after the date of exportation:

(i) *Export by water.* A nonnegotiable copy of an onboard ocean bill of lading, signed, on behalf of the carrier, showing the date and place of loading onboard vessel, the weight of the peanuts, peanut meal, or products exported, the name of the vessel, the name and address of the exporter, and the country of destination. Peanut meal which is unsuitable for use as feed because of contamination by aflatoxin shall be identified on the bill of lading in accordance with this section.

(ii) *Export by rail or truck.* A copy of the bill of lading (showing the weight of the peanuts or peanut meal exported), supplemented by a copy of the Shipper's Export Declaration or other documentation acceptable to the association. Peanut meal which is unsuitable for feed use because of contamination by aflatoxin shall be identified on the bill of lading according to this section.

(iii) *Export by air.* A copy of the Airway Bill (showing weight consignee and shipper) and other acceptable documentation acceptable to the association.

(iv) *Certified statement.* A statement signed by the handler specifying the name and address of the consignee and the applicable Bureau license number if exportation has been made to one or more of the countries or areas for which a validated license is required under regulations issued by the Bureau of International Commerce, U.S. Department of Commerce.

(6) *Penalties.* Failure to dispose of contract additional peanuts acquired by a handler for domestic crushing or export by the final date for exportation shall constitute noncompliance with the provisions of this subpart. In such case, the handler will be obligated to pay a penalty equal to 120 percent of the basic quota support rate on that quantity of the additional peanuts not crushed or exported or such reduced penalty as provided in § 1446.8 (d)(1). In addition to the payment of such penalty, the handler must crush or export such contract additional peanuts.

Authority: Secs. 4 and 5, 62 Stat. 1070, as amended (15 U.S.C. 714 b and c); secs. 101, 108, 401, 63 Stat. 1051, as amended (7 U.S.C. 1441, 1421); sec. 359, 52 Stat. 31, as amended (7 U.S.C. 1359); and sec. 359, 93 Stat. 81 (7 U.S.C. 1359 note).

The Price Support and Loan Division (ASCS) is inviting comments on this proposed rule. All written submissions will be available for public inspection at the office of the Director, Room 3745—South Building, 14th and Independence Avenue, S.W., Washington, D.C. during regular business hours, 8:15 a.m. until 4:45 p.m. (7 CFR 127(b)).

Note.—This proposal has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations". A determination has been made that this action should not be classified "significant" under those criteria. A Draft Impact Analysis has been prepared and is available from Dalton Ustynik (ASCS), 202–447–6733.

Signed at Washington, D.C. on November 27, 1979.

John E. Gibbs,

Acting Executive Vice President, Commodity Credit Corporation.

[FR Doc. 79-37100 Filed 12-3-79; 8:45 am]

BILLING CODE 3410-05-M

Food Safety and Quality Service

9 CFR Parts 307, 381

Overtime or Holiday Inspection Service, Hours Inspectors May Work, Schedules of Operations, Billing; Notice of Proposed Rulemaking

AGENCY: Food Safety and Quality Service.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The Food Safety and Quality Service (FSQS) is considering amending Part 307 of the Federal meat inspection regulations (9 CFR Part 307), and Part 381 of the poultry products inspection regulations (9 CFR Part 381), to provide for uniform requirements and procedures in establishments operating under Federal inspection relative to the days and hours inspectors may be engaged in the performance of duty, schedules of operations, numbers of shifts, overtime and holiday inspection service and charges, and uniform, more efficient billing procedures. The lack of such uniform requirements and procedures have resulted in many functional inspection and administrative problems. The proposed amendments to the regulations are intended to bring about a uniform policy under which inspection service is provided.

DATE: Comments must be received on or before February 4, 1980.

ADDRESSES: Written comments to: Executive Secretariat, Attn: Annie Johnson, Room 3807, South Building, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250. (For additional information on comments: see SUPPLEMENTARY INFORMATION.)

FOR FURTHER INFORMATION CONTACT:
Dr. W. H. Dubbert, Acting Director of Divisions, Technical Services, Food Safety and Quality Service, U.S. Department of Agriculture, Room 4911, South Building, Washington, DC 20250, (202) 447–7470.

SUPPLEMENTARY INFORMATION:

Comments

Interested persons are invited to submit comments concerning this proposal. Written comments must be sent in duplicate to the Executive Secretariat. Comments should bear a reference to the date and page number of this issue of the Federal Register. Any person desiring opportunity for oral presentation of views concerning the proposed amendments to the poultry products inspection regulations must make such request to Dr. Dubbert so that arrangements may be made for such views to be presented. A transcript shall be made of all views orally presented. All comments submitted pursuant to this notice will be made available for public inspection in the Office of the Executive Secretariat during regular hours of business.

Background

This document proposes amendments to the meat and poultry inspection regulations which would appear to aid the Food Safety and Quality Service in providing uniform inspection service to the meat and poultry industry through the efficient utilization of manpower and by establishing uniform and equitable provisions for determining what constitutes overtime and holiday inspection services.

The lack of uniform regulations governing operating schedules and the basis for determining what contitutes an overtime operation have resulted in many functional inspection and administrative problems since the merger of the meat and poultry inspection programs in 1968 and the publication of the initial proposed regulations in December 1972. Different policies and interpretations of policy have contributed to the nonuniform application of policy to various segments of the industry and resulted in some cases, in the inefficient use of Program personnel. The proposals are intended to bring about a uniform policy under which inspection service is rendered.

As a result of the 174 comments received in regard to the initial proposal (37 FR 26429–26430), the Animal and Plant Health Inspection Service (renamed Food Safety and Quality Service), on October 3, 1975, published an amendment (40 FR 45798–45801) to the scheduling and billing regulations which was intended to implement uniform work schedule procedures. However, due to concerns expressed by industry groups and Program employees, several portions of the regulation were either deleted or held in abeyance, pending further consideration. The FSQS is now proposing to remove the current regulation and replace it with one that is more comprehensive and which will provide for consistency in its application; yet provide flexibility in the scheduling of operations.

The October 3, 1975 regulation identified a standard workweek for inspection employees that was found to be unduly restrictive in establishing work schedules. This proposal substitutes a more flexible provision which can be administered in full accordance with all Federal statutes.

The regulations published on October 3, 1975, also contained a requirement (§§ 307.4(e) and 381.37(e)) limiting the number of hours that inspectors may be engaged per shift in the performance of their duty. The Administrator later received information forcing a reassessment of that rule. After full consideration, the requirement was deleted on October 31, 1975.

The Department is now proposing reinstitution of the rule which would limit the time that an inspector could perform postmortem inspection duties to 10 hours daily. In addition, inspection would be limited to 12 clock hours total duty per shift for all inspection duties which may include processing inspection or ante-mortem inspection or a combination of such inspection with post-mortem inspection duties. While processors would experience some slight loss of flexibility of operation, this consideration appears outweighed by the need for an alert inspector, unimpeded by fatigue, to assure the consumer of a properly inspected product. Experts in the field of industrial engineering note that inspectors who work long hours experience a gradual loss of effectiveness. In those operations that are machine-paced and closely repetitive the loss of effectiveness occurs more quickly. The 10 and 12 hour limits proposed on line jobs and on other inspection jobs, respectively, are in accord with general principles of work measurement and are in full agreement with the limits of efficiency derived from years of experience in managing a field inspection force.

The proposal would also clarify the Administrator's policy with respect to staffing the inspection of plants which wish to operate with three shifts in a day. The Administrator proposes, due to fiscal and manpower constraints, to cover those three shifts with two shifts of inspectors, each of whom would work up to 12 hours a day.

The regulations now require all operators to submit for approval their proposed work schedules. The Program representative then considers the efficient and effective use of inspection personnel when approving work schedules. The Department proposes to amplify and clarify that provision (§§ 307.4(d)(1) and 381.37(d)(1)) to more explicitly cover the two situations in which that consideration is most important.

In the first situation, an establishment (frequently a small, remote slaughter establishment) may propose the full use of the services of an inspector for an extremely short period of time, such as an hour or two daily or weekly. If an inspector is available at the time proposed, the work schedule would be approved. If an inspector is not available, that proposed work schedule would be denied. Any alternative schedule proposed by the operator would then be considered.

The second situation involves an establishment (frequently a small processing establishment fairly close to other small processing establishments) which requires some services of an inspector for a full 8-hour shift or less, but not exclusive service throughout that period because of low volume operations. The inspector could also service several other nearby small plants on a patrol basis. The consideration of effective and efficient use of inspection manpower arises because occasionally one such establishment proposes a work schedule that would result in inspector overtime. When that happens, the Program representative would recommend an alternate work schedule that would eliminate or reduce inspector overtime. If the establishment accepts the work schedule, approval would be automatic. If, however, the establishment does not accept the recommended work schedule and chooses to work the one it originally proposed, the original work schedule would be conditionally approved. Inspection service would be provided at those times, but additional inspection overtime may be thereby created. If that occurs the establishment responsible for causing such overtime would be billed for it without regard to the number of hours worked by that establishment in that day or in that week.

References to this possible source of overtime cost would be added to §§ 307.5(a), 307.6(e), 381.38(a) and 381.39(e).

Throughout those regulations, the Department is proposing to substitute

the official import inspection establishment for the importer as the billable entity for overtime charges. The Department is charged with promulgating regulations for the efficient enforcement of the Act. The change would allow for consistency by the Department in its billing operations for overtime services rendered to both official inspection establishments and official import inspection establishments. The implementation of the provisions would result in the inspected entities being billed for overtime charges rather than costs being assessed against individual importers as is the present case. The official import inspection establishment can, in turn, pass the cost along to the individual importer along with his other legitimate charges.

The proposal includes a provision that specifically requires ante-mortem and post-mortem operations to be conducted in the presence of an inspector. This is to clarify that the slaughter of livestock and poultry shall not be conducted without the presence of an inspector to conduct inspections required by the Act.

The Department is also proposing to further amplify a provision (§§ 307.4(d)(2) and 381.37(d)(2)) to specify the notice which must be given for any shift changes, for changes of lesser magnitude than a shift but greater than one hour, and for changes of less than one hour or temporary deviations. The reason for the notice requirement is to allow the Administrator to make use of better personnel management practices. The amplification is for the sake of clarity.

A sentence has been added to make clear that the Administrator would require substantial justification for the establishment of second and third shifts and that frivolous or unsupportable requests for additional shifts would not be allowed as a means of avoiding inspection overtime (§§ 307.4(c) and 381.37(c)). This is to allow for maximum efficiency in the utilization of available manpower resources.

A new provision would be added (§§ 307.6(a) and 381.39(a)) which would provide that no establishment would be billed for overtime when working within an approved work schedule. Another new provision (§§ 307.6(b) and 381.39(b)) would provide that no establishment would be charged overtime unless the inspection employee had worked 8 hours in that day or 40 hours in that week. The purpose of these provisions would be to make clear the Administrator's double statutory responsibility—to make certain that the cost of inspection, other than overtime, is borne by the United States, and to assure that the regulatory provisions are efficiently executed.

The requirement that overtime or holiday inspection shall not be performed for anyone having a delinquent account would be altered to afford the establishment operator the opportunity to present his views prior to a determination by the Administrator that an account is delinquent.

Several other editorial changes have been proposed for the sake of clarity.

Accordingly, Part 307 of the Federal meat inspection regulations (9 CFR Part 307) and Part 381, Subpart G, of the Federal poultry products inspection regulations would be amended as set forth below:

1. It is proposed to amend §§ 307.4, 307.5, and 307.6, and add a new § 307.7 to the Federal meat inspection regulations (9 CFR Parts 307.4, 307.5, 307.6, and 307.7) to read as follows:

§ 307.4 Schedule of operations.

(a) Slaughter of livestock shall not be conducted without the presence of an inspector to conduct the ante-mortem and post-mortem inspections required by the Act, and no other operations requiring inspection shall be conducted except under the supervision of a Program employee to the extent necessary to assure that the meat and meat food products are not adulterated or misbranded. All slaughtering of animals and preparation of products shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime. One lunch period is the only officially authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once an establishment or an exporter fixes the lunch period, it must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. With respect to an establishment or an exporter where a company rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, the lunch period may be scheduled as late as five and one-half hours after the beginning of scheduled operations.

(c) Official establishments (including official import inspection establishments) and exporters shall be provided inspection service, without charge, up to 8 consecutive hours per shift during the approved work schedule subject to the provisions of §§ 307.4(d)(1) and 307.5. Official establishments (including official import inspection establishments) and exporters shall be provided inspection service for up to two shifts per day, without charge, if the Administrator determines that work performed in the second shift is substantial in relation to the establishment's first shift operations, and is over 4 hours in duration. If the establishment wishes to operate a third shift, it may, but the Administrator will staff the establishment, with only two 12-hour shifts of inspectors.

(d)(1) In order to establish an approved work schedule for an official establishment (including an official import inspection establishment) or an exporter, each operator of such establishment or exporter shall submit a proposed work schedule to the area supervisor for approval, consisting of the hours of the day and the days of the week he proposes to work. The work schedule will be approved whenever possible in the light of Program personnel availability and efficiency. With respect to those establishments or exporters requiring less than a full inspector, as determined by the Administrator, the schedule may either be denied, conditionally approved, or approved. If inspection service is not available at the time proposed due to unavailability of inspection personnel, the work schedule will be denied, but any alternative schedule proposed by the operator will be considered. If inspection service is available at the proposed time, but providing service at the proposed time would result in inspector overtime, the area supervisor may recommend an alternative work schedule which would eliminate or reduce inspector overtime. The recommended alternative work schedule will be based upon the most efficient and effective use of available inspection personnel and also upon a consideration of the impact upon establishments or exporters in the area. If the establishment or exporter accepts the recommended work schedule, that work schedule will be the approved work schedule for that establishment or exporter. If the establishment or exporter does not accept the recommended work schedule and chooses to use the work schedule it originally proposed, that originally proposed work schedule will be conditionally approved, and inspection service will be provided at those times. However, this may result in inspection personnel working overtime. If that occurs, the establishment or exporter

whose conditionally approved work schedule causes such overtime shall be billed for such costs without regard to the number of hours worked by the establishment or exporter in that day or in that week. If inspection service is available at the proposed time and the proposed work schedule would not result in inspector overtime, the proposed work schedule will be approved.

(2) Any request by an establishment or exporter for a permanent change in its work schedule involving an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Any request by an establishment or exporter for a permanent change in its work schedule which does not involve an addition or elimination of a shift, but which is in excess of 1 hour, shall be submitted to the area supervisor at least 1 week in advance of the proposed change. Any request for a permanent change of an hour or less or for any temporary deviation from a daily operating schedule shall be submitted to the inspector-in-charge, by the day preceding the day of change.

(3) Requests for inspection service involving overtime work to be performed within that same workday shall be made as early in the day as possible or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided,* That an inspector may be recalled to his assignment after completion of his daily tour of duty under the provisons of § 307.6(d).

§ 307.5 Overtime and holiday inspection service.

(a) The management of an official establishment (including an official import inspection establishment) or an exporter shall pay the sum of $15.44 per hour per Program employee to reimburse the Program for the cost of the inspection service furnished on or as a result of any holiday as specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday; or, when required, as a result of working a conditionally approved work schedule under § 307.4(d)(1).

(b) Holidays for food inspection employees shall be New Year's Day, January 1; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25, (as designated in 21 U.S.C. 1053). When any of the above-listed holidays falls outside the approved work schedule, the affected employees shall be entitled to a holiday as provided by 5 U.S.C. 6103(b) and Executive Order 11582. Inspection service performed by these employees on their holiday shall be treated as reimbursable inspection service, and the affected official establishments (including official import inspection establishments) or exporters will reimburse the Program for the service at the rate provided in paragraph (a) of this Section.

§ 307.6 Basis of billing for overtime and holiday services.

(a) Official establishments (including official import inspection establishments) or exporters, operating within their approved work schedule, as provided under § 307.4, may not be charged for costs of inspection service as the result of a Program employee working more than 8 hours on any one day or working more than 40 hours in any administrative workweek, Sunday through Saturday, but will be charged with any inspection service furnished on any holiday as specified in paragraph 307.5(b).

(b) Official establishments (including official import inspection establishments) or exporters may not be charged for costs of inspection service furnished to them if the Program employee(s) who provides the service has not worked for more than 8 hours in any one day, or more than 40 hours in any administrative workweek, Sunday through Saturday.

(c) Official establishments (including official import inspection establishments) or exporters requesting and receiving inspection services of a Program employee who is called to duty on any holiday shall reimburse the Program for a minimum of two hours holiday pay at the rate provided in Section 307.5(a).

(d) Official establishments (including official import inspection establishments) and exporters requesting and receiving inspection services of a Program employee who is performing work in excess of 8 hours in a day or in excess of 40 hours in an administrative workweek and who either is called back to duty for a period of time separate from his regularly scheduled day's assignment or is called back to duty on a nonscheduled workday shall reimburse the Program for a minimum of 2 hours overtime pay at the rate provided in Section 307.5(a).

(e) Except as provided in paragraphs (a) and (b), each recipient of overtime or holiday inspection service, or both, shall be billed at the rate established in § 307.5(a), in increments of quarter hours, including a part thereof of 8 minutes or more. The particular official establishment(s) (including official import inspection establishments) or exporter(s) whose request for service during conditionally approved hours as defined in § 307.4(d)(1) results in costs specified in § 307.5(a) shall be the business entity billed for such costs.

(f) Bills are payable upon receipt and become delinquent if not paid within 30 days from the date of the bill. Overtime or holiday inspection service shall be refused if the Administrator determines, after an establishment or exporter has been given an opportunity to present its views, that its bill for service has not been paid within 30 days for the date of the bill.

§ 307.7 Limitation of inspectors' duty hours.

Ante-mortem and post-mortem inspectors shall be limited to 10 hours post-mortem inspection duty per shift, including company breaks and including emergencies of less than one-half hour duration. The 10 hours do not include meal times or emergencies of greater duration than one-half hour. In addition, inspectors shall be limited to 12 clock hours duty per shift, including mealtime, company breaks, and emergencies, for other inspection duties which may include processing inspection or ante-mortem inspection or a combination of such inspection with post-mortem inspection duties. (Sec. 21, 34 Stat. 1264, as amended, 21 U.S.C. 621; 42 FR 35625, 35626, 35631.)

2. It is proposed to amend §§ 381.37, 381.38, 381.39, and add a new § 381.40 to the Federal poultry products inspection regulations (9 CFR Parts 381.37, 381.38, 381.39, and 381.40) to read as follows:

§ 381.37 Schedule of operations.

(a) Slaughter of poultry shall not be conducted without the presence of an inspector to conduct the ante-mortem and post-mortem inspections required by the Act, and no other operations requiring inspection shall be conducted except under the supervision of a Program employee to the extent necessary to assure that the poultry and poultry food products are not adulterated or misbranded. All slaughtering of poultry and preparation of poultry food products shall be done with reasonable speed, considering the official establishment's facilities.

(b) A shift is a regularly scheduled operating period, exclusive of mealtime.

One lunch period is the only officially authorized interruption in the inspector's tour of duty once it begins. Lunch periods may be 30 minutes, 45 minutes, or in any case may not exceed one hour in duration. Once an establishment or an exporter fixes the lunch period, it must remain relatively constant as to time and duration. Lunch periods for inspectors shall not, except as provided herein, occur prior to 4 hours after the beginning of scheduled operations nor later than 5 hours after operations begin. With respect to an establishment or an exporter where a company's rest break of not less than 30 minutes is regularly observed, approximately midpoint between start of work and the lunch period, the lunch period may be scheduled as late as five and a half hours after the beginning of scheduled operations.

(c) Official establishments (including official import inspection establishments) and exporters shall be provided inspection service, without charge, up to 8 consecutive hours per shift during the approved work schedule subject to the provisions of §§ 381.37(d)(1) and 381.38. Official establishments (including official import inspection establishments) and exporters shall be provided inspection service for up to two shifts per day, without charge, if the Administrator determines that work performed in the second shift is substantial in relation to the establishment's first shift operations, and is over 4 hours in duration. If the establishment wishes to operate a third shift, it may, but the Administrator will staff the establishment with only two 12-hour shifts of inspectors.

(d)(1) In order to establish an approved work schedule for an official establishment (including an official import inspection establishment) or an exporter, each operator of such establishment or exporter shall submit a proposed work schedule to the area supervisor for approval, consisting of the hours of the day and the days of the week he proposes to work. The work schedule will be approved whenever possible in light of Program personnel availability and efficiency. With respect to those establishments or exporters requiring less than a full inspector, as determined by the Administrator, the schedule may either be denied, conditionally approved, or approved. If inspection service is not available at the time proposed due to unavailability of inspection personnel, the work schedule will be denied, but any alternative schedule proposed by the operator will be considered. If inspection service is available at the proposed time, but providing service at the proposed time would result in inspector overtime, the area supervisor may recommend an alternative work schedule which would eliminate or reduce inspector overtime. The recommended alternative work schedule will be based upon the most efficient and effective use of available inspection personnel and also upon a consideration of the impact upon establishments or exporters in the area. If the establishment or exporter accepts the recommended work schedule, that work schedule will be the approved work schedule for that establishment or exporter. If the establishment or exporter does not accept the recommended work schedule and chooses to use the work schedule it originally proposed, that originally proposed work schedule will be conditionally approved, and inspection service will be provided at those times. However, this may result in inspection personnel working overtime. If that occurs, the establishment or exporter whose conditionally approved work schedule causes such overtime shall be billed for such costs without regard to the number of hours worked by the establishment or exporter in that day or in that week. If inspection service is available at the proposed time and the proposed work schedule would not result in inspector overtime, the proposed work schedule will be approved.

(2) Any request by an establishment or exporter for a permanent change in its work schedule involving an addition or elimination of shifts shall be submitted to the area supervisor at least 2 weeks in advance of the proposed change. Any request by an establishment or exporter for a permanent change in its work schedule which does not involve an addition or elimination of a shift, but which is in excess of 1 hour, shall be submitted to the area supervisor at least 1 week in advance of the proposed change. Any request for a permanent change of an hour or less or for any temporary deviation from a daily operating schedule shall be submitted to the inspector-in-charge, by the day preceding the day of change.

(3) Requests for inspection service involving overtime work to be performed within that same workday shall be made as early in the day as possible or made prior to the end of the day's operation when such a request will result in overtime service at the start of the following day: *Provided,* That an inspector may be recalled to his assignment after completion of his daily tour of duty under the provisions of § 381.39(d).

§ 381.38 Overtime and holiday inspection service.

(a) The management of an official establishment (including an official import inspection establishment) or an exporter shall pay the sum of $15.44 per hour per Program employee to reimburse the Program for the cost of the inspection service furnished on or as a result of any holiday as specified in paragraph (b) of this section; or for more than 8 hours on any day, or more than 40 hours in any administrative workweek Sunday through Saturday; or, when required, as a result of working a conditionally approved work schedule under § 381.37(d)(1).

(b) Holidays for food inspection employees shall be New Year's Day, January 1; Washington's Birthday, the third Monday in February; Memorial Day, the last Monday in May; Independence Day, July 4; Labor Day, the first Monday in September; Columbus Day, the second Monday in October; Veterans' Day, November 11; Thanksgiving Day, the fourth Thursday in November; Christmas Day, December 25, (as designated in 21 U.S.C. 1053). When any of the above-listed holidays falls outside the approved work schedule, the affected employees shall be entitled to a holiday as provided by 5 U.S.C. 6103(b) and Executive Order 11582. Inspection service performed by these employees on their holiday shall be treated as reimbursable inspection service, and the affected official establishments (including official import inspection establishments) or exporters will reimburse the Program for the service at the rate provided in paragraph (a) of this Section.

§ 381.39 Basis of billing for overtime and holiday services.

(a) Official establishments (including official import inspection establishments) or exporters, operating within their approved work schedule, as provided under § 381.37(c), may not be charged for costs of inspection service as the result of a Program employee working more than 8 hours on any one day or working more than 40 hours in any administrative workweek, Sunday through Saturday, but will be charged with any inspection service furnished on any holiday as specified in paragraph 381.38(b).

(b) Official establishments (including official import inspection establishments) or exporters may not be charged for costs of inspection service furnished to them if the Program employee(s) who provides the service

has not worked for more than 8 hours in any one day, or more than 40 hours in any administrative workweek, Sunday through Saturday.

(c) Official establishments (including official import inspection establishments) or exporters requesting and receiving inspection services of a Program employee who is called to duty on any holiday shall reimburse the Program for a minimum of two hours holiday pay at the rate provided in Section 381.38(a).

(d) Official establishments (including official import inspection establishments) or exporters requesting and receiving inspection services of a Program employee who is performing work in excess of 8 hours in a day or in excess of 40 hours in an administrative workweek and who either is called back to duty for a period of time separate from his regularly scheduled day's assignment or is called back to duty on a nonscheduled workday shall reimburse the Program for a minimum of 2 hours overtime pay at the rate provided in Section 381.38(a).

(e) Except as provided in paragraphs (a) and (b), each recipient of overtime or holiday inspection service, or both, shall be billed at the rate established in § 381.38(a), in increments of quarter hours, including a part thereof of 8 minutes or more. The particular official establishment(s) (including official import inspection establishments) or exporter(s) whose request for service during conditionally approved hours as defined in § 381.37(d)(1) results in costs specified in § 381.38(a) shall be the business entity billed for such costs.

(f) Bills are payable upon receipt and become delinquent if not paid within 30 days from the date of the bill. Overtime or holiday inspection service shall be refused if the Administrator determines, after an establishment or exporter has been given an opportunity to present its views, that its bill for service has not been paid within 30 days from the date of the bill.

§ 381.40 Limitation of inspectors' duty hours.

Ante-mortem and post-mortem inspectors shall be limited to 10 hours post-mortem inspection duty per shift, including company breaks and including emergencies of less than one-half hour duration. The 10 hours do not include meal times or emergencies of greater duration than one-half hour. In addition, all Program inspectors, shall be limited to 12 clock hours total duty per shift, including mealtime, company breaks, and emergencies, for other inspection duties which may include processing inspection or ante-mortem inspection or a combination of such inspection with post-mortem inspection duties.

(Sec. 14, 71 Stat. 441, as amended, 21 U.S.C. 463, 42 FR 35625, 35626, 35631.)

Note.—This proposal has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations," and has been designated "significant." An approved Draft Impact Analysis Statement has been prepared and is available from Dr. W. H. Dubbert, Acting Director of Divisions, Technical Services, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC. 20250. The alternatives considered during the analysis are listed in the Draft Impact Analysis Statement.

Done at Washington, D.C., on: November 28, 1979.

D. L. Houston,

Administrator, Food Safety and Quality Service.

[FR Doc. 79-37035 Filed 12-3-79; 8:45 am]

BILLING CODE 3410-DM

DEPARTMENT OF ENERGY

Economic Regulatory Administration

10 CFR Parts 211 and 212

Public Conference Concerning Shell Oil Company's Jet Fuel Pricing Practices at JFK International Airport

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of Public Conference and Request for Written Comments.

SUMMARY: The Economic Regulatory Administration ("ERA") of the Department of Energy ("DOE") will hold a conference on December 14, 1979, beginning 10:00 a.m., e.s.t. in Room 2105, 2000 M Street, N.W., Washington, D.C., with Shell Oil Co. (Shell), El Al Israel Airlines (El Al), Air India, Alitalia Airlines (Alitalia), and Lufthansa German Airlines (Lufthansa). The purpose of the conference is to assist ERA in its evaluation of allegations submitted to it by El Al, Air India, Alitalia and Lufthansa charging that Shell is engaging in discriminatory pricing practices in sales of jet fuel to its international customers at JFK International Airport. The Civil Aeronautics Board and other interested government agencies will be invited to participate in the conference. ERA also invites the participation of any domestic airlines and any other persons having an interest which might be affected by action taken in response to these complaints.

This conference will afford Shell and its domestic and international jet fuel customers the opportunity to present their views on all of the issues relevant to ERA's evaluation of complaints regarding Shell's pricing practices at JFK and will also permit an exchange of views on the issues among Shell, the airlines and ERA officials.

DATES: Conference date: December 14, 10:00 a.m. Telephone requests to speak by COB December 12, 1979; Notification of request to speak by 4:30 p.m., December 13, 1979; Written Comments by December 24, 1979.

ADDRESSES: Conference: Room 2105, 2000 M Street, N.W., Washington, D.C.; All comments should be directed to Office of Public Hearings Management, Economic Regulatory Administration, Room 2313, Box XN, 2000 M Street, N.W., Washington, D.C. 20461. All requests to speak should be by telephone to the Office of Public Hearings Management at (202) 254-5201.

FOR FURTHER INFORMATION CONTACT: Keith Bauer, Economic Regulatory Administration, Room 6222-D, 2000 M Street, N.W., Washington, D.C. 20461, (202) 254-3330.

SUPPLEMENTARY INFORMATION:

Background

Effective February 26, 1979, jet fuel was exempted from pricing and allocation controls, pursuant to the procedures set forth in section 12(c) of the EPAA. However, section 12(f) of the EPAA gives the President the authority to reimpose controls on an exempted product, either by order or by regulation, upon his determination that such action is necessary to obtain, and is consistent with, the objectives specified in section 4(b)(1) of the Act.

In recent months, the ERA has received complaints from several international airlines charging Shell with discriminatory pricing practices in sales of jet fuel to its international customers at JFK International Airport in New York. These airlines—El Al, Air India, Alitalia and Lufthansa—attack Shell's admitted business practice of selling only imported jet fuel to its customers (including U.S. flag carriers) providing foreign air service from JFK. By contrast Shell supplies its airline customers providing domestic air service from JFK with domestically produced jet fuel, which is considerably less expensive than imported fuel. Shell is the only supplier of jet fuel at JFK which follows this "two tier" pricing practice.

Specifically, the four complaining airlines allege that Shell's pricing practice is discriminatory. Since the affected airlines have not been sucessful in efforts to obtain alternate sources of supply at lower prices, they complain that Shell's policy places them at an unfair economic disadvantage relative

to competitors who are able to obtain fuel at lower domestic or "pooled" prices from other suppliers.

El Al contends that Shell's practice is contrary to the objectives of section 4(b)(1) of the EPAA, which include the "equitable distribution of . . . refined petroleum products at equitable prices among all regions and areas of the United States . . . and among all users." El Al contends, moreover, that this economic injury is aggravated by its involvement in the Bilateral Air Transport Agreement in effect between Israel and the United States. Under this Agreement, any fare proposed to be charged by carriers serving routes between the two carriers may be disapproved only by action of both countries. Israel cannot, therefore, protect the economic interests of its own flag carriers through unilateral disapproval of a competing U.S. flag carrier's relatively lower fares. Hence, El Al argues, a fare increase to account for El Al's relatively higher fuel costs (stemming from Shell's pricing practices) would render it uncompetitive with other international airlines supplied with less expensive fuel.

In addition, Air India, Alitalia and Lufthansa contend that Shell's pricing policy is contrary to declared and consistent U.S. policies, international obligations, and specific laws of the United States. Like El Al, these airlines label Shell's pricing practices discriminatory, and point out the resulting competitive disadvantage suffered by Shell's international airline customers.

The airlines have requested that ERA take action pursuant to section 12(f) of the EPAA to relieve the effects of Shell's current pricing policy. Specifically, El Al requests the ERA to either (1) assign it domestically produced kerosene-base aviation fuel to be supplied by Shell at JFK or, alternatively, (2) to assign one or more other major suppliers of domestically produced jet fuel to supply it with domestic-priced jet fuel. Air India, Alitalia, and Lufthansa request, among other suggested alternatives, that ERA (1) issue a specific order to Shall ordering it, with retroactive effect, to distribute the cost of importing fuel required to serve all of its customers on a pooled basis, or (2) if necessary, reimpose controls on jet fuel generally or to the extent necessary to maximize supplies and prohibit the discrimination complained of.

In addition to views received by Shall and its customers of bonded fuel at JFK, several airline customers of Shell who provide only domestic air service have contacted ERA to urge that no action be taken to require Shell to pool its imported supply with its domestic supply. These domestic carriers have asserted that if Shell is required to pool its imported fuel supplies, the prices charged to domestic airline customers may increase by several cents per gallon.

Conference Procedures

ERA is convening this conference pursuant to 10 CFR 205.171 and paragraph 26 of DOE Delegation Order No. 0204–4. The Delegation Order authorizes the Administrator of ERA to conduct conferences, hearings or public hearings with respect to the functions delegated thereby and to administer oaths and affirmations to any person appearing at such conference or hearing. Pursuant to this Delegation Order, the ERA official designed to preside at the conference will be authorized to administer oaths or affirmations to any person presenting testimony at the conference. ERA will request that Shell, Air India, Alitalia and Lufthansa present their testimony under oath due to the complexities of the subject matter of the conference and the necessity for ERA's final determination to be based on as reliable and complete a record as possible. The presiding ERA official will be authorized to conduct the conference in a fashion that will, in his or her judgment, facilitate the orderly presentation of interested parties' oral statements. All interested persons are requested to present views as to the issue or issues involved, and will be afforded the opportunity to make opening and closing statements, which may be subject to time limitations if so specified by the presiding ERA official. Each of these parties will also have the opportunity to ask questions of each other person presenting testimony; *Provided, However,* That the presiding ERA official will determine whether a question is relevant and whether time limitations permit it to be answered.

This conference will be open to the public. Any person who wishes to make an oral statement at the conference must given notice thereof to the Office of Public Hearings Management of the Economic Regulatory Administration, at the above address, by December 12, 1979. This notice should indicate the issues which will be addressed, the amount of time desired, and a person (with address and telephone number) to accept ERA notification of the grant of time for an oral statement and the allotted time for the oral statement. ERA reserves the right to restrict the number of such persons to be heard and to establish procedures governing the presentation of such oral statements.

Any person who wishes to file written comments with ERA will be permitted to do so, either before or after the conference. However, all comments must be sent to the Office of Public Hearings Management at the above address before December 24, 1979. Any information or data considered confidential by the person furnishing it must be identified on a second copy thereof. All comments (with confidential material excluded) received by ERA will be available for public inspection in the Freedom of Information Public Reading Room, Room GA–152, Forrestal Building, 1000 Independence Ave., S.W., Washington, D.C., between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

A transcript of the conference will be made, and it will be available for public review and copying at the Freedom of Information Public Reading Room at the above address between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays. Any person may purchase a copy of the transcript from the reporter.

Issued at Washington, D.C. on November 29, 1979.

David J. Bardin,

Administrator, Economic Regulatory Administration.

[FR Doc. 79–37387 Filed 12–3–79; 8:45 am]

BILLING CODE 6450–01–M

DEPARTMENT OF COMMERCE

Industry and Trade Administration

15 CFR Part 369

Restrictive Trade Practices or Boycotts

AGENCY: Industry and Trade Administration, Department of Commerce.

ACTION: Proposed Rulemaking and Request for Comments.

SUMMARY: The agency proposes to amend the restrictive Trade Practices of Boycotts part of the Export Administration Regulations. The amendment is being made to implement Title II of the Export Administration Amendments of 1977 (Pub. L. 95–52) which has been incorporated into the Export Administration Act of 1979 (Pub. L. 96–72, to be codified at 50 U.S.C. App. 2401, *et seq.*). The proposed change is being made to clarify the application of the regulations to certain boycott restrictions on exports from boycotting countries.

DATES: Comments must be received by the Department before noon, January 4, 1980.

ADDRESSES: Written comments (six copies when possible) should be sent to: Antiboycott Compliance Staff, Industry and Trade Administration, Room 3226, U.S. Department of Commerce, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230.

FOR FURTHER INFORMATION CONTACT: Oral communciations or requests for further information should be directed to: Howard N. Fenton III, Antiboycott Compliance Staff, U.S. Department of Commerce, (202) 377–5914.

SUPPLEMENTARY INFORMATION: It has come to the Department's attention that certain boycotting countries are requesting United States persons to restrict the route of shipment of exports from the boycotting country as well as imposing restrictions on the ultimate destination of the exports. It is the Department's understanding that the object of the boycotting countries in requesting adherence to these restrictions is to prevent exports from the boycotting countries from coming under the control of boycotted countries.

The promulgation of these boycott regulations is exempt from Administrative Procedure Act rulemaking procedures. However, the Department continues to invite public participation in their development. All persons who desire to comment are encouraged to do so at the earliest possible time so as to permit the fullest consideration of their views. Comments may take the form of proposed regulatory language, narrative discussion, hypothetical case situations or any other appropriate format.

The comment period for submission of comments on these proposed regulations will close at noon, January 4, 1980.

In consideration of the foregoing, § 369.3(d) of Title 15 of the Code of Federal Regulations is proposed to be revised as set forth below. The arrows indicate additions to § 369.3(d).

§ 369.3 Exceptions to Prohibitions.

* * * * *

(d) *Shipment and Transshipment of Exports Pursuant to a Boycotting Country's Requirements.*

Compliance With a Boycotting Country's Requirements Regarding Shipment and Transshipment of Exports

(1) A United States person may comply or agree to comply with the export requirements of a boycotting country with respect to shipments or transshipments of exports to:

(i) A boycotted country;

(ii) Any business concern of a boycotted country;

(iii) Any business concern organized under the laws of a boycotted country; or

(iv) Any national or resident of a boycotted country.

(2) This exception permits compliance with restrictions which a boycotting country may place on direct exports to a boycotted country; on indirect exports to boycotted country (i.e., those that pass via third parties); and on exports to residents, nationals, or business concerns of, or organized under the laws of, a boycotted country, including those located in third countries.

►(3) This exception also permits compliance with restrictions which a boycotting country may place on the route of export shipments, when the restrictions are reasonably related to preventing the export shipments from coming into contact with or under the jurisdiction of the boycotted country. This exception applies whether a boycotting country or the purchaser of the shipment:

(i) Explicitly states that the shipment should not pass through a port of the boycotted country enroute to its final destination; or

(ii) Affirmatively describes a route of shipment that does not include a port of the boycotted country◄

The following examples are to be added following 15 CFR 369.3(d) example (vi):

►(vii) a, a U.S. petroleum company, exports petroleum products to 20 countries from boycotting country Y. Y requires, as a condition of sale, that A not ship the products to be exported from Y to or through boycotted country X.

A may comply or agree to comply with this requirement, because it is an export requirement of Y designed to prevent Y-origin products from coming into contact with or under the jurisdiction of a boycotted country.

(viii) Same as (vii), except that boycotting country Y's export regulations require that products to be exported from Y not pass through a port of boycotted country X.

A may comply with Y's regulations prohibiting Y-origin exports from passing through a port at boycotted country X, because they are export requirements of Y designed to prevent Y-origin products from coming into contact with or under the jurisdiction of a boycotted country.

(ix) Same as (vii), except that Y's export regulation require that A not transship the exported products in or at boycotted country X.

A may comply with Y's regulations with respect to the transshipment of goods in or at X, because they are export requirements of Y designed to prevent Y-origin products from coming into contact with on under the jurisdiction of a boycotted country◄

Dated: November 28, 1979.

Stanley J. Marcuss,

Acting Assistant Secretary for Industry and Trade.

[FR Doc. 79-37217 Filed 12-3-79; 8:45 am]

BILLING CODE 3510-25-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 58

[Docket No. 76N-0400]

Nonclinical Laboratory Studies; Amendment of Good Laboratory Practice Regulations

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The agency proposes to amend the good laboratory practice regulations (GLP's) to delete the provision which requires the retention of reserve samples of test or control article-carrier mixtures. The enforcement of the provision is stayed until the time when action on the proposal has been concluded. These actions are taken because the agency has received petitions that question the value of the reserve sample retention requirement in assuring the quality of safety testing and that request agency reconsideration of the need for this requirement.

DATE: Written comments by February 4, 1980; proposed effective date of the final regulation based on this proposal is the date 30 days after publication of the final regulation in the **Federal Register.**

ADDRESS: Written comments to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Paul D. Lepore, Bioresearch Monitoring Staff (HFC–30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2390.

SUPPLEMENTARY INFORMATION: The good laboratory practice regulations were published as a final rule in the **Federal Register** of December 22, 1978 (43 FR 59986) and became effective on June 20, 1979. Section 58.113(b) (21 CFR 58.113(b)) of the regulations requires that "For studies of more than 4 weeks' duration, a reserve sample of each test or control article-carrier mixture shall be taken and retained for the period of time provided by § 58.195." The Food and Drug Administration (FDA) has

received petitions from both Riker Laboratories Inc. (Riker) and the Pharmaceutical Manufacturers Association requesting the agency to delete § 58.113(b) and to stay the enforcement of this section until agency action on the requests has been concluded.

FDA has also received correspondence in support of these petitions. Copies of the petitions and the associated correspondence have been placed on file in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen between 9 a.m. and 4 p.m., Monday through Friday.

Section 58.113(b) requires testing facilities to take and retain reserve samples from each batch of test or control article-carrier mixture for all nonclinical laboratory studies lasting more than 4 weeks. These samples are to be retained even if the batches are prepared daily, but only sufficient sample need be retained to permit meaningful reanalysis of the test or control article. The samples must be retained either for the periods of time specified in § 58.195 (21 CFR 58.195) or for the useful life of the sample (dependent on the stability or the quality of the sample), whichever is shorter. Storage conditions should be those that minimize the deterioration of sample quality, but exhaustive study to determine those conditions that maximize stability is not required.

The purpose of § 58.113(b) was described in paragraphs 179 and 191 of the preamble to the December 22, 1978 final order on the GLP's. The agency concluded that maintaining a reserve sample of the test or control article-carrier mixture was necessary to provide independent assurance (either from a firm's quality assurance unit or an agency analysis of the mixture) that the test system was exposed to the test article as specified in the protocol. Further, if the study results raise questions as to the composition of the test or control article, retention of reserve samples allows resolution of the question. The agency noted, in the preamble to the November 19, 1976 GLP proposal (41 FR 51206), that one of the deviations found in early agency investigations of nonclinical laboratories was that "drugs under study were administered to animals in a manner that made it impossible to determine how much, if any, of the required dosage was actually ingested by the animal." Such a determination could be facilitated by the existence of reserve samples.

The petitioners argue that § 58.113(b) is excessively burdensome and is not necessary to ensure the quality and integrity of test data that are submitted to the agency. Riker argued that a 3-month oral (daily intubation) rat study in which batches of test or control article mixtures would be prepared daily would result in 720 separate samples. A 2-year oral (diet) rat study in which mixtures needed to be adjusted frequently to maintain an accurate daily dosage would yield 400–500 samples to be retained. These figures, for Riker, would result in the required storage of some 25,000 samples over the minimum 5-year term required by the regulations.

Both petitioners contend further that certain other provisions of the GLP's coupled with the agency nonclinical laboratory inspection program provide assurance that the test systems are being exposed to protocol-specified quantities of test article and obviate the need to retain samples as required by § 58.113(b). The provisions noted by the petitioners include—

(1) Section 58.113(a)(1), which provides for the conduct of tests to assure the adequacy of the test or control article mixing procedures and for periodic analysis of the concentration of the test or control article in mixtures;

(2) Section 58.113(a)(2), which provides for the determination of the stability of the test or control article in mixtures;

(3) Section 58.81(b)(3) (21 CFR 58.81(b)(3)), which provides for establishing standard operating procedures for mixing test or control articles;

(4) Section 58.130(e) (21 CFR 58.130)(e)), which provides that study records document, among other things, the use of test or control article mixtures;

(5) Section 58.107 (21 CFR 58.107), which provides for accountability and controls for test and control article handling;

(6) Sections 58.105(a) and 58.185(a)(4) (21 CFR 58.105(a) and 58.185(a)(4)), which provide for documentation of the identity of the components comprising the batch;

(7) Sections 58.120(a)(11) and 58.185(a)(8) (21 CFR 58.120(a)(11) and 58.185(a)(8)), which provide that study records document the quantities of test or control article-carrier mixtures received by the test system;

(8) Subparts B, C, and D of Part 58 (21 CFR Part 58), which provide for adequate facilities, equipment, and sufficiently qualified personnel; and

(9) Section 58.35(b)(3) (21 CFR 58.35(b)(3)), which requires the quality assurance unit to inspect the operations and records described in items 1 through 7 above.

The agency has considered the views expressed by the petitioners and agrees with many of the points raised. Public comments directed toward the GLP proposal did not include the quantitative data on reserve sample retention which has been provided by Riker. Accordingly, agency consideration of the comments for preparation of the final rule focused primarily on the standard four dose level, 2-year oral (diet) rat study in which test article diet mixtures are adjusted monthly. Such a study yields 96 samples for retention. Apparently, however, many studies require more frequent diet adjustment to provide a more accurate daily dosage with the test article. The agency has received information on study designs requiring separate mixtures of test articles to be fed to males and females, with dietary dosage adjustment being made weekly for the first year of the study, biweekly for the next 6 months, and monthly for the last 6 months. Such a study at the four dose level would yield more than 500 samples, which would have to be retained to comply with § 58.113(b). Thus, the volume of samples required to be retained appears to have been underestimated both by FDA and by persons commenting on the proposal by a factor of about five.

Public meetings on the GLP's were held by the agency on May 1, 2, and 3, 1979 in Washington, Chicago, and San Francisco and were attended by members of the regulated industry. The reserve sample retention requirement evoked the greatest number of questions at each briefing. Attendees emphasized that the requirement was unreasonably burdensome and questioned the utility and validity of any analytical data from these reserve samples for validating study results, especially after the samples had been stored for several years. The attendees argued that instability of active ingredients in feed mixtures is a well-established scientific fact; as feed is stored, the components decompose and interact with each other and with any test article present to produce complex byproducts, which would make it very difficult to conduct accurate analyses of the test article. The practical value of the reserve sample, therefore, diminishes with age.

The agency agrees with this rationale. The agency has also reviewed the results of both the nonclinical laboratory inspection program and the study audits that have been conducted. Since December 1976, over 400 inspections and study audits have been

made. During this time, there has not been a single occasion for the agency to require analysis of the reserve sample as part of a study validation. FDA therefore is persuaded that the reserve sample retention requirement is not essential and may impose an unreasonable burden upon industry.

The agency believes that proper exposure of test systems to test or control articles includes—

The preparation of a batch of test or control article which has been appropriately characterized;

The determination of test or control article stability in mixtures;

The determination of mixing procedures resulting in uniform test or control article mixtures;

The periodic analysis of batches of test or control article mixtures;

The documentation of the quantities of test or control article mixtures used by the test systems; and

The development of procedures to document the receipt and distribution of each batch of test or control article.

FDA is convinced that the last step is of most importance in assuring proper test article dosage. Section 58.107(d) requires that study records contain an inventory of test article disposition that demonstrates test article accountability for the study. Such records must show the initial quantity of test article used to prepare the mixture and must show also the quantity of test article remaining after each mixture has been prepared. These records will document adequately the amount of test article that has been used to prepare each mixture.

The agency has reevaluated the GLP regulation and tentatively concludes that provisions other than § 58.113(b) assure that test system exposure to test or control articles is in accordance with the protocol and is adequately controlled. In addition, assurance of such exposure can be gained independently by inspection of the documentation of the steps listed above, either by the firm's quality assurance unit or by the agency during the conduct of its nonclinical laboratory inspection program.

Thus, the agency is proposing to grant the petitions and delete the reserve sample retention requirements listed in § 58.113(b) of the regulations. The agency advises that until comments submitted in response to this proposal can be evaluated and a final decision made as to the need for § 58.113(b) to assure adequate control of test system exposure, FDA will not enforce the requirements to take and retain reserve samples of each test or control article-carrier mixture used in a nonclinical laboratory study.

FDA has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly effect the quality of the human environment, has concluded that an environmental impact statement is not required. A copy of the environmental impact assessment is on file with the Hearing Clerk, Food and Drug Administration.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 406, 408, 409, 502, 503, 505, 506, 507, 510, 512–516, 518–520, 701(a), 706, 801, 52 Stat. 1049–1053 as amended, 1055, 1058 as amended, 55 Stat. 851 as amended, 59 Stat. 463 as amended, 68 Stat. 511–517 as amended, 72 Stat. 1785–1788 as amended, 76 Stat. 794 as amended, 82 Stat. 343–351, 90 Stat. 539–574 (21 U.S.C. 326, 346, 346a, 348, 352, 353, 355, 356, 357, 360, 360b–360f, 360h–360j, 371(a), 376, and 381)) and the Public Health Service Act (secs. 215, 351, 354–360F, 58 Stat. 690, 702 as amended, 82 Stat. 1173–1186 as amended (42 U.S.C. 216, 262, 263b–263n)) and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Part 58 be amended as follows:

§ 58.113 [Amended]

1. By amending § 58.113 by deleting and reserving paragraph (b).

§ 58.195 [Amended]

2. By amending § 58.195 by deleting from paragraph (c) the phrase "samples of test or control article carrier mixtures."

Interested persons may, on or before February 4, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: November 26, 1979.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 79–36991 Filed 11–28–79; 11:52 am]

BILLING CODE 4110–03–M

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21 CFR Part 131

[Docket No. 78N–0351]

Butteroil and Anhydrous Butteroil and Anhydrous Milkfat; Termination of Consideration of Codex Standard

AGENCY: Food and Drug Administration.

ACTION: Notice of termination of consideration.

SUMMARY: This notice terminates the review by the United States of the Codex Alimentarius Commission (Codex) "Recommended International Standard for (i) Butteroil and (ii) Anhydrous Butteroil and Anhydrous Milkfat." The response to the Food and Drug Administration's (FDA's) request for comments on the provisions of the Codex standard and on the desirability of establishing a U.S. standard for butteroil and anhydrous butteroil and anhydrous milkfat indicates there is neither sufficient interest nor need to warrant proposing a U.S. standard for these foods. Therefore, FDA has terminated consideration of developing a U.S. standard for butteroil and anhydrous butteroil and anhydrous milkfat based on the Codex standard.

EFFECTIVE DATE: December 4, 1979.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF–215), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St., SW., Washington, DC 20204, 202–245–1155.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 23, 1979 (44 FR 10720), FDA published an advance notice of proposed rulemaking that offered interested persons an opportunity to review the Codex "Recommended International Standard for (i) Butteroil and (ii) Anhydrous Butteroil and Anhydrous Milkfat" and to comment on the desirability and need for a U.S. standard for this food. The Codex standard was submitted to the United States for consideration for acceptance by the Joint Food and Agriculture Organization/World Health Organization Codex Alimentarius Commission.

Four letters were received in response to the advance notice of proposed rulemaking: three opposed a U.S. standard, and one letter offered information to be used in the event a

U.S. standard is developed. In general, the comments opposing the standard stated that there was no need for a U.S. standard. One of the opposing comments stated that anhydrous butteroil and anhydrous milkfat are made in this country, but these products are not intended for distribution directly to consumers. Since the purpose of standards of identity, as the comment understood it, is to protect consumers, and these products are not made for direct consumer consumption, there is no demonstrated need for a standard for these foods.

Having considered the comments received, FDA has concluded that there is neither sufficient interest nor need to warrant proposing a U.S. standard at this time for butteroil and anhydrous butteroil and anhydrous milkfat under the authority of section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

Therefore, under the procedures in 21 CFR 130.6, notice is given that the Commissioner of Food and Drugs has terminated consideration of developing a U.S. standard for butteroil and anhydrous butteroil and anhydrous milkfat based on the Codex standard. This action is without prejudice to future consideration of the development of a U.S. Standard for butteroil and anhydrous butteroil and anhydrous milkfat upon appropriate justification.

The Codex Alimentarius Commission will be informed that an imported food that complies with the requirements of the Codex standard for butteroil and anhydrous butteroil and anhydrous milkfat may move freely in interstate commerce in this country, providing it complies with applicable United States laws and regulations.

Dated: November 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-37134 Filed 12-3-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 131

[Docket No. 78N-0353]

Edible Caseinate; Termination of Consideration of Codex Standard

AGENCY: Food and Drug Administration.

ACTION: Notice of Termination of Consideration.

SUMMARY: This notice terminates the review by the United States of the Codex Alimentarius Commission (Codex) "Recommended International Standard for Edible Caseinate." The response to the Food and Drug Administration's (FDA's) request for comments on the provisions of the Codex standard and on the desirability of establishing a U.S. standard for edible caseinate indicates there is neither sufficient interest nor need to warrant proposing a U.S. standard for this food. Therefore, FDA has terminated consideration of developing a U.S. standard for edible caseinate based on the Codex standard.

EFFECTIVE DATE: December 4, 1979.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF-215), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St., SW., Washington, DC 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 23, 1979 (44 FR 10719), FDA published an advance notice of proposed rulemaking that offered interested persons an opportunity to review the Codex "Recommended International Standard for Edible Caseinate" and to comment on the desirability and need for a U.S. standard for this food. The Codex standard was submitted to the United States for consideration for acceptance by the Joint Food and Agriculture Organization/World Health Organization Codex Alimentarius Commission.

Six letters were received in response to the advance notice of proposed rulemaking; four voiced opposition to a United States standard. One comment favored a U.S. standard and suggested changes, and one comment offered information to be used in the event a U.S. standard is developed. In general, the comments opposing the standard stated that there was no need for a U.S. standard. One of the opposing comments stated that two aspects of caseinate manufacture, functional applications and production technology, are still in the developmental stages in this country. The comment questioned whether it is appropriate to adopt a standard, at this time, that may inhibit future advances in these areas. The comment in favor of a standard offered no support for its position.

Having considered the comments received, the FDA has concluded that there is neither sufficient interest nor need to warrant proposing a U.S. standard at this time for edible caseinate under the authority of section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341).

Therefore, under the procedures in 21 CFR 130.6, notice is given that the Commissioner has terminated consideration of developing a U.S. standard for edible caseinate based on the Codex standard. This action is without prejudice to future consideration of the development of a U.S. standard for edible caseinate upon appropriate justification.

The Codex Alimentarius Commission will be informed that an imported food that complies with the requirements of the Codex standard for edible caseinate may move freely in interstate commerce in this country, providing it complies with applicable United States laws and regulations.

Dated: November 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-37135 Filed 12-3-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 320

[Docket No. 79N-0133]

Certain Sulfonamide Anti-Infectives; Proposed Bioequivalence Requirements; Correction

AGENCY: Food and Drug Administration.

ACTION: Correction.

SUMMARY: This notice corrects the proposal to establish bioequivalence requirements for certain sulfonamide drug products.

EFFECTIVE DATE: This correction is effective as of October 19, 1979.

FOR FURTHER INFORMATION CONTACT: Henry J. Malinowski, Bureau of Drugs (HFD-525), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1640.

SUPPLEMENTARY INFORMATION: In FR Doc. 79-32216 appearing at page 60320 in the **Federal Register** of October 19, 1979, the following corrections are made:

1. On page 60325, second column, paragraph (2) is corrected to read as follows:

"(2) In at least 75 percent of the subjects administered the drug, the test product should be at least 75 percent as bioavailable as the administered reference material using the subjects as their own controls, that is, administering both the reference material and the test drug material to each subject sequentially."

2. On page 60327, third column, § 320.110(g)(2)(ii) is corrected to read as follows: § 320.110(g)(2)(ii) is corrected to read as follows:

§ 320.110 Certain oral sulfonamides.

* * * * *

(g) * * *

(2) * * *

(ii) In at least 75 percent of the subjects administered the drug, the test product is at least 75 percent as bioavailable as the administered reference material using the subjects as their own controls, that is, administering both the reference material and the test drug material to each subject sequentially; and

* * * * *

Dated: November 27, 1979.

J. Richard Crout,

Director, Bureau of Drugs.

[FR Doc. 79-37133 Filed 12-3-79; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 452

[Docket No. 79N-0459]

Erythromycin Estolate; Revocation of Provisions for Certification of Adult Dosage Forms

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) proposes to amend the antibiotic drug regulations by revoking provisions for certification of adult dosage forms of erythromycin estolate. This action is being taken because the drug is unsafe in adults because the risks presented by the drug outweigh its benefits. This action, when final, would require removal of all adult dosage forms (conventional tablets and capsules) from the market.

DATES: Comments by January 3, 1980; requests for an informal conference by December 19, 1979. FDA proposes that the final rule based on this proposal be effective on the day a final regulation is published.

ADDRESS: Written comments or requests for an informal conference to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nathan J. Treinish, Bureau of Drugs (HFD-32), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3650.

SUPPLEMENTARY INFORMATION:

Background

Erythromycin estolate was one of the drugs reviewed in the Drug Efficacy Study. In the Federal Register of August 29, 1970 (35 FR 13803) (DESI 8582), as amended in the Federal Register of October 14, 1971 (36 FR 19988), FDA published its findings on the National Academy of Sciences/National Research Council (NAS/NRC) review of the effectiveness of erythromycin preparations for oral and parenteral use. The products were classified as effective in the treatment of various infections, probably effective in the treatment of *Neisseria gonorrhoeae*, and possibly effective in the treatment of *Hemophilus influenzae*. These less-than-effective indications were reclassified to become effective upon publication in the Federal Register of September 17, 1976 (41 FR 40209).

In 1958, FDA first approved Ilosone containing erythromycin estolate for marketing by Dista Products Co., Division of Eli Lilly & Co., P.O. Box 1407, Indianapolis, IN 46206. Lilly is the holder of the following antibiotic Form 5's and Form 6's; 50-010, 50-365, 50-426, 60-431, 60-558, and 60-559 (all of which products are no longer marketed), and 61-893, 61-894, 61-895, 61-896, and 61-897. Of the five Lilly products that are currently marketed, three are pediatric dosage forms and are not affected by this proposal. They are 61-893 and 61-894 for oral (liquid and drops) suspensions and 61-895 for chewable tablets. The remaining Lilly products are subject to this proposal. Danbury Pharmacal, Inc., 131 West St., P.O. Box 296, Danbury, CT 06810, is the holder of an antibiotic Form 6, 62-087, for capsules containing 250 milligrams of erythromycin estolate. This product is also subject to this proposal.

Safety Issues

The first reports of hepatotoxicity associated with erythromycin estolate were published in 1961 (Refs. 1 and 2). The adverse reaction was considered to be cholestatic hepatitis. Symptoms of this hepatotoxicity may include nausea, vomiting, abdominal cramps, fever, malaise, and sometimes jaundice. Some patients may experience abdominal pain resembling the pain due to pancreatitis, biliary colic, perforated ulcer, or other acute surgical disease of the abdomen.

Symptoms of hepatotoxicity may appear after a few days of a course of erythromycin estolate, but they generally appear only after 1 or 2 weeks of therapy. Laboratory findings have been characterized by abnormal liver function test values, peripheral eosinophilia, and leukocytosis. When erythromycin estolate is readministered to sensitized patients, these symptoms reappear within 48 hours. After the drug is discontinued, symptoms disappear and liver function tests return to normal. Hepatotoxicity probably represents a hypersensitivity reaction.

Hepatotoxicity occurs primarily in adults. Its occurrence in children is less common (Ref. 15). Moreover, as discussed below, the incidence of hepatotoxicity with erythromycin estolate is much higher than the incidence of this condition with other erythromycin preparations. Other erythromycin preparations are certified for the same indications as erythromycin estolate.

In 1962, the package insert for Ilosone was revised to add information about recognized hepatotoxicity with erythromycin estolate.

On April 24, 1973, the Health Research Group (HRG) petitioned the agency to withdraw approval of erythromycin estolate. In May 1973, FDA's Anti-Infective Agents Advisory Committee (the Committee) met to discuss the safety and effectiveness of erythromycin estolate. The Committee considered information suggesting that, because the blood levels of erythromycin estolate were higher than those of other oral erythromycin products, erythromycin estolate was likely to be therapeutically superior to other erythromycins. In support of this view, the Committee cited a cooperative study sponsored by the Venereal Disease Branch of the Center for Disease Control (CDC) (Ref. 3). The authors (Schroeter, et al.) compared the efficacy of penicillin, tetracycline, and erythromycin base as therapeutic agents for early syphilis. They predicted greater efficacy with erythromycin estolate because of its higher blood levels. However, the efficacy of erythromycin estolate was not studied; rather, the study compared re-treatment rates for the three preparations tested with the re-treatment rates for erythromycin estolate found in an earlier study by Brown et al. (Ref. 10). The Committee reported to FDA that, in view of the likely superiority in efficacy, the risks presented by erythromycin estolate were not sufficient to warrant removing the drug from the market; however, the Committee recommended strengthening the hepatotoxicity warning in the erythromycin estolate labeling. As a consequence, the package insert for erythromycin estolate was revised again to include a boxed warning of the hepatotoxic potential of this drug. In keeping with the Committee's recommendations, the agency published an article in the January 1974 *Drug Bulletin* calling attention to the revised warning and describing the higher risk of hepatotoxicity associated with the use of erythromycin estolate.

On August 8, 1973, FDA denied the HRG petition urging the withdrawal of erythromycin estolate because FDA believed that the benefits of the drug

outweighed its risks. The agency agreed with the petitioner that erythromycin estolate is unique among the erythromycin preparations in its potential for producing hepatotoxicity in adults. The agency believed, however, that this increased risk of erythromycin estolate was balanced by a potential therapeutic superiority to other erythromycin preparations because of the higher blood levels that the estolate appeared to produce. The agency concluded that the benefits of the drug were sufficient to justify its continued marketing, provided that the medical profession was warned of the risk of hepatotoxicity by means of revised labeling and the FDA *Drug Bulletin.*

Prescriptions dispensed for erythromycin estolate reached a high of 10.3 million in 1972. After addition of the boxed warning to the labeling and issuance of the *Drug Bulletin* concerning the drug, the number of prescriptions dispensed dropped to 8 million in 1974, but then increased to 8.3 million in 1975. In 1977, prescriptions declined to 7.2 million, but again increased to 7.8 million in 1978 (Ref. 15).

Recently, FDA's Bureau of Drugs has again considered whether erythromycin estolate preparations offer benefits that outweigh their risks and whether their continued certification is justified. Because of its longstanding concern about the hepatotoxic potential of erythromycin estolate preparations, the Bureau has maintained a continuing review of drug experience reports and other information bearing on the benefits and risks of these drugs. Based on new information, including recent bioavailability studies and analysis of adverse reaction data, and a reevaluation of existing information on the drug's efficacy, the Bureau has now concluded that erythromycin estolate is unsafe in adults because it presents risks to adults that outweigh its benefits, and that the provisions for certification of adult dosage forms should be revoked.

By letters dated August 29, 1979, to Lilly and September 10, 1979, to Danbury, the Bureau of Drugs requested the firms to remove the products from the market voluntarily. The letters asked for removal of both the solid and liquid (pediatric) dosage forms. On September 13, 1979, Lilly replied that it would not remove the products from the market because it believes that they are safe and effective antibiotics that should continue to be available to patients. On September 20, 1979, Danbury replied that if all concerned definitely determine that erythromycin estolate is harmful, it would voluntarily remove the drug from the market. Danbury stated that before it could make a decision on voluntary removal, it would need time to evaluate available information. Copies of these letters have been placed on file in the office of the Hearing Clerk (address above).

By letter dated August 30, 1979, the Health Research Group petitioned the Secretary of Health, Education, and Welfare to ban erythromycin estolate under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)). Although this proposal is on the Bureau's own initiative, the Bureau includes the HRG petition in the administrative record. A copy of the petition has been placed on file in the office of the Hearing Clerk (address above).

At the October 25, 1979, meeting of the Anti-Infective Drugs Subcommittee of the Anti-Infective and Topical Drugs Advisory Committee, statements were made that erythromycin estolate has certain advantages in children over erythromycin ethylsuccinate, the only other available pediatric dosage form of erythromycin in the U.S., and data were presented in support of the statement. To allow time for FDA to consider the data, this notice proposes to revoke provisions for certification of adult dosage forms only. These forms are conventional tablets and capsules, which forms are intended to be swallowed without chewing. The notice does not propose to revoke the regulations for flavored chewable tablets or for pediatric drops or oral suspension. Chewable tablets are primarily intended for children who cannot be relied upon to swallow drugs without chewing, and are specially flavored for that purpose. Pediatric drops and oral suspension are primarily for use in infants and in children who cannot swallow tablets either whole or after chewing, or for whom a liquid form is otherwise preferable. A decision on whether or not to propose withdrawal of those pediatric dosage forms is still pending. Should withdrawal not be proposed, revised labeling will be published for these dosage forms that will limit their use to pediatric patients.

Th Bureau's Division of Drug Experience has examined erythromycin estolate in relation to the other erythromycins (ethylsuccinate, stearate, and base) most frequently prescribed to outpatients (Ref. 15). The data on adverse hepatic events for the erythromycins under study came from FDA's computerized national file of spontaneously reported adverse drug reactions. From 1969 to 1978, FDA received reports of 452 patients with hepatotoxicity due to all forms of oral erythromycin products. Of these 452 patients, 34 had received an unspecified form of erythromycin. Of the remaining 418 patients, 388 (93 percent) had hepatotoxicity associated with the administration of erythromycin estolate. (Based on 1978 prescription data, the estolate's share of the erythromycin market was approximately 20 percent.) The Bureau believes it fair to assume, therefore, that hepatotoxicity can be attributed to erythromycin estolate to a degree far greater than that explained by its market share, and in any event to a degree far greater than that for other erythromycins.

The data discloses a lesser risk when erythromycin estolate is used in children. Of the 209 cases in which age was reported, 38 cases, or 18 percent, were reported for the birth-to-11-years age group and 171, or 82 percent, were reported for those who were 12 years of age or older. Considering that an estimated 55 percent of prescriptions of erythromycin estolate are for children under 10 years of age and 45 percent are for those older (Ref. 15), these figures demonstrate that adults receiving erythromycin estolate are at greater risk of hepatotoxicity than are children.

The Bureau's concern in this proceeding is with the safety of erythromycin estolate, not its effectiveness. To determine whether the drug still has a favorable benefit/risk ratio, however, the agency must consider evidence concerning the drug's effectiveness. Although erythromycin estolate serum concentrations appear to be higher than those with other erythromycin preparations. there is scanty evidence in the literature that erythromycin estolate is therapeutically superior according to current standards of medical practice. In the Bureau's opinion, the 12 reports in the scientific literature on this drug that the Bureau has identified (Refs. 3 through 14) do not indicate that erythromycin estolate is therapeutically superior to other erythromycin preparations in clinical practice. As discussed earlier, the agency believed in 1973 that the estolate form of erythromycin produced higher blood levels of active erythromycin, thus resulting in potentially greater efficacy. Recent information demonstrates that this belief is no longer correct.

Bioavailability Data

FDA's reevaluation of the benefit/risk ratio of erythromycin estolate is prompted by new evidence that the blood levels of active erythromycin produced by the drug are no better than, and for the first day of administration are inferior to, those of other

erythromycin preparations. Under a contract with the University of Texas at Austin, FDA conducted bioavailability and bioequivalence studies on erythromycin products (Ref. 16). One study determined the comparative bioavailability of erythromycin estolate and erythromycin stearate following single-dose oral administration under fasting conditions. A second bioequivalence study compared erythromycin base, erythromycin stearate, and erythromycin estolate following multiple-dose oral administration. These studies measured the blood levels of erythromycin estolate in a manner that differed from its measurement in the past. Previous blood levels studies had simply measured levels of erythromycin estolate in the blood. The new method of measurement separated erythromycin base (the active moiety) from the estolate (the inactive ester) and measured the blood level of the two compounds separately. The estolate, through hydrolysis, appears in serum both as the inactive propionyl ester of erythromycin and as the active free base. The studies used an assay method that quantitatively differentiated the free base in the presence of the ester. The resulting bioequivalence comparisons were based on free erythromycin base serum concentrations achieved as a function of time. When measured in this manner, blood levels of erythromycin derived from the estolate were found to be no greater than those of other forms of erythromycin administered orally. Moreover, these studies showed that the blood levels of erythromycin produced by erythromycin estolate are inferior to those of the other erythromycins tested during the first day of administration and therefore that erythromycin estolate offers none of the advantages it was believed to have on the basis of older methods for determining bioavailability.

The relevance of the bioavailability studies in the context of this proceeding should be understood. If safety were not at issue, the studies would not warrant removal of erythromycin estolate from the market. Given the documented safety problems with the drug, however, the studies show that erythromycin estolate does not offer compensating therapeutic advantages over other erythromycin preparations that justify continued marketing of the adult dosage forms in the face of the hepatotoxicity of this drug.

Summary

1. The frequency of the reported adverse hepatic events associated with erythromycin estolate use in adults is far greater than that of other erythromycin preparations.

2. Erythromycin estolate has not been shown in controlled studies or clinical practice to have a compensating therapeutic superiority over other erythromycin preparations.

3. The bioavailability of erythromycin estolate in terms of free base is, if anything, poorer than that of other erythromycins tested. The estolate does not offer, as was once believed, a potential advantage over the base in terms of higher levels of the active drug in serum or greater bioavailability.

4. Erythromycin estolate thus has an unacceptable benefit/risk ratio in adults when compared with the other equally effective erythromycin preparations that are being marketed.

References

The following items are on file and available for inspection at the office of the Hearing Clerk (address given above).

1. Johnson, D. F. and W. H. Hall, "Allergic Hepatitis Caused by Propionyl Erythromycin Ester of Lauryl Sulfate," *New England Journal of Medicine*, 26:1200–1202, 1961.

2. Letters to the Journal: Robinson, M. M., "Antibiotics Increase Incidence of Hepatitis," and Kholstaedt, K. G., "Propionyl Erythromycin Ester Lauryl Sulfate and Jaundice," *Journal of the American Medical Association*, 178(1):89–90, 1961.

3. Schroeter, A. L., et al., "Treatment of Early Syphilis and Reactivity of Serologic Tests," *Journal of the American Medical Association*, 221(5):471–476, 1972.

4. Howie, V. M., et al., "Compliance Dose-Response Relationships in Streptococcal Pharyngitis," *American Journal of Diseases of Children*, 123:18–25, 1972.

5. Bass, J. W., et al., "Erythromycin Concentration in Middle Ear Exudates," *Pediatrics*, 48(3):417–422, 1971.

6. Brown, S. T., et al., "Comparison of Erythromycin Base and Estolate in Gonococcal Urethritis," *Journal of the American Medical Association*, 238(13):1371–1373, 1977.

7. Billow, B. W., et al., "A Clinical Study of Erythromycin: A Comparative Evaluation of Several Salts," Current Therapeutic Research, 6(5):381–384, 1964.

8. Ginsburg, C. M. and H. F. Eichenwald, "Erythromycin: A Review of Its Uses in Pediatric Practice," *The Journal of Pediatrics*, 89(6):872–884, 1976.

9. Eichenwald, H. F. and G. H. McCracken, Jr., "Antimicrobial Therapy in Infants and Children" (Review of Antimicrobial Agents, Part I), *The Journal of Pediatrics*, 93(3):337–356, 1978.

10. Brown, W. J., et al., "Oral Propionyl Erythromycin in Treating Early Syphilis," *Public Health Reports*, 78(10):911–917, 1963.

11. Janicki, R. S., et al., "Comparison of Erythromycin Estolate Treatments of Group A Streptococcal Infections of the Upper Respiratory Tract," *Clinical Pediatrics*, 14(12):1098–1107, 1975.

12. Zimmerman, H., "Hepatotoxicity: Adverse Effects of Drugs and Other Chemicals on the Liver," Appleton Century Crofts, pp. 474–476, 1978.

13. McCormack, W. M., et al., "Hepatotoxicity of Erythromycin Estolate During Pregnancy," *Antimicrobial Agents and Chemotherapy*, 12(5):630–635, 1977.

14. Nicholas, P., "Erythromycin: Clinical Review," *New York State Journal of Medicine, pp. 2088–2094, November 1977.*

15. Jones, J. K., et al., "Review of Erythromycin: Use, Adverse Reactions and Differences in Usages and Adverse Reactions by Salt and Age Group," Unpublished Data Compiled by the Division of Drug Experience, Food and Drug Administration.

16. Yakatan, G. J., et al., "Bioequivalence Comparisons of Erythromycin Sterate, Erythromycin Estolate, and Erythromycin Base After Multiple Dosing," Unpublished Data Compiled by the Division of Biopharmaceutics, Food and Drug Administration and the Drug Dynamics Institute, College of Pharmacy, University of Texas at Austin, 12 pp.

Conclusion

On the basis of all the data and information available to him, the Director of the Bureau of Drugs concludes that erythromycin estolate is unsafe in adults because the risks involved in its use outweigh any benefits from such use and that provisions for certification of dosage forms (conventional tablets and capsules) intended for use in adults should be revoked.

FDA proposes to make this revocation effective on the day a final regulation is published. If this proposal to revoke certification of adult dosage forms of erythromycin estolate is made final, all outstanding certificates for batches of adult dosage forms of erythromycin estolate will be revoked on the day the regulation becomes effective. On that basis the agency proposes to request that all products covered by these certificates be recalled from the retail level. In the event of a recall, holders of the certificates will be notified by letter of the revocation and the details of the recall request.

The agency has determined that this document does not contain an agency action covered by 21 CFR 25.1(b); therefore, consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 507, 59 Stat. 463 as amended (21 U.S.C. 357)), and under authority delegated to the Director of the Bureau of Drugs (21 CFR 5.78) it is proposed that Part 452 of Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

§ 452.115a [Revoked]

1. By revoking § 452.115a *Erythromycin estolate tablets.*

§ 452.115b [Revoked]

2. By revoking § 452.115b *Erythromycin estolate capsules.*

Interested persons may, on or before January 3, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments on this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above-named office between 9 a.m. and 4 p.m., Monday through Friday.

Interested persons may also, on or before December 19, 1979, submit to the Hearing Clerk (address above) a request for an informal conference. If an informal conference is held, interested persons will have until January 3, 1980, or 15 days from the date of the conference, whichever is later, to submit their comments.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: November 28, 1979.

J. Richard Crout,

Director, Bureau of Drugs.

[FR Doc. 79-37122 Filed 11-29-79; 10:46 am]

BILLING CODE 4110-03-M

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21 CFR Part 868

Medical Devices; Classification of Anesthesiology Devices

Correction

In the documents appearing as Part III in the issue of Friday, November 2, 1979, make the following corrections:

(1) In the middle column of page 63352, second line from the bottom of the page should have read ". . . America, the Girl Scouts of America, and various volunteer rescue . . .".

(2) In the middle column of page 63358, second line from the bottom of paragraph "3.", ". . . establish a standard . . ." should have read ". . . establish a performance standard . . .".

(3) In the middle column of page 63374, in the last line of paragraph "2.", ". . . a low priority." should have read ". . . a high priority."

(4) In the same column, in the second line from the bottom of the page, ". . . 710(a)" should have read "701(a)".

(5) In the middle column of page 63385, the section heading now reading "§ 8698.5580 . . ." should have read "§ 868.5580 . . .".

(6) On page 63391, middle column, in the fourth line of the first complete paragraph, ". . . 371(A) . . ." should have read ". . . 371(a) . . .".

(7) In the first paragraph of page 63399, in the ninth line of the third complete paragraph, ". . . establish to provide . . ." should have read ". . . establish a standard to provide . . .".

(8) In the first column of page 63400, in the fourth line of the fourth complete paragraph, ". . . 371(A) . . ." should have read ". . . 371(a) . . .".

(9) On page 63402, first column, the address given in the paragraph *For Further Information Contact* now reading ". . . 8747 Georgia Avenue . . ." should have read" . . . 8757 Georgia Avenue . . .".

(10) On page 63403, the Docket Number in the heading of the document which begins in the middle column now reading "(Docket No. 78N–1870)" should have read "(Docket No. 78N–1780)".

(11) In the first column of page 63404, fifth complete paragraph, in the fourth line, ". . . 371(as)" should have read ". . . 371(a) . . .". Also, in the next line, ". . . (21 CFR 5.12) . . ." should have read ". . . (21 CFR 5.1) . . .".

(12) In the first column of page 63412, in the second to the last line of the sixth full paragraph, ". . . new § 869.5915 . . ." should have been ". . . new 868.5915 . . .".

BILLING CODE 1505-01-M

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

24 CFR Part 570

[Docket No. R-79-746]

Community Development Block Grants; Small Cities Program

AGENCY: Department of Housing and Urban Development, Assistant Secretary for Community Planning and Development.

ACTION: Advance Notice of Proposed Rulemaking.

SUMMARY: This advance notice requests advice and information from the public on revisions which may be appropriate to clarify and simplify the Small Cities Program regulations (published in the **Federal Register** June 26, 1979 (44 FR 37478) and revised July 19, 1979 (44 FR 42179)) without necessitating significant restructuring of the program. Because of the Department's desire to issue final regulations which are effective no later than September 1, 1980, the period for response to this advance notice is limited to 30 days.

DATE: Comments are due on or before January 3, 1980. Comments received after this date will be considered to the extent possible.

ADDRESS: Comments should be sent to: Rules Docket Clerk, Office of the Secretary, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, D.C. 20419.

FOR FURTHER INFORMATION CONTACT: Richard J. Kennedy, Small Cities Division, Office of Community Planning and Development; Department of Housing & Urban Development, Washington, D.C. 20410, 202–755–6322. (This is not a toll free number.)

SUPPLEMENTARY INFORMATION: This notice is being issued to elicit suggestions for improvement of the Small Cities Program regulations which are not being examined for possible change, to identify program features which should be considered for revision, and to learn how the public believe those features should be revised. The Department is also considering information previously received from the public, public interest groups, other governmental agencies, and its own experience in administering the program, in identifying specific issues to be considered for possible amendment.

Some revisions which the Department is considering are listed below. The Department requests comments on the questions cited for each issue along with suggested revisions.

Sections 570.425, 570.426, 570.429, 570.430

Currently preapplications are rated and ranked to determine those applicants to be invited to submit full applications for funding. The Department is considering an alternate concept that would permit the applicant to submit a simple notice of intent to apply for a grant to local clearinghouses and to HUD Area Offices and then to submit one application for selection and funding. The Department is also particularly interested in the public's comments concerning timing of submission of a HAP; i.e., with the application for funds, or under

notification of conditional selection for funding. What are the advantages to the applicant of this concept? What disadvantages to the applicant would this concept pose? What alternate course could be considered? What form of citizen particiption would be appropriate at the "intent to apply" stage?

Section 570.420(i)

The data used to determine the housing needs score is of questionable utility and accuracy. What would be the implications of deleting the housing needs score from the Selection System?

Sections 570.420(g) and 570.421(b)

The current regulations allow States and Counties to apply in behalf of units of local government, and units of local government to file joint applications. Are these viable options? What advantages to applicants do these procedures afford? Would deletion of these options cause disadvantages? What alternate forms of application could be considered?

Sections 570.424 and 570.428

The program impact factor equals 400 out of 1025 possible points in the Comprehensive Program, and helps to assure that quality projects are funded. In the Single Purpose Program, the factor equals only 200 out of 875 possible points, and program quality considerations are therefore weighted less. Should the Single Purpose Program factor's possible points be increased, and to what extent?

Section 570.424

The Comprehensive Program specifies eleven design criteria. Should any of these criteria be deleted, clarified, or modified? Are there criteria that should be added?

Sections 570.424 and 570.428

Points are now awarded for housing and equal opportunity efforts. Should this point concept be strengthened or refocused to further encourage fair housing and equal opportunity efforts? Is clarification or change needed? Also, is there a way of recasting these points to better enable communities with no past experience with HUD programs to qualify for them?

Sections 570.431 and 570.303

Citizens participation regulations for Entitlement applicants in Section 570.303 presently apply to applicants for Small Cities comprehensive grants. Citizen participation regulations for single purpose applicants are contained in Section 570.431. How could the citizen participation process be simplified for the applicant while at the same time achieving meaningful citizen participation?

Suggestions for other changes in the program regulations will, of course, be considered. In view of the number of comments anticipated, it is absolutely imperative that comments be identified with the section number of the regulations that is being addressed. Communications should also identify the regulations docket number.

Issued at Washngton, D.C., November 28, 1979.

Robert C. Embry, Jr.,

Assistant Secretary for Community Planning and Development.

[FR Doc. 79-37132 Filed 12-3-79; 8:45 am]

BILLING CODE 4210-01-M

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Parts 5, 13, 19, 170, 173, 186, 194, 195, 196, 197, 200, 201, 211, 212, 213, 231, 240, 250, 251 and 252

[Notice No. 330]

Distilled Spirits Tax Revision Act of 1979 (Public Law 96-39); Public Seminars

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF).

ACTION: Notice of public seminars.

SUMMARY: The Bureau of Alcohol, Tobacco and Firearms, in recognition of the forthcoming publication in the **Federal Register** of the temporary regulations and notice of proposed rulemaking with respect to final regulations which implement the Distilled Spirits Tax Revision Act of 1979, Subtitle A of Title VIII of the Trade Agreements Act of 1979 (Pub. L. 96-39), has scheduled public seminars in December at various locations throughout the United States.

The purpose of these seminars will be to discuss the new law and implementing regulations with the distilled spirits and wine industries. Many industry representatives have already been notified of these meetings. However, these meetings are open to all interested industry representatives and to the public.

DATES: For dates of public seminars see "Supplementary Information".

ADDRESSES: For addresses of public seminars see "Supplementary Information".

FOR FURTHER INFORMATION CONTACT: Melvin T. Bruce, All-In-Bond Coordinator, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226, Telephone: 202-566-7568.

SUPPLEMENTARY INFORMATION:

Dates and Addresses of Public Seminars

Central Region

Public Seminar, Owensboro, KY

Date: 8:30 a.m. on December 6, 1979.
Address: Army Reserve Building, Dublin Lane, Owensboro, KY.

Public Seminar, Frankfort, KY

Date: 8:30 a.m. on December 12, 1979.
Address: John Watts Building, Room 345, Frankfort, KY.

Public Seminar, Louisville, KY

Date: 8:30 a.m. on December 13, 1979.
Address: Federal Building, Room 183, Louisville, KY.

Public Seminar, Cincinnati, OH

Date: 8:30 a.m. on December 10, 1979.
Address: Federal Building, Room 4022, 550 Main Street, Cincinnati, OH.

Mid-Atlantic Region

Public Seminar, Cranford, NJ

Date: From 9:00 a.m. to 5:00 p.m. on December 10, 1979, and from 9:00 a.m. to 5:00 p.m. on December 11, 1979.
Address: The Coachman Inn and Restaurant, 10 Jackson Drive, Cranford, NJ.

Public Seminar, Philadelphia, PA

Date: From 9:00 a.m. to 5:00 p.m. on December 17, 1979, and from 9:00 a.m. to 5:00 p.m. on December 18, 1979.
Address: William J. Green Federal Building, Room 3306, 6th and Arch Streets, Philadelphia, PA.

Public Seminar, Baltimore, MD

Date: From 9:00 a.m. to 5:00 p.m. on December 17, 1979, and from 9:00 a.m. to 5:00 p.m. on December 18, 1979.
Address: Holiday Inn, 301 W. Lombard Street, Baltimore, MD.

Midwest Region

Public Seminar, Peoria, IL

Date: From 9:00 a.m. to 4:30 p.m. on December 3, 1979, and from 9:00 a.m. to 12:00 p.m. on December 4, 1979.
Address: Hiram Walker & Sons, Inc., Deluxe Room, Edmund Street, Peoria, IL.

Public Seminar, St. Louis, MO

Date: From 9:00 a.m. to 4:30 p.m. on December 5, 1979.
Address: Federal Building, Conference Room 613, 12th & Market Streets, St. Louis, MO.

Public Seminar, St. Paul, MN

Date: From 9:00 a.m. to 4:30 p.m. on December 7, 1979.
Address: Federal Building & U.S. Courthouse, Room 525, 316 N. Robert Street, St. Paul, MN.

Public Seminar, Chicago, IL

Date: From 9:00 a.m. to 4:30 p.m. on December 10 and 11, 1979.

Address: Insurance Exchange Building, Room A–535, 175 West Jackson Blvd., Chicago, IL.

North-Atlantic Region

Public Seminar, Boston, MA

Date: The first session will be held on December 4 and 5, 1979, from 9:00 a.m. to 4:00 p.m. The second session will be held on December 6 and 7, 1979, from 9:00 a.m. to 4:00 p.m.
Address: Ramada Inn, 225 McClellan Street, East Boston, MA.

Public Seminar, Hartford, CT

Date: From 9:00 a.m. to 4:00 p.m. on December 10 and 11, 1979.
Address: Heublein, Inc., 330 New Park Avenue, Hartford, CT.

Public Seminar, New York, NY

Date: From 9:00 a.m. to 4:00 p.m. on December 12 and 13, 1979.
Address: U.S. Post Office Building, Criminal Enforcement Conference Room, 90 Church Street, New York, NY.

Southeast Region

Public Seminar, Atlanta, GA

Date: From 8:30 a.m. to 4:30 p.m. on December 4, 1979.
Address: Squire Inn, Piedmont Road, NE, Atlanta, GA.

Public Seminar, Lynchburg, TN

Date: From 8:30 a.m. to 4:30 p.m. on December 6, 1979.
Address: Jack Daniel Distillery, Bethel House, Lynchburg, TN.

Public Seminar, Auburndale, FL

Date: From 8:30 a.m. to 4:30 p.m. on December 12, 1979.
Address: Jacquin-Florida Distilling Company, Conference Room, 425 Recker Highway, Auburndale, FL.

Southwest Region

Public Seminar, Houston, TX

Date: From 9:00 a.m. to 5:00 p.m. on December 11, 1979, (Industrial).
Address: Astro Village Hotel, Tower Room No. 9, 2350 South Loop West, Houston, TX.

Public Seminar, Houston, TX

Date: From 9:30 a.m. to 5:00 p.m. on December 12, 1979, (Beverage).
Address: Astro Village Hotel, Tower Room No. 9, 2350 South Loop West, Houston, TX.

Western Region

Public Seminar, Seattle, WA

Date: From 9:00 a.m. to 4:00 p.m. on December 3 and 4, 1979.
Address: Federal Building, Room 2866, 915 Second Avenue, Seattle, WA.

Public Seminar, Los Angeles, CA

Date: From 9:00 a.m. to 4:00 p.m. on December 4 and 5, 1979.
Address: Federal building, Room 8544, 300 N. Los Angeles Street, Los Angeles, CA.

Public Seminar, Santa Ana, CA

Date: From 9:00 a.m. to 4:00 p.m. on December 6 and 7, 1979.
Address: Federal building, Rooms 924 and 925, 34 Civic Center Plaza, Santa Ana, CA.

Public Seminar, San Francisco, CA

Date: From 9:00 a.m. to 4:00 p.m. on December 10, 1979.
Address: U.S. Customhouse, Room 503, 555 Battery Street, San Francisco, CA.

Public Seminar, Lodi, CA

Date: From 9:00 a.m. to 4:30 p.m. on December 10 and 11, 1979.
Address: American Legion Hall, 320 N. Washington Street, Lodi, CA.

Public Seminar, San Jose, CA

Date: From 9:00 a.m. to 4:30 P.m. on December 11, and 12, 1979.
Address: Community Bank Building, Executive Conference Room, 111 West St. John Street, San Jose, CA.

Public Seminar, Fresno, CA

Date: From 9:00 a.m. to 4:30 p.m. on December 13 and 14, 1979.
Address: Sheraton Inn, Silver Room No. 1, 2550 West Clinton Street, Fresno, CA.

Headquarters

Public Seminar, Washington, DC

A public seminar will be held to discuss with manufacturers of nonbeverage products the requirements for qualification as distilled spirits plants.
Date: 10:00 a.m. on December 10, 1979.
Address: Bureau of Alcohol, Tobacco and Firearms, Room 5041, 1200 Pennsylvania Avenue, NW., Washington, DC.

Authority and Issuance: This notice is issued under the authority contained in 26 U.S.C. 7805 (68 Stat. 917).

Signed: November 30, 1979.

G. R. Dickerson,

Director.

[FR Doc. 79-37373 Filed 11-30-79; 3:48 pm]
BILLING CODE 4810-31-M

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Parts 11, 1999

DOL NEPA Compliance Procedures

AGENCY: Department of Labor.

ACTION: Proposed rules.

SUMMARY: These proposed rules set out procedures to be used by Department of Labor agencies to insure compliance with the National Environmental Policy Act of 1969 (NEPA) in accordance with regulations issued by the Council on Environmental Quality. These procedures would replace 29 CFR Part 1999, "OSHA's Procedures for the Preparation and Circulation of Environmental Impact Statements," with a new Part (29 CFR Part 11) applicable to all Department of Labor agencies.

DATE: Comments, suggestions, etc., on these proposed procedures must be postmarked or delivered to the address below on or before February 4, 1980.

ADDRESS: Comments should be submitted to the Docket Officer, Docket No. NEPA–1, Room S–6212, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210. All comments will be available for examination and copying at this address.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Copeland, Director, Office of Health and Disability, ASPER, Room S–2121, U.S. Department of Labor, 200 Constitution Avenue, NW., D.C. 20210 (202–523–7303).

SUPPLEMENTARY INFORMATION:

1. Background

In 1969, Congress enacted the National Environmental Policy Act (NEPA) which requires all Federal agencies to prepare detailed statements on their "proposals for legislation and other major Federal actions significantly affecting the quality of the human environment" (Sec. 102(2)(c)). The Act also established the Council on Environmental Quality (CEQ), in the Executive Office of the President, to oversee Federal efforts to comply with NEPA and to formulate and recommend national policy to improve environmental quality.

In 1973, CEQ issued *Guidelines* for use by Federal agencies in the preparation of environmental impact statements (EIS), although CEQ states that it "conceived of the *Guidelines* as non-discretionary standards for gency decisionmaking." Federal agencies generally considered them to be advisory and the Courts differed over the extent to which compliance with the *Guidelines* was indicative of compliance with NEPA. While many agencies, including OSHA (at 29 CFR Part 1999), adopted binding NEPA implementation procedures, agency practices in implementing the *Guidelines* differed. According to CEQ, these inconsistencies "impeded Federal coordination * * * made it more difficult for those outside government to understand and participate in the environmental review process * * * [and] caused unnecessary duplication, delay and paperwork" (see 43 FR 55978).

To correct these problems, the President issued Executive Order 11991 (May 27, 1977) which directed CEQ to issue regulations, binding on all Federal agencies, to provide uniform standards for conducting environmental reviews. CEQ issued these regulations in final form on November 29, 1978 (43 FR

55978). The regulations directed Federal agencies to adopt implementing procedures to supplement the CEQ regulations (40 CFR 1507.3). Accordingly, the purpose of these proposed rules is to establish procedures to be used by Department of Labor agencies when they are considering actions which may require review pursuant to NEPA.

2. Applicability

All Federal agencies are subject to NEPA. Therefore, the procedures proposed below would apply to any Department of Labor agency considering major actions or legislative proposals which may have a significant impact on the human environment. However, only three Departmental agencies, the Occupational Saftey and Health Administration (OSHA), the Mine Safety and Health Administration (MSHA) and the Employment and Training Administration (ETA) (in connection with certain Job Corps actions) routinely consider actions which may require preparation of environmental documents pursuant to NEPA. For this reason the procedures described below have been designed primarily to meet the particular needs of these agencies. Nevertheless, the general procedures proposed below have sufficient flexibility to be adequate for use by all agencies within the Department. If it becomes necessary, however, additional sections will be added to these procedures for special use by other Department agencies.

3. Consideration of Enviornmental Effects of OSHA/MSHA Regulatory Actions

The basic mission of both OSHA and MSHA is to assure safe and healthful conditions in the Nation's workplaces. In developing standards to fulfill this mandate, both agencies must fully evaluate the potential effects of such standards on the worker and his or her environment. If the potential environmental effects are significant, they inevitably become important issues early in the rulemaking process and will be considered during each phase of the rulemaking. The following paragraphs describe the basic OSHA/MSHA rulemaking process, how it has related to NEPA in the past, and how the Department will institute the additional requirements of CEQ's new NEPA-implementing regulations.

Summary of the OSHA/MSHA rulemaking process. An OSHA/MSHA action may originate in any of several ways. It may evolve from an internal initiative within either agency, or from a recommendation from a person, organization or agency outside of OSHA or MSHA. Typically, the regulatory development process begins with the identification of a problem which may require promulgation of a standard or some other action. Identification of such a problem triggers a series of preliminary analyses of relevant existing standards and regulations, industrial conditions, employee exposures, major environmental concerns and related problems. In accordance with a May 30, 1979, Order of the Secretary of Labor (S.O. 6–79) pertaining to the implementation of Executive Order 12044 (Improving Government Regulations) and the Department's implementing guidelines (44 FR 5570), a "concept paper" containing these and other considerations is then prepared and submitted to the Secretary and other Departmental officials. These activities culminate in determinations of whether to proceed with development of a standard or some other action and whether it is likely that preparation of a regulatory analysis (pursuant to Executive Order 12044) will be required.

Integration of NEPA with OSHA/MSHA rulemaking processes. When it has been determined what type of action should be proposed (for example, a new standard, revocation or modification of an existing standard, etc.), the agency will continue to explore the substantive issues surrounding the action and begin development of a proposal. The exploration of these issues, including alternatives to the proposal, may be preliminary to preparation of a regulatory analysis.

It is also at this early stage of rulemaking that consideration of the environmental effects of the proposal under consideration and its alternatives will begin. In accordance with the CEQ regulations, the agency will preliminarily determine whether the proposal qualifies for categorical exclusion from environmental analysis or whether an environmental assessment or an environmental impact statement (EIS) will be prepared. If there is uncertainty as to whether the proposal would significantly affect the environment, or if it is determined that preparation of an assessment is desirable, although not required, an environmental assessment shall be developed.

When the environmental assessment is completed or progresses to a stage where it can be determined whether preparation of an EIS is required, the agency will proceed in one of the following ways:

(1) If, on the basis of the environmental assessment it is determined that no further environmental analysis is required, the agency will publish a notice of "finding of no significant impact" in the **Federal Register** and place the environmental assessment into the rulemaking record or make it available to the public by some other means.

(2) If, however, it is determined on the basis of the environmental assessment that preparation of an EIS is required, the agency will announce in the **Federal Register** its intent to prepare such a document, and invite interested parties to participate in the scoping process (40 CFR 1501.7). Following the scoping process, the agency will prepare the draft EIS.

Subsequent to preparation of the draft EIS, any applicable economic and technological feasibility studies and, if appropriate or required, a draft regulatory analysis, the proposed action will be published in the **Federal Register** and documents will be either published or notice given in the **Federal Register** of their availability to the public (40 CFR 1506.6(e)). Thereafter, a period of time will be given for submission of comments on any or all of these documents. A public hearing may also be held during this period at which further evidence and testimony on any or all of these documents may be submitted.

Following the comment period and, if applicable, the closing of the public hearing record, OSHA or MSHA officials will review all of the data and information submitted and prepare the final EIS and, where appropriate, the final regulatory analysis. After the appropriate filings and circulations of these documents (40 CFR 1506.9 and 1502.19), the agency will publish its final rule with a concise general statement of its bases and purposes, or otherwise make its record of decision available to the public. Normally, a period of at least 30 days will be given before the final action becomes effective so that affected parties will have an opportunity to review any new regulations. The OSHA/MSHA statutory procedures provide for full public participation in their rulemaking processes and are consistent with the requirements of NEPA and the CEQ regulations. Accordingly, at each key stage in the NEPA process, the public will be given notice in the **Federal Register** and ample opportunity to present their views on the relevant environmental issues and to comment on the environmental documents produced by the agencies.

4. Consideration of Environmental Effects of Certain Job Corps Actions

The ETA's Job Corps undertakes construction, purchase and leasing

activities in connection with the establishment or substantial alteration of centers for training workers. These actions will normally require the preparation of an environmental assessment which must consider a variety of factors concerning the potential impacts of the Job Corps' activity on the human environment. The proposed rules make special provision with respect to such assessments, and require the Job Corps to obtain written authorization from the Assistant Secretary of Labor for Administration and Management before proceeding with selection of a site or project for which it has been determined preparation of an EIS will be required.

5. Proposed Department of Labor Procedures

The following sections present an analysis of the major NEPA-implementing procedures proposed for adoption by the Department in accordance with the directives of 40 CFR Part 1500:

Responsible officials. The proposed procedures designate the Assistant Secretary of Labor for Policy, Evaluation and Research (ASPER) as the Department's NEPA Liaison and the official responsible for coordinating compliance with NEPA and the CEQ regulations on a Departmental basis. All Assistant Secretaries of Labor or equivalent level officials (OSHA, MSHA, LMSA, ESA, ETA, etc.) have responsibility for: (1) Compliance with NEPA and CEQ regulations on actions within his or her authority, (2) the appointment of an agency NEPA liaison, and (3) providing detailed information to the public on actions proposed under his or her authority.

By separating Departmental from agency responsibilities, it is anticipated that each agency will retain its autonomy in making environmental analyses and decisions within a framework of review and direction by the Department. The Department's NEPA liaison will act as the central contact and clearinghouse for the other Federal agencies and the public when general questions, or those dealing with more than one Departmental agency, arise.

Identification of agency actions. In accordance with CEQ regulations (40 CFR 1501.4) these proposed procedures identify and classify major agency actions on the basis of whether each action would: (1) Normally require the preparation of an EIS, (2) normally not require the preparation of either an EIS or an environmental assessment (categorical exclusion) or (3) normally require the preparation of an environmental assessment but not necessarily an EIS. The types of actions to be categorically excluded from environmental analysis are those which have virtually no possibility of significantly affecting the human environment. In classifying certain actions as categorical exclusions, particular attention was given to the factors CEQ enumerated in its regulations concerning the likely severity of an action's impact (40 CFR 1508.27). Such actions include, among others, agency requests for appropriations; recordkeeping and reporting requirements; equipment approvals; personnel actions and training; enforcement and certification proceedings; and variances from standards.

Also categorically excluded from environmental analysis are all actions relating to the promulgation of safety standards. Safety standards, as distinct from health standards, promote injury avoidance by means of mechanical applications or work practices, the effects of which do not impact on air, water or soil quality, plant or animal life, the use of land or other aspects of the human environment.

Health standards, in contrast to safety standards, may affect air, soil or water quality, etc. as a result of employer efforts to modify or eliminate employee exposures to toxic substances or other workplace health hazards. Because they may have impacts on the human environment, health standards proposals will normally require the preparation of environmental assessments and, based on the "significance" of these effects (see 40 CFR 1508.27), preparation of an EIS may be required.

Other categorically excluded actions are those taken to implement Department of Labor authorities related to wages and hours; equal employment opportunity; employee benefits or other employment standards or practices, including retirement benefits; authorities which provide for the expenditure of funds in connection with wage replacement for unemployment or underemployment for any reason; and administrative practices of the Department. While some of these authorities may involve actions related to human health, by virtue of permitting or forbidding the employment of certain persons in hazardous areas, such actions do not, in and of themselves, have any impact upon the hazards themselves. Therefore, they are being placed in the categorical exclusion group to avoid confusion with respect to NEPA applicability.

Content, format and development of environmental documents. In the interest of reducing delay, paperwork and duplication of effort, the CEQ regulations encouraged agencies to combine environmental documents with other agency documents. Accordingly, the proposed procedures would permit Departmental agencies to combine environmental documents with the preamble (part of the **Federal Register** notice of proposed rulemaking) to the proposed action or with the regulatory analysis if the agency determines such to be appropriate. Combining documents does not alter the filing requirements imposed by the CEQ regulations for draft EIS. However, the CEQ regulations specifically permit public health and safety agencies engaged in rulemaking to waive the rules requiring deferral of a decision on the proposed action until thirty days after notice of the availability of the final EIS is published by the Environmental Protection Agency (40 CFR 1506.10).

The agency will decide in each instance whether the objectives of efficiency and reduced delay and paperwork are severed by combining environmental documents with other analyses or with the preambles to proposed or final standards. When documents are combined, the CEQ's recommended format for an EIS (40 CFR 1502.10) will generally be modified to promote the integration of the statement into these other documents.

Public participation. The CEQ regulations require that interested parties be given opportunities to participate in the NEPA process. Therefore, the proposed Departmental procedures also provide for such public participation.

6. Revocation of 29 CFR Part 1999

In 1974, pursuant to the CEQ *Guidelines,* OSHA promulgated agency procedures for the preparation and circulation of environmental impact statements (see 39 FR 9959). These procedures, codified at 29 CFR Part 1999, applied only to actions being considered by OSHA and, therefore, were not applicable to other Department of Labor agencies. As the new CEQ regulations require all Federal agencies to develop NEPA-implementing procedures, the following proposal is intended to extend beyond OSHA to all Departmental agencies. Therefore, 29 CFR Part 1999 would be revoked and replaced by the following proposed procedures.

7. Procedures for Public Comment

In accordance with CEQ requirements that these proposed procedures be adopted only after an opportunity for public review and comment (42 CFR 1507.3), interested persons are invited to submit comments, views and arguments on any issues raised by these proposed rules. Comments must be submitted on or before February 4, 1980, to the Docket Officer, Docket No. NEPA–1 Room S–6212, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, D.C. 20210 (Telephone: 202–523–7895). The comments will be available for public inspection and copying at the above address and will be carefully evaluated and considered by the Department before it promulgates final regulations.

8. Regulatory Assessment

In accordance with Executive Order 12044 (43 FR 12661, March 24, 1978) and Department of Labor Guidelines (44 FR 5570), it has been concluded that these proposed procedures do not constitute a "significant" or "major" action which would require the preparation of a regulatory analysis. This conclusion is based on the finding that these proposed procedures do not meet the Department's criteria for determining significance of regulations (cf. 44 FR 5576).

9. Authority

This document was prepared under the direction of Ray Marshall, Secretary of Labor, U.S. Department of Labor, Room S–2018, 200 Constitution Avenue, NW., Washington, D.C. 20210.

Accordingly, pursuant to NEPA (42 U.S.C 4321, et seq.), Executive Order No. 11514, Protection and Enhancement of Environmental Quality (March 5, 1970, as amended by Executive Order 11991, May 24, 1977), and the Council of Environmental Quality's Regulations on National Environmental Policy Act, Implementation of Procedural Provisions (40 CFR Parts 1500–1508), it is proposed to amend Title 29 of the Code of Federal Regulations by adding a new Part 11 containing Department procedural rules for the implementation of NEPA.

Signed at Washington, D.C., this 29th day of November 1979.

Ray Marshall,

Secretary of Labor.

1. A new Part 11, and subparts thereto, are proposed to be added to Title 29 of the Code of Federal Regulations, reading as follows:

PART 11—DEPARTMENT OF LABOR NATIONAL ENVIRONMENTAL POLICY ACT (NEPA) COMPLIANCE PROCEDURES

Subpart A—General Provisions

Sec.

11.1 Purpose and scope.
11.2 Applicability.
11.3 Responsible agency officials.

Subpart B—Administrative Procedures

11.10 Identification of agency actions.
11.11 Development of environmental analyses and documents.
11.12 Content and format of environmental documents.
11.13 Public participation.
11.14 Legislation.

Authority.—NEPA, (42 U.S.C. 4321 *et seq.*), Executive Order 11514, Protection and Enhancement of Environmental Quality (March 5, 1970, as amended by Executive Order 11991, May 24, 1977) and Council on Environmental Quality Regulations (National Environmental Policy Act, Implementation of Procedural Provisions) 40 CFR Parts 1500–1508 (43 FR 55978).

Subpart A—General Provisions

§ 11.1 Purpose and scope.

(a) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*) directs that, "to the fullest extent possible, * * * the policies, regulations and public laws of the United States shall be interpreted and administered in accordance with the policies set forth" in the Act for the preservation of the evnironment. As a means for achieving this objective, Executive Order 11991 of May 24, 1977 (amending E.O. 11514 of March 5, 1970) directed the Council on Environmental Quality (CEQ) to issue uniform regulations for implementation of NEPA by all Federal agencies. These regulations were published in final form on November 29, 1978 (43 FR 55978) as 40 CFR Parts 1500–1508. The CEQ's NEPA regulations require that each Federal agency adopt implementing procedures to supplement their regulations (40 CFR 1507.3). Accordingly, the purpose of this Part is to prescribe procedures to be followed by Department of Labor agencies when such agencies are contemplating actions which may be subject to the requirements of NEPA. These regulations do not replace 40 CFR Parts 1500–1508; rather they are to be read together with, and as a supplement to, the CEQ's regulations.

(b) It is the responsibility of each agency to comply with the policies set forth in NEPA to the fullest extent possible and consistent with its statutory authority. Each agency shall comply with all applicable requirements of this Part except where compliance would be inconsistent with other statutory requirements. However, no trivial violation of, or noncompliance with, these procedures shall give rise to an independent cause of action (cf. 40 CFR 1500.3 and 1507.3(b)).

§ 11.2 Applicability.

Although all Department of Labor agencies are subject to NEPA, only three of its agencies routinely propose or consider actions which may require the preparation of environmental assessments or environmental impact statements. These are the Occupational Safety and Health Administration (OSHA), which acts pursuant to the Occupational Safety and Health Act of 1970 (29 U.S.C. 651, *et seq.*); the Mine Safety and Health Administration (MSHA), which acts pursuant to the Federal Mine Safety and Health Act of 1977 (30 U.S.C. 801, *et seq.*); and the Employment and Training Administration (ETA) (through one of its major bureaus, the Job Corps) which purchases and leases land and constructs Job Corps centers pursuant to the Comprehensive Employment and Training Act (29 U.S.C. 801, *et seq.*). Therefore, these procedures have been designed primarily with the duties and rulemaking processes of these agencies in mind. If and when other Department of Labor agencies propose actions requiring environmental impact analysis, they shall use these procedures, to the extent that they are applicable, in performing such analyses.

§ 11.3 Responsible agency officials.

(a) The Assistant Secretary of Labor for Policy, Evaluation and Research (ASPER) shall be responsible for the following:

(1) Overall review of Department of Labor agency compliance with the requirements of NEPA, the CEQ's regulations and these Department procedures;

(2) Maintaining contacts with CEQ and the Environmental Protection Agency (EPA) as the Departmental NEPA liaison; and

(3) Preparing and coordinating Departmental comments in response to environmental impact statements prepared by other Federal agencies which have been submitted to the Department for review, as required by 40 CFR 1503.2.

(b) Assistant Secretaries of Labor and other officials of equivalent rank or responsibility (hereinafter "agency heads") shall be responsible for their agencies' compliance with NEPA.

(1) These responsibilities shall include the following:

(i) Assuring that the agencies under their control observe the requirements of 40 CFR 1507.2 on compliance capability;

(ii) Preparing environmental impact assessments and statements in accordance with the requirements of these regulations and 40 CFR Parts 1501 and 1502, and advising private applicants, or other non-Federal entities, of the possible need for information foreseeably required for later Federal action pursuant to 40 CFR 1501.2(d);

(iii) Assuring public participation in the NEPA process in accordance with 40 CFR Parts 1503 and 1506;

(iv) Commenting on environmental impact statements prepared by other agencies, when their agencies have jurisdiction by law or special expertise with respect to any environmental impacts connected with a proposed action, as required by 40 CFR Part 1503;

(v) Assuring that environmental documents prepared by their agencies accompany proposed actions through existing agency review processes, and that, along with other relevant materials, and consistent with 40 CFR 1505.1(e), the full range of alternatives discussed in these documents are considered in the planning of agency actions and in the making of decisions and that the alternatives considered are encompassed by those discussed in the documents; and

(vi) Assuring, where possible, the mitigation of adverse environmental effects of agency actions.

(2) In accordance with 40 CFR 1506.5(c), agency heads will also be responsible for assuring the quality of environmental impact statements prepared by their agencies. Where environmental impact statements will be prepared by a contractor, the agency heads will assure that their agencies furnish guidance to the contractor, participate in the document's preparation, independently evaluate the statement prior to approval and take responsibility for the scope and contents.

(c) Agency heads may designate program offices or individuals as NEPA contacts for their agencies. The name and address of the NEPA contact shall be included on the cover sheet of each environmental document published by the agency, or if no cover sheet is provided, the name and address of this office or individual shall be included with any instructions to the public on obtaining further information or submitting comments on the document.

(1) It shall be the duty of an agency's NEPA contact to know the status of all environmental documents being prepared by the agency or in cooperation with another agency;

(2) The NEPA contact shall receive and respond to inquiries concerning the status of all environmental documents being prepared within the agency or in cooperation with another agency.

Subpart B—Administrative Procedures

§ 11.10 Identification of agency actions.

Pursuant to the CEQ definition of "major Federal action" (40 CFR 1508.18) and 40 CFR 1507.3(b)(2), the following paragraphs identify and classify Department of Labor actions which: Normally will not require preparation of an environmental document (i.e., an environmental assessment or an environmental impact statement) or usually will require preparation of an environmental document.

(a) *OSHA/MSHA actions.* Actions of the Occupational Safety and Health Administration (OSHA) and the Mine Safety and Health Administration (MSHA) are classified as follows:

(1) *Categorically excluded actions.* OSHA/MSHA actions listed in the following Table will normally qualify for categorical exclusion from NEPA requirements, i.e., such actions do not require preparation of either an environmental assessment or an environmental impact statement, because they do not have a significant impact on the quality of the human environment. Classification as a categorical exclusion, however, does not prohibit OSHA or MSHA from preparing an environmental assessment or environmental impact statement on any of the following actions when OSHA or MSHA determines it to be appropriate. Also, in extraordinary circumstances where a normally excluded action is found to have a potentially significant environmental effect, OSHA or MSHA shall prepare an environmental assessment and/or an environmental impact statement as required.

OSHA/MSHA Categorical Exclusions

Type of action	Reason for exclusion
(i) Promulgation, modification or revocation of any safety standard. Examples of these actions are: machine guarding requirements, safety lines, warning signals, etc.	Safety standards promote injury avoidance by means of mechanical applications or work practices, the effects of which do not impact on air, water or soil quality, plant or animal life the use of land or other aspects of the human environment.
(ii) Approval of petitions for variances from MSHA/OSHA safety standards or OSHA health standards.	Variances are taken from existing standards; thus, environmental documents, as appropriate, will already have been prepared. In terms of worker health and safety, any variance must be at least as effective as the original standard.
(iii) Agency legislative requests for appropriations	Exempted by 40 CFR 1508.17.
(iv) Recordkeeping and reporting requirements	No possibility of significant environmental impact.
(v) Routine agency personnel actions	Such actions typically involve small numbers of individuals and have no possibility of significant environmental impact.
(vi) Training of employers, employees, agency personnel and others in the recognition, avoidance or abatement of occupational hazards. Providing consultative services to industry.	These actions involve educational activities which have no possibility of significant environmental impact.
(vii) Enforcement proceedings	Exempted by 40 CFR 1508.18.
(viii) Equipment approvals	No possibility of significant environmental impact.
(ix) State grants under Sec. 503 of the Federal Mine Safety and Health Act.	These grants assist states in developing and implementing laws to improve mine safety and health and to promote coordination between State and Federal governments. They have no possibility of significant environmental impact.
(x) Certification or qualification proceedings	No possibility of significant environmental impact.

(2) *Actions requiring environmental assessment.* Several classes of OSHA/MSHA actions normally require the preparation of an environmental assessment prior to determining whether either a finding of no significant impact or an environmental impact statement must be prepared. (However, OSHA or MSHA may proceed to prepare an environmental impact statement, without first preparing an environmental assessment, if it determines such action to be appropriate or necessary, as provided by 40 CFR 1501.3(a)). Actions in this classification include:

(i) Promulgation, modification or revocation of a health standard, and

(ii) Approval or revocation of State plans for the enforcement of safety and health standards (not applicable to MSHA).

(3) *Actions requiring preparation of an environmental impact statement.* Preparation of an environmental impact statement will always be required for proposals for promulgation, modification or revocation of health standards which will significantly affect air, water or soil quality, plant or animal life, the use of land or other aspects of the human environment.

(4) *Emergency temporary standards.* Situations requiring the issuance of emergency temporary standards (issued

for a period of up to six months, pursuant to Sec. 6(c) of the Occupational Safety and Health Act of 1970, and for a period of up to nine months, pursuant to Sec. 101(b) of the Federal Mine Safety and Health Act of 1977) are of such nature that the provisions of 40 CFR Parts 1500 *et seq.* may not be strictly observable. Pursuant to 40 CFR 1506.11, however, OSHA or MSHA will consult with the Council on Environmental Quality in connection with such situations, and will, in any event, prepare environmental assessments or environmental impact statements, as appropriate, on any proposed permanent regulation to be promulgated for the purpose of replacing the temporary action.

(b) *Job Corps actions.* Actions which will involve construction, or the purchase or lease of property, in connection with the establishment or substantial alteration of a Job Corps center or of any similar Jobs Corps facility, will normally require the preparation of an environmental assessment prior to determining whether either a finding of no significant impact or an environmental impact statement must be prepared.

(c) *Other Departmental actions.* Certain actions taken to implement other Department of Labor programs will normally qualify for categorical exclusion from NEPA requirements. These matters are excluded because the possibility of environmental impact is remote. However, classification as a categorical exclusion does not prohibit or release an agency from preparing an environmental assessment or environmental impact statement when the agency determines it to be appropriate. These actions include:

(1) U.S. Employment Service activities and related placement, counseling, recruitment, information, testing, certification and associated actions;

(2) Apprenticeship activities and related certification and technical assistance actions;

(3) Training activities, other than Job Corps, including work experience, classroom training and public service employment;

(4) Unemployment insurance, trade adjustment assistance, workers' compensation programs, retirement programs, employee protection programs, and related employee benefit programs or activities involving the replacement or regulation of employee wages;

(5) Wage and hour programs to protect low-income workers, eliminate discriminatory employment practices, prevent curtailment of employment and earnings for certain groups of workers, minimize loss of income due to indebtedness, protect farm and migrant labor and related activities;

(6) Contract compliance programs to ensure equal employment opportunity and related actions;

(7) Labor-management relations activities and activities of labor organizations, employers and their officers or representatives;

(8) Research, evaluation, development and information collection projects related to any of the aforementioned activities;

(9) Labor statistics programs; and

(10) Matters involving personnel policy, procurement policy, freedom of information and privacy policy, and related matters of Departmental management.

§ 11.11 Development of environmental analyses and documents.

(a) Environmental factors shall begin to be examined at the time a topic for potential regulation modification or revocation of an existing OSHA/MSHA health standard or other action is submitted to the agency staff for research and proposal development, or when it is determined that a Job Corps action as described in § 11.10(b) may be appropriate.

(1) During this stage the agency shall determine whether the type of action which may be proposed may be categorically excluded from NEPA environmental analysis requirements pursuant to § 11.10.

(2) If the type of action being considered is not categorically excluded, or is an extraordinary case of a normally excluded action which may have significant environmental impacts, development of the information needed to make an environmental assessment shall begin.

(b) When information gathered during the early stages of proposal development indicates that preparation of an environmental impact statement will be required, the agency shall begin preparation of such a document by initiating the scoping process in accordance with 40 CFR 1501.7. However, if the information is not clearly indicative of the need for preparation of an environmental impact statement, an environmental assessment shall be prepared.

(c) In making environmental assessments of Job Corps actions described in § 11.10(b), factors to be considered include:

(1) The nature and degree of any former use of a proposed facility and the number of individuals the facility formerly served, as compared with its use and population to be served under the new proposal.

(2) The population of the area (numbers, density and makeup);

(3) Community facilities and services, taking into consideration capacity and present and former use, including: health services (hospitals, physicians), business and community development policy, recreational facilities (parks, theaters), fire and police protection, schools, energy resources, waste disposal, water, traffic and roadway systems, sewage systems, communications, and public transportation;

(4) The proximity of the facility to residential areas;

(5) The quality of drinking water, air quality, noise levels, designated scenic areas, land use, soil quality (including drainage or erosion problems), buildings valued for their design or which are otherwise locally significant, neighborhood character, and health and safety of residents;

(6) Natural systems and resources including: rivers and streams, forests, wetlands, wilderness areas or places, and species designated for preservation, including species of plants and animals and their critical habitats as identified in regulations published by the Secretary of the Interior (50 CFR Chapter I, Part 17), and by the Secretary of Commerce (50 CFR Chapter II, Parts 217, 222.23, 223, and 227.4); and

(7) Other considerations appropriate in light of the nature and size of the project.

(d) If the agency determines, on the basis of the environmental assessment, that preparation of an environmental impact statement is not required, notice of a finding of no significant impact and the availability of the environmental assessment shall be prepared and published in the **Federal Register.** In the case of proposed rulemaking, the notice of a finding of no significant impact may be published in the **Federal Register** at any time prior to the publication of the proposed action, or it may be included in the **Federal Register** notice of proposed rulemaking. The Department of Labor notes CEQ's intent, as stated in 40 CFR 1500.3, that issuance of a finding of no significant impact at the proposal stage of rulemaking shall not be considered a final agency action since the finding will not foreclose further consideration of environmental issues during the rulemaking proceedings, or result in action significantly affecting the environment, or cause irreparable injury to any member of the public.

(1) If it is determined that preparation of an environmental impact statement is not required for an action, but that

action is one which would normally require the preparation of an environmental impact statement, an action closely similar to one which would normally require the preparation of an environmental impact statement, or an action without precedent in this regard, the agency shall make a preliminary finding of no significant impact available for public review and comment. In accordance with 40 CFR 1501.4(e)(2), this finding shall be made available for at least 30 days before a final determination is made as to whether an environmental impact statement will be prepared, and before any public record may be closed and the proposed action may become effective.

(2) Although not required by 40 CFR 1501.4(e)(2) an agency may use the procedure described in 11.11(d)(1) whenever the agency determines it to be appropriate.

(e) If it is determined on the basis of an environmental assessment, prepared in connection with a Job Corps action described in § 11.10(b), that preparation of an environmental impact statement is required, the agency shall consider altering the proposed action or changing the site of the proposed project, and shall proceed with preparation of an environmental impact statement only after obtaining written authorization from the Assistant Secretary for Administration and Management.

(f) Filing of any draft environmental impact statement with the Environmental Protection Agency (EPA), pursuant to 40 CFR 1506.9, and circulation to the public, will ordinarily coincide with publication of the proposed agency action, which is the subject of that document, in the **Federal Register**. In any event, the statement will be made available for public comment for at least a 45-day period.

(g) The final decision on the proposed action shall be made not earlier than 90 days following publication of EPA's notice of the filing of the draft environmental impact statement, and, except as provided below, not earlier than 30 days following publication of EPA's notice of the filing of the final environmental impact statement.

(1) In accordance with 40 CFR 1506.10, an agency engaged in rulemaking under the Administrative Procedure Act or other statute, for the purpose of protecting the public health or safety, may waive the 30-day time period noted above and publish a decision on a final rule simultaneously with publication of the notice of the availability of the final environmental impact statement. Therefore, Departmental agencies (such as OSHA and MSHA) meeting these requirements, may file and circulate the final environmental impact statement at the same time a notice of decision is being published, provided that the final rule or action may not become effective for at least 30 days from the date of publication of the EPA's notice of filing of the final environmental impact statement.

(2) If a supplement to a final environmental impact statement is prepared, it shall be incorporated into the rulemaking record. If the supplement is prepared following the close of the rulemaking record and is based on, or introduces, new data or major new alternatives or analyses, the rulemaking record will be reopened for at least 30 days to receive public comments. The final action may not become effective for at least 30 days following EPA publication of the filing of the supplemental statement.

(h) In accordance with 40 CFR 1505.2, when an agency prepares a final environmental impact statement, the agency shall prepare a concise public record of decision detailing what the decision was, what alternatives were considered (specifying the environmentally preferable alternative), how those considerations entered into the decision, and whether all practicable means to avoid or minimize environmental harm from the alternative selected have been adopted, and if not, the reason they were not. This record may be contained in, or integrated with, the preamble to the **Federal Register** notice of final action or in any other public document considered appropriate by the agency.

§ 11.12 Content and format of environmental documents.

(a) An environmental assessment may be prepared in any format considered effective by the agency involved. When such a document is prepared in connection with a proposed action, it must be made readily available to the public either by placement into the public record (with public notice provided in accordance with 40 CFR Part 1506) or by publication in the **Federal Register**. The preamble to the **Federal Register** notice of proposed rulemaking may be considered the environmental assessment provided that the document contains the elements required by 40 CFR 1508.9(b).

(b) A finding of no significant impact (40 CFR 1508.13) may be prepared in any format considered to be effective or necessary by the agency involved in the proposed action.

(c) The finding of no significant impact, and the environmental assessment on which it was based, as well as any comments received in response to these documents shall be included in the public record of the proposed action.

(d) Department of Labor agencies shall comply with the format requirements for environmental impact statements as set forth at 40 CFR 1502.10, except when an agency determines that there is a compelling reason to do otherwise, such as more effective communication or reduced duplication of effort and paperwork (40 CFR 1506.4). For example, in OSHA/MSHA informal rulemaking proceedings, environmental documents may be combined with the **Federal Register** notice of proposed or final rulemaking. Filing and circulation of the combined preamble/environmental document shall be in accordance with the requirements of 40 CFR 1506.9.

(e) The final environmental impact statement shall contain any changes in information or supplemental information received since the filing and circulation of the draft environmental impact statement, as well as a summary, or copies of the substantive comments received in response to the draft environmental impact statement. If such changes and comments are minor, an agency may circulate only the changes and comments, including responses to the comments, rather than the entire impact statement, to the extent permitted by 40 CFR 1502.19. However, the entire document, with a new cover sheet shall be filed with EPA and placed in the rulemaking record.

§ 11.13 Public participation.

(a) When an agency has determined that preparation of an environmental impact statement is required, the agency shall publish a notice of intent to prepare an environmental impact statement in the **Federal Register** and shall invite public participation in the agency's scoping process as required by 40 CFR 1501.7.

(b) When the draft environmental impact statement has been prepared and filed with the EPA pursuant to § 11.11(f), comments on the document shall be solicited from appropriate Federal, State and local agencies, Indian tribes, and other persons or organizations who may be interested or affected, as required by 40 CFR 1503.1.

§ 11.14 Legislation.

Notwithstanding any provisions of this part, environmental assessments or impact statements prepared in connection with requests for new legislation or modification of existing statutes shall be handled in accordance with applicable OMB and Department of Labor procedures on the preparation

and submission of legislative proposals and the requirements of 40 CFR 1506.8.

PART 1999—PROCEDURE FOR THE PREPARATION AND CIRCULATION OF ENVIRONMENTAL IMPACT STATEMENTS [REVOKED]

2. It is further proposed that upon the issuance of the new Part 11 of Title 29 of the Code of Federal Regulations, Part 1999 of that Title be revoked.

[FR Doc. 79-37292 Filed 12-3-79; 8:45 am]
BILLING CODE 4510-23-M

POSTAL SERVICE

39 CFR Part 927

Proposed Revisions to Regulations Dealing with Penalties or Fines, Deductions, and Damages Related to Transportation of Mail

AGENCY: Postal Service.

ACTION: Proposed rule.

SUMMARY: The Postal Service proposes to revise its regulations dealing with civil penalties, fines, deductions, and damages assessed in the administration of the mail transportation statutes. The proposed changes would introduce more detailed procedures for the impostition of penalties and other assessments. The proposal also would update the regulations to reflect the current organization of the Postal Service.

DATE: Comments must be received on or before January 4, 1980.

ADDRESS: Written comments should be addressed or delivered to Robert A. Scherr, Assistant General Counsel, Transportation Division, U.S. Postal Service, 475 L'Enfant Plaza, West, SW., Room 9417, Washington, D.C. 20260. Copies of all comments received will be available for public inspection and photocopying between 9 a.m. and 4 p.m. outside Room 9010 at the foregoing address.

FOR FURTHER INFORMATION CONTACT: Robert A. Scherr, (202) 245-4625.

SUPPLEMENTARY INFORMATION: By various statutes, the Postal Service is empowered to provide for the transportation of mail (39 U.S.C. 404(1) and 5401(a), 49 U.S.C. 1375(a)); and to issue such rules and regulations as are necessary to carry out this power (39 U.S.C. 401(2) and 5401(b), 49 U.S.C. 1375(a)).

The Postal Service, by statute, regulation and contract provision, may assess penalties and fines for unreasonable or unnecessary delay to mail or other delinquencies in the transportation of mail, make deductions from pay otherwise due for the transportation of mail for failure to perform mail transportation service, and collect damages for loss or damage to the mail or other failure to perform service as provided for under the terms of a contract for the transportation of mail. All of these provisions are intended to foster compliance with applicable statutes, regulations, and contract terms.

In the administration of these provisions, the Postal Service has found the need for a set of more detailed and uniform administrative procedures, to assure fairness and to promote efficient administration. Three classes of carriers which provide transportation services are covered by the provisions: contractors who transport mail pursuant to Postal Service contract, noncontractual carriers of mail by vessel, and noncontractual air carriers. For contract carriers, these regulations are contained in section 19, Postal Contracting Manual (Publication 41), which is incorporated at 39 CFR 601.100 (1979); and in PS Form 7407, Basic Surface Transportation Services Contract General Provisions, and PS Form 7451, Air Taxi Contract General Provisions, which are incorporated into the respective contracts. These provisions, consequently, need not be repeated and are to be eliminated from Part 927, title 39, Code of Federal Regulations, by this proposed rule. For noncontractual carriers, the proposed regulations would introduce a generally uniform set of procedures.

The proposed regulations provide that for noncontractual carriers of mail by vessel and noncontractual air carriers penalty action will be proposed only after a full investigation. The transporter of mail will receive written notice of any proposed penalty and will be advised of a right to answer the charges through the presentation of evidence and argument in writing. He will be advised in writing of the decision in the matter, and will be accorded the right to appeal within the Postal Service any decision to impose a penalty. The decision of the Director, Office of Transportation Services, U.S. Postal Service, who will be authorized to impose penalties, will be subject to appeal in writing to the Assistant Postmaster General, Mail Processing Department.

Accordingly, although exempt from the notice and comment provisions of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking, 39 U.S.C. 410(a), the Postal Service invites public comment on the following proposed revision of Title 39, CFR:

PART 927—RULES OF PROCEDURE RELATING TO FINES, DEDUCTIONS, AND DAMAGES

Sec.

927.1 Noncontractual carriage of mail by vessel.
927.2 Noncontractual air service.
927.3 Other remedies.

Authority: 39 U.S.C. 401, 2601, Chap. 54, section 5604; 49 U.S.C. 1357, 1471.

§ 927.1 Noncontractual carriage of mail by vessel.

(a) *Report of infraction.* Where evidence is found or reported that a carrier of mail by vessel which has transported mail pursuant to the provisions of section 19-504, Postal Contracting Manual, has unreasonably or unnecessarily delayed the mails, has committed other delinquencies in the transportation of mail, has failed to carry the mail in a safe and secure manner, or has caused loss or damage to the mail, the facts will be reported to the General Manager, Logistics Division, of the postal region in which the mail was dispatched or was received.

(b) *Review, investigation, recommendation.* The General Manager, Logistics Division, will investigate the matter. The Manager will record findings of fact and make a recommendation concerning the need for imposition of fine or penalty with the reasons for the recommendation. The Manager will then forward the file to the Director, Office of Transportation Services, and will advise the carrier of the recommendation.

(c) *Penalty action.* The Director, Office of Transportation Services, upon review of the record, may impose a fine or penalty against a carrier for any irregularity properly documented, whether or not penalty action has been recommended. A tentative decision of the Director, Office of Transportation Services, to take penalty action will set forth in detail the facts and reasons upon which the determination is based. The Director will send the tentative decision, including notice of the irregularities found and the amount of fine or penalty proposed, to the carrier. The carrier may present a written defense to the proposed action within 30 days after receipt of the tentative decision. The Director, after review of the record, will advise the carrier of the final decision.

(d) *Appeal.* If the final decision includes a penalty, the Director will advise the carrier that it may, within 30 days, appeal the action in writing to the

Assistant Postmaster General, Mail Processing Department, U.S. Postal Service, and that its written appeal should include all facts and arguments upon which the carrier relies in support of the appeal. If an appeal is not received, the Director will close the record. When an appeal is taken, the Assistant Postmaster General, Mail Processing Department, will review the complete record and decide the appeal. He will advise the carrier of the decision in writing and will take action consistent with that decision. The Assistant Postmaster General, Mail Processing Department, may sustain, rescind, or compromise a fine or penalty. The decision of the Assistant Postmaster General, Mail Processing Department, on appeal shall be the final decision of the Postal Service. The Postal Service may, in its discretion, deduct from pay otherwise due the carrier an amount necessary to satisfy the penalty action taken under this section.

(e) *Details of administration.* For further administrative details, see section 19–504, Postal Contracting Manual (Publication 41).

§ 927.2 Noncontractual air service.

(a) *Report of infraction.* Each mail handling irregularity will be reported on a prescribed form by the cognizant postal official or designated representative. As soon as possible the reporting authority will ask the local representative of the air carrier to provide an explanation of the irregularity. A summary of the explanation, if any, will be entered on the form. A copy of the form will be provided to the local station manager of the carrier concerned at the close of each tour and not less frequently than each 24 hours.

(b) *Carrier conferences.* At least once per month, postal officials will schedule a meeting with the local representatives of the affected air carriers to discuss the reported irregularities. The carrier's representative will be advised of any irregularity for which the reporting authority will recommend penalty action. The carrier's representative will be offered the opportunity to comment on any irregularity, and any comments will be attached to the form. The form on which penalty action is recommended will then be forwarded to the General Manager, Logistics Division, of the appropriate postal region.

(c) *Review, investigation, recommendation.* The General Manager, Logistics Division, will review the matter. In those instances in which a monetary fine or penalty appears warranted but the carrier has disputed the facts alleged by the reporting authority, the General Manager, Logistics Division, will investigate the matter to resolve the differences. The Manager will record findings of fact and make a recommendation concerning the need for imposition of a fine or penalty, with the reasons for the recommendation. The Manager will then forward the file to the Director, Office of Transportation Services, U.S. Postal Service, and will advise the carrier of the recommendation.

(d) *Penalty action.* The Director, Office of Transportation Services, upon review of the record, may impose a fine or penalty against an air carrier for any irregularity properly documented, whether or not penalty action has been recommended. A tentative decision of the Director, Office of Transportation Services, to take penalty action will set forth in detail the facts and reasons upon which the determination is based. The Director will send the tentative decision, including notice of the irregularities alleged and the amount of fine or penalty proposed, to the carrier. The carrier may present a written defense to the proposed action within 30 days after receipt of the tentative decision. The Director, after review of the record, will advise the carrier of the final decision.

(e) *Appeal.* If the final decision includes a penalty, the Director will advise the carrier that it may, within 30 days, appeal the action in writing to the Assistant Postmaster General, Mail Processing Department, U.S. Postal Service, and that its written appeal should include all facts and arguments upon which the carrier relies in support of the appeal. If an appeal is not received, the Director will close the file. When an appeal is taken, the Assistant Postmaster General, Mail Processing Department, will review the complete record and decide the appeal. He will advise the carrier of the decision in writing and will take action consistent with that decision. The Assistant Postmaster General, Mail Processing Department, may sustain, rescind, or compromise a fine or penalty. The decision of the Assistant Postmaster General, Mail Processing Department, on appeal shall be the final decision of the Postal Service. The Postal Service may, in its discretion, deduct from pay otherwise due the air carrier an amount necessary to satisfy the penalty action taken under this section.

(f) *Details of administration.* For further administrative details, forms, and other implementing materials adapted to the respective modes of transportation, see Transportation Handbook M–31, Air Service Instructions, Part 320, for interstate air transportation; Transportation Handbook T–1, International Airmail, Exchange Office Procedures, Part 4, for foreign air transportation; and Transportation Handbook T–7, Handling, Dispatch, and Transportation of Military Mail, Part 10, for overseas air transportation.

§ 927.3 Other Remedies.

The procedures and other requirements of this part apply only where the Postal Service proposes to assess penalties, fines, deductions, or damages. This part does not limit other remedies available to the Postal Service, including such remedies as summary action to withhold tender of the mail to protect the public interest in the event of major irregularities such as theft, deliberate loss, damage, or abandonment of the mail.

W. Allen Sanders,

Associate General Counsel for General Law and Administration.

[FR Doc. 79-37138 Filed 12-3-79; 8:45 am]

BILLING CODE 7710-12-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FRL 1352-4]

Approval and Promulgation of Implementation Plans; Florida: Variance for Particulates, SO2, Visible Emissions and Excess Emissions for Florida Power and Light Generating Plants

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: On August 31, 1979, the State of Florida submitted to EPA, as a SIP revision, a variance which had been adopted by the Environmental Regulation Commission. This variance allows the Florida Power & Light Company (FP&L) to continue certain operations during the current low-sulfur oil shortage. The variance relaxes the requirements which certain FP&L generating units must meet with regard to emissions of particulates and sulfur dioxide, visible emissions and excess emissions. EPA proposes to approve the revision except for certain portions which the Agency proposes to disapprove. The public is invited to comment on the proposed actions.

DATES: To be considered, comments must be received on or before January 3, 1980.

ADDRESSES: Written comments should be addressed to Archie Lee of EPA Region IV's Air Programs Branch (See EPA Region IV address below). Copies of the materials submitted by Florida may be examined during normal business hours at the following locations:

Public Information Reference Unit, Library Systems Branch, Environmental Protection Agency, 401 M Street, S.W., Washington, D.C. 20460

Library, Environmental Protection Agency, Region IV, 345 Courtland Street, N.E., Atlanta, Georgia 30308

Florida Bureau of Air Quality Management, Department of Environmental Regulation, Twin Towers Office Building, 2600 Blair Stone Road, Tallahassee, Florida 32301

FOR FURTHER INFORMATION CONTACT: Archie Lee of EPA Region IV's Air Programs Branch, 345 Courtland Street, N.E., Atlanta, Georgia 30308. Telephone 404/881-3286 (FTS 257-3286).

BACKGROUND: In early 1979 Florida Power and Light Company was unable to obtain a sufficient supply of low-sulfur fuel oil due in part to the decreased availability of crude and the disappearance of "spot market" low-sulfur oil supplies. Consequently, FP&L petitioned and received emergency relief under section 110(f) of the Clean Air Act. The relief granted under section 110(f) is limited in time and therefore the need for a longer period of relief has arisen. On August 28, 1979, the Florida Department of Environmental Regulation issued a variance which relaxes the current particulate limits of 0.1 lbs. per MM BTU and 20% opacity. Under the variance Cape Canaveral 1 & 2, Fort Myers 1 & 2, Manatee 1 & 2 and Sanford 3, 4, and 5 may emit 0.3 lbs. per MM BTU, and Port Everglades 1, 2, 3, and 4, Riviera 3 & 4, and Turkey Point 1 & 2 may emit 0.4 lbs. per MM BTU. Opacity limits for all units are relaxed to 40%. Additionally, the variance stipulates that if fuel oil with asphaltene content of less than or equal to 9% by weight is burned, the following limits will apply to all units: (1) 0.3 lbs. per MM BTU, or (2) 0.2 lbs. per MM BTU (for units with low excess air burners).

Excess emissions are allowed during periods of malfunction and startup/shutdown operations. During boiler cleaning and load changes, emission limits of 0.6 lbs. particulate per MM BTU and 60% opacity apply. (These periods are not to exceed 3 hours in any 24-hour period.) Opacity greater than 60% is allowed for not more than four 6-minute periods during the 3-hr. period, providing the unit has installed and operating, or has committed to install and operate, continuous opacity monitors.

The sulfur dioxide limitations for Manatee Units 1 & 2 are relaxed from 1.1 lb. per MM BTU to 2.75 lbs. per MM BTU.

Control strategy demonstrations purporting to show compliance with the National Ambient Air Quality Standards and PSD increments for total suspended particulates and sulfur dioxide are included with the State submittal.

EPA has reviewed the materials submitted by the State of Florida and finds the revision to be approvable except for the following areas:

1. No testing method for compliance is specified. The State, in a recent supplement to the variance, has ordered FP&L to test for particulates using EPA test method 5 or 17. This information, along with the testing method for sulfur dioxide, should be submitted to EPA as part of the SIP revision package.

2. Relaxing the TSP limits for the Turkey Point and Port Everglades plants would allow FP&L to burn higher sulfur fuel, thereby violating the sulfur dioxide Class I increments in the Everglades National Park. The alternate Class I PSD increments for sulfur dioxide were used (in the control strategy) to accommodate emissions from the Turkey Point and Port Everglades plants.

EPA has determined that since this SIP revision does not involve the permitting of a major new source or major modification, the alternative Class I increments cannot be used. Therefore the air quality impact of the SIP revision must not violate the standard Class I increments. Since the limits on allowable sulfur dioxide emissions for the Turkey Point and Port Everglades plants would not be violated even by the higher sulfur oil projected in the variance, it is evident that the current SO_2 emission limits applicable to these plants are not adequate to protect the Class I increments. The State should initiate action to revise the SO_2 emission limits for these two plants.

EPA is today proposing to approve the Florida revision except for the portions affected by the deficiencies just described; it is proposed to disapprove the latter portions.

The public is invited to participate in this rulemaking action by submitting written comments. After reviewing pertinent comments and all other information available to him, the Administrator will take final action on the Florida revision.

(Section 110 of the Clean Air Act (42 U.S.C. 7410))

Dated: November 1, 1979.

Thomas Devine,

Acting Regional Administrator.

[FR Doc. 79-37163 Filed 12-3-79; 8:45 am]

BILLING CODE 6560-01-M

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40 CFR Part 52

[FRL 1369-7]

Implementation Plan Revisions for Nonattainment Areas in California; Receipt/Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt and availability.

SUMMARY: The purpose of this notice is to announce receipt of revisions to the California State Implementation Plan (SIP) and to invite public comment. The Nonattainment Area Plans for Fresno, Kern, Kings, Madera, Merced, San Joaquin, Stanislaus, Tulare, and Imperial Counties have been submitted to EPA by the California Air Resources Board in accordance with the requirements of Part D of the Clean Air Act, as amended in 1977, "Plan Requirements for Nonattainment Areas," and are available for public inspection at the addresses below. Notices of proposed rulemaking discussing the revisions will be published in the **Federal Register** at a later date. The period for submittal of public comments will end not less than 60 days from this date and not less than 30 days from the published dates of EPA's notices of proposed rulemaking.

ADDRESSES: Copies of the SIP revisions are available for inspection during normal business hours at the following locations:

Air and Hazardous Materials Division (A-4-2), Environmental Protection Agency, Region IX, 215 Fremont Street, San Francisco, CA 94105.

Public Information Reference Unit, Environmental Protection Agency, 401 "M" Street, SW., Room 2404, Washington, D.C. 20460.

California Air Resources Board, 1102 "Q" Street, Sacramento, CA 95814.

In addition, copies of the applicable SIP revision are available for public inspection during normal business hours at each of the following locations:

Fresno County Air Pollution Control District, 1246 "L" Street, Fresno, CA 93721.

Kern County Air Pollution Control District, 1700 Flower Street, Bakersfield, CA 93305.

Kings County Air Pollution Control District, 330 Campus Drive, Hanford, CA 93230.

Madera County Air Pollution Control District, 135 West Yosemite Avenue, Madera, CA 93637.

Merced County Air Pollution Control District, 240 East 15th Street, Merced, CA 95340.

San Joaquin County Air Pollution Control District, 1601 East Hazelton Avenue, Stockton, CA 95201.
Stanislaus Area Association of Governments, 814–14th Street, Modesto, CA 95354.
Tulare County Air Pollution Control District, Health Building, County Civic Center, Visalia, CA 93277.
Imperial County Air Pollution Control District, 940 West Main Street, El Centro, CA 92243.

FOR FURTHER INFORMATION CONTACT: Douglas Grano, Chief, Regulatory Section, Air Technical Branch, Air and Hazardous Materials Division, Environmental Protection Agency, Region IX, 215 Fremont Street, San Francisco, CA 94105, (415) 556–2938

SUPPLEMENTARY INFORMATION: New Provisions of the Clean Air Act, enacted in August 1977, Pub. L. No. 95–95, require states to revise their SIP's for all areas that do not attain the National Ambient Air Quality Standards (NAAQS). The amendments required each state to submit to the Administrator a list of the NAAQS attainment status for all areas within the state. The Administrator promulgated these lists, with certain modifications, on March 3, 1978 (43 FR 8962) and March 19, 1979 (44 FR 16388). State and local governments were required by January 1, 1979 to develop, adopt, and submit to EPA revisions to their SIP's which provide for attainment of the NAAQS as expeditiously as practicable.

The entire eight-county San Joaquin Valley Air Basin is designated nonattainment for total suspended particulates and for ozone. Fresno, Kern, San Joaquin, and Stanislaus Counties are designated nonattainment for carbon monoxide. Kern County is designated nonattainment for sulfur dioxide. Imperial County is designated nonattainment for ozone.

The Governor's designee submitted to EPA the nonattainment area plans for the San Joaquin Valley Air Basin and for Imperial County on October 11, 1979.

EPA is reviewing the revisions for conformance with the requirements of Part D of the Clean Air Act, as amended. Following EPA's review of the revisions, notices of proposed rulemaking will be published in the **Federal Register** and will provide descriptions of the proposed SIP revisions, summarize the Part D requirements, identify the major issues in the proposed revisions, and suggest corrections. An additional 30 days will be provided for public comments at that time.

The intent of this notice is to notify the public that the revisions have been formally submitted to EPA for approval, that they are available for public inspection, and that interested persons are encouraged to submit written comments.

(Sections 110, 129, 171 to 178 and 301(a) of the Clean Air Act, as amended (42 U.S.C. 7410, 7429, 7501 to 7508, and 7601(a)))

Dated: November 21, 1979.

Sheila M. Prindiville,

Acting Regional Administrator.

[FR Doc. 79-37161 Filed 12-3-79; 8:45 am]

BILLING CODE 6560-01-M

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40 CFR Parts 52 and 81

[FRL 1345-6]

Missouri Proposal Revision to Air Quality Implementation Plan

Correction

In FR Doc. 79–32866, appearing at page 61384 in the issue of Thursday, October 25, 1979, the tenth line of the "Summary" section should read, "June 30, 1979. The requirements for an".

BILLING CODE 1505-01-M

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40 CFR Part 65

[Docket No. 9-79-266; FRL 1370-4]

Proposed Delayed Compliance Order for General Motors Corp., General Motors Assembly Division, Fremont, Calif.

AGENCY: Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: EPA proposes to issue a Federal Delayed Compliance Order (DCO) to General Motors Corporation (GMC), General Motors Assembly Division, Fremont, California. The DCO requires GMC to bring its two paint spray booths at Fremont, California, into compliance with 40 CFR 52.254(d), part of the Federally promulgated California State Implementation Plan (SIP). Because GMC is unable to comply with this regulation at this time and GMC will use a new means of emission limitation to achieve compliance with the regulations, the proposed DCO would establish an expeditious schedule requiring final compliance by August 31, 1981. Source compliance with the DCO would preclude suits under the Federal enforcement and citizen suit provisions of the Clean Air Act for violation of the SIP regulation covered by the DCO. The purpose of this notice is to invite public comment and to offer an opportunity to request a public hearing on this proposed DCO.

DATES: Written comments must be received on or before January 3, 1980, and requests for a public hearing must be received on or before December 19, 1979. All requests for a public hearing should be accompanied by a statement of why the hearing would be beneficial and a text or summary of any proposed testimony to be offered at the hearing. If there is significant public interest in a hearing, it will be held after twenty-one days prior notice of the date, time and place of the hearing has been given in this publication.

ADDRESSES: Comments and requests for a public hearing should be submitted to Director, Enforcement Division, EPA, Region IX, 215 Fremont Street, San Francisco, California 94105, material supporting the DCO and public comments received in response to this notice may be inspected and copied (for appropriate charges) at this address during normal business hours.

FOR FURTHER INFORMATION CONTACT: David S. Mowday, Chief, Air and Hazardous Materials Branch, Enforcement Division, Environmental Protection Agency, Region IX, 215 Fremont Street, San Francisco, CA 94105, Phone: (415) 556–6150.

SUPPLEMENTARY INFORMATION: General Motors Corporation assembles passenger cars and pick-up trucks at its assembly plant located in Fremont, California. On April 15, 1977, pursuant to Section 113(a)(1) of the Clean Air Act, 42 U.S.C. 7413(a)(1), EPA issued a Notice of Violation to GMC for violation of 40 CFR 52.254(d), dealing with the control of organic solvent emissions. On July 25, 1979, GMC proposed the use of two control systems, new means for reducing solvent emissions of organic materials from automotive paint spray booths, to meet the requirements of 40 CFR 52.254(d). One system will consist of carbon absorption, higher solids paint, electrostatic paint spray equipment, and catalytic incineration. The other system will consist of carbon adsorption, higher solids paint and electrostatic paint spray equipment. After a thorough evaluation, EPA has determined that the GMC's proposed organic solvent reduction systems do constitute a "new means of emission limitation" as defined by Section 113(d)(4) of the Clean Air Act. EPA, therefore, proposes to issue a DCO which requires final compliance with 40 CFR 52.254(d) by August 31, 1981. The source has consented to the terms of the DCO and has agreed to meet the DCO's remaining increments during the period of this informal rulemaking. If the DCO is issued, source compliance with its terms would preclude further EPA enforcement against this source for violation of the applicable regulation covered by the DCO while the DCO is in effect.

Enforcement against the source under the citizen suit provision of the Clean Air Act (Section 304) would be similarly precluded.

Comments received by the date specified above will be considered in determining whether EPA should issue the DCO. Testimony given at any public hearing concerning the DCO will also be considered. After the public comment period and any public hearing, the Administrator of EPA will publish in the Federal Register the Agency's final action on the DCO in 40 CFR Part 65.

(Sections 113 and 301 of the Clean Air Act, as amended (42 U.S.C. 7413 and 7601))

Dated: September 28, 1979.

Paul De Falco, Jr.,

Regional Administrator, Environmental Protection Agency, Region IX.

In consideration of the foregoing, it is proposed to amend 40 CFR Chapter 1, as follows:

PART 65—DELAYED COMPLIANCE ORDER

1. By amending the table in § 65.90 Federal delayed compliance orders issued under Sections 113(d)(1), (3), and (4) of the Act, to reflect approval of the following order: Docket No. 9–79–266.

The text of the order reads as follows:

United States Environmental Protection Agency Region IX

[Docket No. 9–79–266]

DELAYED COMPLIANCE ORDER

In the Matter of: General Motors Corporation, General Motors Assembly Division, Fremont, California.

Proceeding under Section 113(d)(4) of the Clean Air Act, as Amended

This Order is issued this date pursuant to Section 113(d)(4) of the Clean Air Act, as amended, 42 U.S.C. 7413(d) (hereinafter referred to as the "Act") and contains a schedule for compliance, interim control requirements, and reporting requirements. Public notice, opportunity for a public hearing, and thirty (30) days notice to the State of California have been provided pursuant to Section 113(d)(1) of the Act.

FINDINGS

On April 15, 1977, R. L. O'Connell, Director, Enforcement Division, Region IX, United States Environmental Protection Agency (hereinafter referred to as "U.S. EPA"), pursuant to authority delegated to him by the Administrator of the U.S. EPA, issued a Notice of Violation to the General Motors Corporation (hereinafter "GMC"), General Motors Assembly Division, Fremont, California (hereinafter "source") pursuant to Section 113(a)(1) of the Act, 42 U.S.C. 7413(a)(1), informing GMC that the No. 1 passenger color spray booth and the No. 2 truck color spray booth at the source were found to be in violation of 40 CFR 52.254(d), dealing with the control of organic solvent emissions. The regulation is part of the Federally promulgated implementation plan for California. Said violations have continued beyond the thirtieth day after the date of the Enforcement Division Director's notification.

On July 25, 1979, GMC met with representatives of the U.S. EPA, Region IX and proposed the use of two control systems, new means for reducing solvent emissions of organic materials from automotive paint spray booths, to meet the requirements of 40 CFR 52.254(d). The systems would be implemented on the No. 1 color booth on the passenger car line and on the No. 2 color booth on the truck line at the source. The system for the No. 1 passenger color booth will consist of carbon adsorption, higher solids paint, electrostatic paint spray equipment and catalytic incineration. The system for the No. 2 truck color booth will consist of carbon adsorption, higher solids paint and electrostatic paint spray equipment. GMC requested from the U.S. EPA a delayed compliance Order for the time necessary to install and implement such innovative technology as provided by Congress in Section 113(d)(4) of the Act.

After a thorough investigation of all relevant facts, EPA has determined that:

(1) GMC is unable to immediately comply with 40 CFR 52.254(d);

(2) The control systems are new means of emission limitation for control of solvent emissions from automotive paint spray booths;

(3) The use of this innovative technology is likely to be adequately demonstrated upon expiration of this Order;

(4) This means of emission reduction has a substantial likelihood to achieve interim reductions and to achieve greater final equivalent emission reductions than required by 40 CFR 52.254(d) at substantial economic and energy savings and with substantial non-air quality environmental benefit over conventional technology;

(5) Such new means is not likely to be used without this Order;

(6) Compliance with 40 CFR 52.254(d) is impractical prior to or during installation of the new means; and,

(7) That the issuance of this Order is consistent with the policy and intent of Section 113(d)(4).

Order

After a thorough investigation of all relevant facts including public comment, it is determined that the schedule for compliance set forth in this Order is as expeditious as practicable, and that the terms of this Order comply with Section 113(d) of the Act. Therefore, it is hereby Agreed and Ordered that:

A. GMC shall bring the No. 1 color booth on the passenger car line and the No. 2 color booth on the truck line at the source into compliance with the emission limitation and standards contained in 40 CFR 52.254(d) no later than August 31, 1981.

B. GMC shall achieve compliance with 40 CFR 52.254(d) in accordance with the following schedule:

No. 1 Color Booth on the Passenger Car Line

(1) Award of contract for installation of catalytic incineration on oven; August 1, 1979.
(2) Complete installation of spinning disc electrostatic station #1 side spray equipment; August 27, 1979.
(3) Complete conversion of all colors to 22% dispersion lacquer; August 31, 1979.
(4) Complete installation of fixed bed carbon adsorption unit and catalytic incineration on first color oven; November 26, 1979.
(5) Complete construction of floor conveyor in spray booth; January 20, 1979.
(6) Complete installation of spinning disc electrostatic station #1 top spray, stations #2 and #3 side and top sprays; January 27, 1980.
(7) Complete Phase I testing; April 1, 1980.
(8) Issue report on Phase I testing and determine if system should continue into Phase II; April 15, 1980.
(9) If Phase II is to continue:
a. Complete installation of hand electrostatic spray equipment if permitted by contract and otherwise necessary; May 15, 1980.
b. Let contract for additional carbon adsorption units; June 1, 1980.
c. Complete conversion of all colors to 27% dispersion lacquer; September 15, 1980
d. Complete installation of additional carbon adsorption units; July 1, 1981.
(10) If Phase I has not resulted in compliance and Phase II is not to continue:
a. Initiate conversion to waterborne painting system; April 15, 1980.
b. Complete conversion to waterborne painting system; August 31, 1981.
(11) Achieve final compliance with 40 CFR 52.254(d) and submit performance test results to demonstrate compliance; August 31, 1981.

No. 2 Color Booth on the Truck Line

(1) Complete conversion of all enamel from 35% to 42%; September 14, 1979.
(2) Complete installation of 20,000 CFM carbon adsorption unit; January 7, 1980.
(3) Complete installation of spinning disc electrostatic stations #1 and #2; January 21, 1980.
(4) Complete Phase I testing; April 1, 1980.
(5) Issue report on Phase I testing and determine if system should continue into Phase II; April 15, 1980.
(6) If Phase II is to continue:
a. Complete installation of hand electrostatic spray equipment if permitted by contract and otherwise necessary; May 15, 1980.
b. Let contract for additional carbon adsorption units; June 1, 1980.
c. Complete installation of additional carbon adsorption unit; July 1, 1981.
(7) If Phase I has not resulted in compliance and Phase II is not to continue:
a. Initiate conversion to waterborne painting system; April 15, 1980.
b. Complete conversion to waterborne painting system; August 31, 1981.
(8) Achieve final compliance with 40 CFR 52.254(d) and submit performance test results to demonstrate compliance. August 31, 1981.

C. No later than five (5) days after the end of each quarter, GMC shall notify U.S. EPA in writing of its compliance or noncompliance with any incremental step or final compliance date provided in this Order and reasons therefor. If any delay is anticipated in meeting any requirements of this Order, GMC

shall immediately notify U.S. EPA in writing of the anticipated delay and reasons therefor. Notification to U.S. EPA of any anticipated delay does not excuse the delay. All submittals and notifications to U.S. EPA, pursuant to this Order, shall be made to Clyde B. Eller, Director, Enforcement Division, Region IX, U.S. EPA, 215 Fremont Street, San Francisco, California 94105. In addition, all submittals and notifications required in this Order shall stimultaneously be transmitted to the California Air Resources Board (CARB) and the Bay Area Air Quality Management District (BAAQMD).

D. GMC shall provide the U.S. EPA, CARB, and BAAQMD at least 30 days notice prior to the conducting of any performance tests in order to afford an opportunity to evaluate test method and procedure and to have an observer present at such testing.

E. Upon completion of the installation, operation, and testing increments shown for the source, GMC will present to the U.S. EPA, the CARB and the BAAQMD all pertinent test results and data, including spray booth parameters so as to allow each agency to evaluate the performance of the new system. At the same time, GMC will prepare a report for the U.S. EPA, CARB and BAAQMD (1) evauating test results, (2) demonstrating compliance with 40 CFR 52.254(d) or noncompliance therewith, (3) describing why compliance was or was not achieved, (4) if compliance was achieved, describing the key operational and design factors that contributed to compliance and whether any other changes could be made to improve performance, and (5) if compliance was not achieved, describing key operational and design factors explaining such noncompliance and an engineering assessment as to whether ultimate compliance could be achieved and specifying operational and design parameters which can be instituted to achieve compliance. At each of the enumerated increments in the compliance schedule, GMC will advise the U.S. EPA, CARB and BAAQMD of its progress. After the reports of April 15, 1980 required by the schedule are issued, upon request of the designated representatives of each agency, GMC agrees to consult with them as to all engineering assessments and future design or operational changes necessary to achieve compliance or improve upon it.

F. Pursuant to Section 113(d)(7) of the Act, during the period of this Order GMC shall use the best practicable systems of emission reduction so as to minimize organic solvent emissions from each booth and shall further comply with the requirements of the applicable implementation plan insofar as it is able to. The source shall in the minimization of organic solvent emissions from both booths on a day-to-day basis during the interim period preceding final compliance.

G. Nothing contained in these Findings or Order shall affect GMC's responsibility to comply with State or local laws or regulations or other Federal laws or regulations.

H. GMC is hereby notified that its failure to meet the interim requirements of this DCO or to achieve final compliance by August 31, 1981 at the source covered by this Order may result in a requirement to pay a noncompliance penalty in accordance with Section 120 of the Act, 42 U.S.C. 7420. In the event of such failure, GMC will be formally notified pursuant to Section 120(b)(3), 42 U.S.C. 7420(b)(3), and any regulations promulgated thereunder of its noncompliance.

I. This Order shall be terminated in accordance with Section 113(d)(8) of the Act if the Administrator or his delegate determines on the record, after notice and hearing, that an inability to comply with 40 CFR 52.254(d) no longer exists.

J. Violation of any requirement of this Order shall result in one or more of the following actions:

1. Enforcement of such requirement pursuant to Section 113 (a), (b) or (c) of the Act, 42 U.S.C. 7413 (a), (b) or (c), including possible judicial action for an injunction and/or penalties and in appropriate cases, criminal prosecution.

2. Revocation of this Order, after notice and opportunity for public hearing, and subsequent enforcement of 40 CFR 52.254(d) in accordance with the preceding paragraph.

K. This schedule is protected by Section 113(d)(10) against Federal enforcement action and citizen suits under Section 304 until August 31, 1981, where the owner or operator of said source is in compliance with the terms of such Order.

L. Nothing herein shall be construed to be a waiver by the Administrator of any rights or remedies under the Act, including, but not limited to Section 303 of the Act, 42 U.S.C. 7503.

M. In the event that the California State Implementation Plan shall be substantially modified or amended during the period of time in which this Order is in effect so as to make the above-described control program inadequate or unnecessary to achieve compliance with such modified or amended California State Implementation Plan, GMC and the U.S. EPA shall forthwith meet to discuss possible or appropriate modification of this Order as circumstances shall then require. No decision shall be necessary until U.S. EPA approves any proposed revisions to the California State Implementation Plan. Any such discussions shall not operate so as to amend or modify the obligations and undertakings herein contained pending the issuance of any amending or modifying Order.

N. This Order shall become effective upon final promulgation in the **Federal Register.**

Dated:

Administrator, U.S. Environmental Protection Agency.

GMC has reviewed this Order, consents to the terms and conditions of this Order, and believes it to be a reasonable means by which the sources can achieve final compliance with 40 CFR 52.254(d).

Dated: September 20, 1979.

Kenneth M. Brooks,

General Motors Corporation.

[FR Doc. 79-37162 Filed 12-3-79; 8:45 am]

BILLING CODE 6560-01-M

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40 CFR Part 410

[FRL 1370-3]

Textile Mills Point Source Category Effluent Limitations Guidelines Pretreatment Standards, and New Source Performance Standards; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; correction.

SUMMARY: The following corrections should be made in EPA's October 29, 1979, proposed regulation implementing Sections 301, 304, 306, and 307 of the Clean Water Act (44 FR 62204)

FOR FURTHER INFORMATION CONTACT: James R. Berlow, Effluent Guidelines Division (WH-552), Environmental Protection Agency, 401 M St. SW., Washington, D.C. 20460, Telephone (202) 426-2554.

Corrections

In FR Document 79-33067, make the following changes:

1. On page 62205, column 3, line 26, insert after "Paragraph": "8".

2. On page 62212, column 3, line 51, change "35" to "25".

3. On page 62214, column 1, line 1, insert ", 84" after "84".

4. On page 62230, column 2, line 58, the table in § 410.23 is corrected by changing Subpart A (3,300 kkg/yr or greater), BCT, TSS limitation, average of daily values for 30 consecutive days, from "16.3" to "6.3".

5. On page 62235, column 1, line 22, the table in § 410.57 is corrected by changing Subpart D—Simple Processing, PSNS, Total zinc limitation, maximum for any one day from "0.80" to "1.80".

6. On page 62236, column 3, line 35, the table in § 410.65 is corrected by changing Subpart E—Hosiery Products, NSPS, Total chromium limitation, average of daily values for 30 consecutive days, from "0.003" to "0.03".

7. On page 62237, column 2, line 61, § 410.67 is corrected by changing "a" after "provided" to "as".

8. On page 62238, column 1, line 4, § 410.70 is corrected by inserting "]" after "backing".

9. On page 62238, column 2, the table in § 410.74 is corrected by deleting "5" after "COD".

10. On page 62238, column 3, line 56, the table in § 410.77 is corrected by

changing Subpart F, PSNS, Total zinc limitation, maximum for any 1 day," from "1.08" to "0.08".

11. On page 62240, column 2, line 39, the table in § 410.95 is corrected by changing Subpart H, NSPS, Total phenol limitation, average of daily values for 30 consecutive days, from "0.006 to "0.0006".

12. On page 62241, column 3, line 38, § 410.107 is corrected by deleting "After November 23, 1979."

Dated: November 26, 1979.

Swep T. Davis,

Assistant Administrator Office of Water and Waste Management.

[FR Doc. 79-37307 Filed 12-3-79; 8:45 am]

BILLING CODE 6560-01-M

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40 CFR Part 425

[FRL 1368-8]

Leather Tanning and Finishing Point Source Category Effluent Limitations Guidelines; Pretreatment Standards and New Source Performance Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of comment period.

SUMMARY: On July 2, 1979, EPA proposed regulations under the Clean Water Act to limit effluent discharges to waters of the United States and the introduction of pollutants into publicly owned treatment works from facilities engaged in processing animal hides and skins into finished leather (44 FR 38746–38776). EPA is extending the period for comment on the proposed regulations from November 26, 1979, until February 25, 1980.

DATES: Comments on the proposed regulations for the leather tanning and finishing industry (44 FR 38746) must be submitted to EPA by February 25, 1980.

ADDRESS: Send comments to: Mr. Donald F. Anderson, Effluent Guidelines Division (WH–552), Environmental Protection Agency, 401 M Street S.W., Washington, D.C. 20460, Attention: Docket Clerk, Proposed Leather Tanning Rules. The supporting information and all comments on this proposal will be available for inspection and copying at the EPA Public Information Reference Unit, Room 2404 (Rear) PM–213. The EPA information regulation (40 CFR Part 2) provides that a reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Donald F. Anderson, (202) 426–2707.

SUPPLEMENTARY INFORMATION: On July 2, 1979, EPA proposed regulations to limit effluent discharges to waters of the United States and the introduction of pollutants into publicly owned treatment works from facilities engaged in processing animal hides and skins into finished leather (44 FR 38746–38776). The proposal provides effluent limitations guidelines for "best practicable technology", "best available technology", and "best conventional technology", and establishes new source performance standards and pretreatment standards under the Clean Water Act. The July 2 notice stated that comments on the proposal were to be submitted within 60 days from the date of availability of the technical development document for the proposed regulations. On September 26, 1979, EPA published a Notice of Availability of the technical development document and economic analysis, which stated that the comment period would end November 26, 1979. See 44 FR 55401.

On September 27, 1979, the Tanners' Council of America (TCA), the trade association representing nearly the entire tanning industry, sent to EPA a letter requesting that the comment period be extended for six months. The TCA reiterated and amplified this request in a meeting with EPA representatives on November 9, 1979.

Although the TCA's letter advanced several justifications for its request, the thrust of its comments on November 9, 1979, concerned alleged inaccuracies in EPA's technical data base, particularly regarding plant flows, and alleged underestimation of treatment costs. The Tanners' Council expressed its desire to submit meaningful comments on the proposed regulations, including technical and economic studies by TCA's consultants, which, in its opinion, would require a six month extension of the comment period.

While EPA desires and encourages maximum public participation in its rulemakings, the Agency believes that a six month extension of the comment period would be unreasonable and unwarranted. EPA's technical data base has been provided primarily by the industry; and while a portion of the industry has submitted data, many facilities have failed to do so, despite follow-up letters and telephone calls from the Agency.

Moreover, in the notice of proposed rulemaking on July 2, 1979, EPA expressed its concerns about the adequacy and accuracy of its data base. In the "Solicitation of Comments" portion of the preamble, EPA (1) requested voluntary sampling and analyses and data submission by the industry; (2) noted anomalies or potentially erroneous data and requested that "plants review all data submitted to the Agency, including data for flow and production, to insure their accuracy"; (3) recognized the importance of proper estimation of control costs and sought detailed cost data; and (4) stated that "[p]lants which have not submitted data, or which have compiled more recent data or engineering studies than already submitted, are requested to forward these data to EPA." See 44 FR 38765–5. Despite the foregoing, EPA has received little, if any, additional data from the industry.

Nonetheless, EPA is very concerned about the allegation of the Tanners' Council that the data base contains serious inaccuracies and understated treatment costs. In addition, the Agency is aware that some supporting data, including the economic analysis, were not available for review on the anticipated dates.

Therefore, EPA is extending the period for comment on the proposed regulations for the leather tanning and finishing industry (44 FR 38746) until February 25, 1980. The basis for this extension is premised on several understandings between the Agency and the Tanner's Council.

First, the Tanners' Council will immediately begin its review of EPA's technical data base, and within 45 days of November 26, 1979, will provide EPA with all data corrections. Second, by December 3, 1979, the Tanners' Council will provide EPA with the models and other information thus far generated by its consultants. Third, by December 26, 1979, the Tanners' Council will provide EPA with updated economic data to characterize the industry. Within 60 days of November 26, 1979, EPA intends to publish in the **Federal Register** a notice of availability of additional data for review during the remaining thirty days of the comment period.

This extension of the period for comment on the regulations proposed on July 2, 1979, is not limited to the Tanners' Council. EPA encourages all interested persons to submit comments by February 25, 1980.

Dated: November 27, 1979.

Swep T. Davis,

Assistant Administrator for Water and Waste Management.

[FR Doc. 79-37252 Filed 12-3-79; 8:45 am]

BILLING CODE 6560-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

Center for Disease Control

42 CFR Parts 85 and 85a

Decision To Develop Regulations on NIOSH Research Investigations and Health Hazard Evaluations

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Center for Disease Control, PHS, HEW.

ACTION: Notice of Decision to Develop Regulations.

SUMMARY: As part of HEW's "Operation Common Sense" program, NIOSH is proposing to develop integrated regulations to cover NIOSH research investigations and health hazard evaluations. At the present time, two regulations cover NIOSH investigative procedures (42 CFR Parts 85 and 85a). Many of the procedures in the two regulations are essentially the same. Having a single regulation for the various types of research investigations will eliminate duplicate provisions, reduce procedural errors, and cause less confusion for the public. The revisions are expected to be primarily technical changes to clarify and simplify existing procedures; however, NIOSH will review policies in the regulations to determine if changes in procedures are indicated. To assure adequate public participation, these revisions will be published as a proposed rule with a 60-day comment period.

FOR FURTHER INFORMATION CONTACT: Ms. Mary L. Flint, Regulations Specialist, National Institute for Occupational Safety and Health, 5600 Fishers Lane (Room 8–11), Rockville, MD 20857. Phone: (301) 443–3745.

Dated: November 28, 1979.

Julius B. Richmond,

Assistant Secretary for Health.

[FR Doc. 79-37304 Filed 12-3-79; 8:45 am]

BILLING CODE 4110-87-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR PART 90

[PR Docket No. 79-315; FCC 79-757]

Providing for Operation of Tactile Paging Devices for the Deaf, Blind, and Physically Handicapped

AGENCY: Federal Communications Commission.

ACTION: Notice of Proposed Rule Making.

SUMMARY: The FCC proposes to permit operation of paging stations using digital techniques by the deaf, deaf-blind, and others who have severe physical handicaps. Two frequencies are proposed to be allocated for this purpose, 35.02 and 43.64 MHz. Existing licensees on these frequencies would not be displaced.

DATES: Comments and Reply Comments are due by February 5, 1980, March 6, 1980.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Arthur C. King, Private Radio Bureau, (202) 632–6497.

In the matter of amendment of Part 90 of the Commission's rules to provide for operation of tactile paging devices for the deaf, blind, and physically handicapped. (PR Docket No. 79–315, RM–2001)

Adopted: November 20, 1979; Released: December 4, 1979.

1. Bell & Howell Communications Company (B & H) has filed with the Commission a petition requesting amendment of the rules to provide for the operation of tactile paging devices for persons with total or nearly total hearing loss. The petition was originally filed as a comment in Docket 19185. In that Docket, we provided for auditory training devices operating in the 72–76 MHz band under Part 15 of the Rules. While that proposal was under consideration, B & H submitted comments requesting that their tactile pager proposal be included in whatever action was taken, or alternatively, that a new proceeding be opened. Since the B & H proposal was beyond the scope of Docket 19185, it was not acted upon at that time. However, the proposal does have merit and we are therefore proposing its adoption.

2. Throughout the United States approximately 6 percent of the population is handicapped by various degrees of deafness.[1] These range from the 400,000 who are totally deaf, unable to hear any sound of any intensity, to the 10,800,000 whose hearing is impaired to the extent that they require some kind of hearing aid. There are 800,000 who cannot understand any kind of speech unless it is amplified to a medically dangerous level. These are the people who could be helped with a paging device which vibrates instead of emitting a tone or voice message.

3. There have been a number of Commission actions dealing with the needs of the deaf and the hearing impaired. Docket 19185 dealt primarily with a means of providing strong, distortionless reproduction of the human voice for persons having moderate hearing deficiencies. It was principally for use within an enclosed area such as a school environment. Similarly, Part 15 devotes Subpart G to auditory training devices and provides for their use as restricted radiation devices without licensing in institutional education programs for persons having speech or hearing deficiencies. Recently, in Docket 78–50, a Notice of Inquiry explored the communication needs of the deaf and of the barriers to establishment of a teletype service especially keyed to their unique problems, over existing toll teletype circuits. There is also now under development by three television networks, a system using line 21 of the vertical blanking interval of the television frame, (Docket 20693) for digital transmission and alpha-numeric display of textual matter at the bottom of the TV screen, for the benefit of the deaf. All of these systems would be of value to the deaf in a variety of ways but none touches upon the areas addressed by the petitioner, the need of a mother to call a deaf child from play, the requirement of a teacher in a school to gain the attention of a deaf child or children at a distance, the need of a deaf person to be alerted when a smoke detector or burglar alarm is actuated in the night, or to know when the telephone or doorbell is ringing. These and other applications outside the classroom and home as well as within are the areas addressed in this proposal. There is no overlap but considerable contiguity in the systems the Commission has previously considered and those in this Notice.

4. The tactile paging unit proposed for use by B & H would not provide for voice communication. It would be activated by a coded tone and would thereupon vibrate so the deaf person wearing or carrying the pager would be alerted. He could then press the transmit button sending an acknowledgement signal to the person at the paging point. Pagers for use in institutions where a large number of people would be paged at one time would probably be receivers only, without transmitting capability, it being understood that the persons paged would respond in a certain agreed-upon manner.

5. Specifically, the B & H Petition requests:

[1] Jerome D. Schein and Marcus T. Delk, Jr., *The Deaf Population of the United States* (National Association of the Deaf, (1974) p. 4, "National Census of the Deaf Population" (1971)).

a. An exclusive frequency for paging the deaf [2] via a tactile paging receiver.

b. Transmitter power levels of 10 watts for base stations and 3 watts for hand-held units. The hand-held unit would be used by the deaf person to respond to a call.

c. Simplified application form similar to the Citizens Radio Service application.

d. Exemption from a filing fee for persons with hearing acuity below a specified level, parents/guardians of such persons, and schools and other institutions for the deaf.[3]

6. The petitioner states that an exclusive frequency is needed for the tactile pagers since operation on a shared frequency could result in capture of the pagers by nearby powerful voice transmitters with calls missed because of such interference. The petitioner requested a frequency in the range 150–160 MHz but indicated that the cost of equipment could possibly be reduced if a lower frequency could be found. To meet the stated requirement and because no suitable frequency is available in the 150 MHz range, we propose to establish a new eligibility category in the Special Emergency Radio Service and to make two frequencies rather than one available (for reasons developed hereafter), specifically limited to persons with hearing deficiencies as defined and to such other persons whose medically certified handicaps require them to have the ability to summon help if needed. Additionally, we propose to include parents and guardians of such handicapped persons and institutions devoted to the care and training of the deaf-blind and physically handicapped.[4] It might be argued that the licensees under the proposed system do not properly fit any of the existing categories of the Special Emergency Radio Service. The same could have been said of beach patrols, ski patrols, Veterinarians, and school buses before they became eligible in that service. It would seem that handicapped people fit into the Special Emergency Radio Service at least as well as do any of the users mentioned. Since the proposed system is related to the physical condition of the users, it appears to be suited to the Special Emergency Radio Service in much the same way as other medical paging operations in that service.

7. Although not specifically touched upon by the petitioner, we are proposing that the rules provide for digital messages to be transmitted if desired, along with the paging signal. We believe this could be of significant value to the deaf if light emitting diode or liquid crystal alpha-numeric readout were provided or, to the deaf-blind, if tactile, braille-type readout were incorporated into the paging receiver. Since there is also a need in many instances for the deaf and deaf-blind to let the caller know the call has been received, we are also proposing that two-way paging be permitted. With this capability, the person could push a button and transmit an acknowledgement signal.

8. Developments over the past few years in the fields of large scale integration and microcomputers open a number of possibilities that were not apparent when the original B & H petition was filed. Consequently, we are enlarging the proposal to take full advantage of the latest technology. We believe enough memory and logic to provide for a number of sub-channels and message processing and storage can be incorporated on a small chip at modest cost. This type of capability may make it desirable to limit emission to F9Y to permit sub-channeling, making one channel the equivalent of ten or more using conventional tone paging techniques. Using F9Y emission and a bit rate of 1200 bits per second, a paging transmission and a message of nearly 150 letters could be transmitted in one second. Shorter messages would require proportionately less time. This technique would permit large numbers of handicapped people to transmit within a single channel with minimal interference since the statistical likelihood of any two transmitting at the same moment within range of each other is quite small. If this did happen, capture effect would permit at least one message to be received unless the two signals were of almost identical strength. This is not to say that two users in close proximity to each other could transmit their messages simultaneously. There would clearly be destructive interference. It is to say that a user, such as a school for the deaf could assign sub-channels for discrete purposes and use one or more at a time without the various sub-channels interfering with one another. It would also be practical for several users in a given area to agree among themselves to use certain sub-channels so that they would not receive one another's paging messages.

9. If this technique were used it might be possible to provide for not only the deaf and deaf-blind, but other handicapped persons as well, who have needs for communications similar to those of the deaf. We would like, if possible, to provide for all of the severely handicapped who have no way of communicating when necessary, calling for help from an overturned wheelchair, for example. This and other applications become feasible if the channel space can be used efficiently. An institution for the training of deaf children could, by using the techniques described to derive sub-channels, provide a communications channel for each classroom or each separate kind of activity, all without disrupting any of the other channels.

10. Most of the same arguments can be made for including the physically handicapped among the eligibles in this proposal as would apply to the deaf and the deaf-blind. Physically handicapped persons have the same kind of problems involving mobility and the need for prompt warning in case of emergency. The primary difference is that they do not necessarily need tactile paging since they do have hearing ability. This, however, is a minor difference. Regular paging channels or citizens band paging are equally unsatisfactory for the physically handicapped as they are for the deaf. Regular paging channels are dominated by high power stations that would make low power paging by the deaf and handicapped impossible. None of the existing citizens band channels is suitable for paging due to overcrowding, aside from the existing restriction against use of frequency modulation. If digital paging were authorized in the General Mobile Radio Service, not only could there be an interference problem from higher powered stations but there would be a cost penalty as well which the deaf and physically handicapped are, in general, ill equipped to handle. For these reasons we are including the handicapped as well as the deaf in our proposal.

11. We are therefore proposing that not only the deaf and deaf-blind, but persons who are otherwise physically handicapped as well, be defined as eligibles in the Special Emergency Radio Service. All would have to present medical certification attesting to their disability along with the license application. We are also proposing to limit authorization of F9Y emission so as to maximize channel capacity and to thereby provide for the expanded numbers of licensees that eligibility

[2] Persons having a hearing deficiency such that average hearing threshold levels are 90DB above ANSI (American National Standards Institute) 1969 or ISO (International Standards Organization) 1964 reference levels and such other persons who submit medical certification of similar hearing deficiency.

[3] No longer pertinent but may become so should filing fees be assessed again in the future.

[4] Throughout this notice the term "physically handicapped" is used to differentiate persons with motor problems or loss of limbs from those with hearing deficiencies.

expansion makes probable without undue channel congestion.

12. Section 90.425 of the Commission's Rules requires stations to be identified either by voice or Morse Code using automatic or live techniques. Absent such identification, stations suffering harmful interference and our Field Operations Bureau field personnel are forced to operate at a disadvantage. At the same time though, we recognize that the addition of voice or Morse Code identification will increase by many times the air time for each transmission with the message requiring a few tens or hundreds of milliseconds and identification requiring several seconds. Aside from the air time is the matter of increased cost. Voice or code capability in addition to the F9Y emission proposed will raise the total cost per unit substantially. We do not wish to see any sizable part of the potential beneficiaries of this proposal denied participation because of cost.

13. Considering the short duration of a digital paging transmission, the probability of very low concentrations of such stations, and the resulting low interference potential, we believe that Morse Code or voice identification should not be required. The appendix at Section 90.425(d)(6) reflects exemption of the identification requirement for tactile paging stations.

14. We solicit comments from manufacturers of electronic equipment addressing the economics of these proposals as well as the probable retail costs to the users, taking into account the effects of volume production. Since the handicapped are not, as a group, affluent, it is highly desirable that the cost of all units, both base and hand-carried, be kept to a minimum. We foresee mass distribution of these units if rules are adopted permitting their use and hope that a public-spirited organization with extensive distribution facilities may be induced to market them at minimum markup to the handicapped.

15. We recognize that tactile paging units might be useful to persons with significant hearing impairments not meeting the criteria as specified in footnote 2, yet we are also mindful that the number of pagers in use in a given area is limited by the allocation of only one frequency pair. We will welcome comments addressed to the establishment of a reasonable hearing threshold for use of the tactile pagers.

16. With only 44 licensees nationwide, 43.64 MHz offers the advantages of light loading, low equipment cost for the handicapped, and good coverage. This frequency is presently allocated to the Special Emergency Radio Service and representatives of that service have voiced dissatisfaction with low band frequencies because of skip problems during the present peak sun spot portion of the solar cycle. It will be several years before the sun spot numbers subside sufficiently to again permit effective low band Special Emergency Radio Service use without skip problems and by then we anticipate fairly heavy shifts to the 800 MHz region. For these reasons we are proposing to authorize operation of paging base stations for the deaf, blind, and physically handicapped on 43.64 MHz while continuing to authorize existing Special Emergency Radio Service stations on a secondary basis after December 31, 1984. Until that date, existing stations authorized after January 1, 1980, in the Special Emergency Radio Service and digital paging stations will be on a co-equal basis. We do not anticipate any severe skip problems from digital paging station users during the current sun spot cycle because of the low power, short distance nature of this type of paging application though there may be some interference to them from higher powered distant Special Emergency Radio Service paging stations when skip brings them in for short periods. Normally, even during the period of high sun spot activity, the digital paging stations should be largely immune to interference because they will respond only to digital modulation modes.

17. A second channel would permit two-channel simplex (also known as half-duplex) operation with the base stations on one channel and all mobile units on the other. This would offer the same advantages as two channel operation provides users of the land mobile frequencies where mobile units do not have to compete with higher powered base stations. It would be of particular advantage to users of several sub-channels with some mobile units strapped for one sub-channel and some for another. We are proposing that the mobile units be permitted to use 35.02 MHz which is presently allocated for low power mobile use in the Business Radio Service. We further propose that the Business, deaf, and physically handicapped users be on a co-equal basis rather than placing one on a secondary basis. Since 35.02 MHz is lightly used, with only 180 licensees nationwide, we are confident that the two groups can co-exist with little if any disruption to either. The deaf and handicapped users will, by and large, be in residential neighborhoods where there is little likelihood of interference to Business Radio Service users which are predominantly in industrial areas. Accordingly, we propose to permit use of 35.02 MHz in the Special Emergency Radio Service for digital paging mobile units only, while continuing to license low power mobile units in the Business Radio Service.

18. The power levels requested by B & H would be sufficient to permit reliable communications over a distance of ¼ to ½ mile and response with hand-carried units over the same distance. Under some conditions they contend such as in institutions where the signal must penetrate to interior spaces, B & H says higher power may be required and they requested up to 30 watts ERP (Effective Radiated Power) for such installations. In all cases the hand-carried units would be limited to a transmitter power of 3 watts. Since it is anticipated that the hand-carried units would be designed with ferrite loops instead of whip antennas, the effective radiated power would be greatly reduced, to the order of a fraction of a watt. Even if some were used with whip antennas (which are far less efficient than a dipole) the effective radiated power would still be below two watts which is the amount of power permitted in the Business Radio Service with no restriction in that service with respect to use of high gain antennas.

19. We do not believe that a two-tier power scheme is desirable for an obvious reason. Every applicant, fearing a stronger station nearby, would attempt to qualify for the maximum power. The result would be an added administrative burden on the Commission staff who would have to determine which applicant really needs the additional power and which does not. We believe that a waiver of the power limitation in those instances where a higher power base station is essential to the proper operation of a system is a more desirable alternative and this portion of the B & H petition will be denied. Maximum power, as proposed in the attached appendix will be 10 watts and high gain antennas will not be permitted except under exceptional circumstances. Waiver of either power or antenna gain (but not both) will only be granted in accordance with § 90.151.

20. B & H feels that a simple application form is necessary, that a form similar to the Personal Radio Class C or D application would be ideal. We agree that a simple form would be desirable and should rules eventually be adopted permitting tactile paging, such a form will be designed.

21. More than 20 years ago, in the General Mobile Allocation proceeding, the Commission announced the following two principles for evaluating requests for frequency allocations:

(A) . . . all radio services should not be evaluated alike. Radio services which are necessary for the safety of life and property deserve more consideration than those services which are more in the nature of convenience or luxury; and

(B) The Commission considered the total number of people who would probably receive benefits from a particular service. Where other factors were equal, the Commission attempted to meet the requests of those services which proposed to render benefits to large groups of the population rather than of those services which would aid relatively small groups.

22. This request for a very modest frequency allocation for a tactile paging system is fully consistent with both principles. The tactile paging system has a very definite safety application and will benefit a substantial segment of the population.

23. Therefore, the petition, RM–2001, filed by B & H is granted to the extent indicated in this Notice.

24. Regarding questions on matters covered in this document, contact Art King, telephone (202) 632–6497.

25. Pursuant to applicable procedures set forth in § 1.415 of the Commission's rules, interested persons may file comments on or before February 5, 1980, and reply comments on or before March 6, 1980. All relevant and timely comments and reply comments will be considered by the Commission before final action is taken in the proceeding. In reaching its decision, the Commission may take into consideration information and ideas not contained in the comments, provided that such information or a writing indicating the nature and source of such information is placed in the public file, and provided that the fact of the Commission's reliance on such information is noted in the Report and Order.

26. In accordance with § 1.419 of the Commission's Rules, an original and five (5) copies of all comments, reply comments, and other pleadings and submissions shall be furnished to the Federal Communications Commission, Washington, D.C. 20554. If it is desired for each Commissioner to have a copy of the submission an original and eleven (11) copies should be submitted. All documents will be available for public inspection during regular business hours in the Commission's Public Reference Room at its headquarters in Washington, D.C.

27. The proposed amendments to the rules as set forth in the appendix are issued pursuant to the authority contained in Sections 4(i), 303(b), (f), and (r) of the Communications Act of 1934, as amended.

Federal Communications Commission,

William J. Tricarico,

Secretary.

Appendix

Part 90 of Chapter 1 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 90—PRIVATE LAND MOBILE SERVICES.

1. Add a new § 90.38, Physically Handicapped, as follows:

§ 90.38 Physically handicapped.

(a) *Eligibility.* (1) Any person having a hearing deficiency such that average hearing threshold levels are 90 DB above ANSI (American National Standards Institute) 1969 or ISO (International Standards Organization) 1964 levels and such other persons who submit medical certification of similar deficiency.

(2) Any person having visual acuity corrected to no better than 20/200 in the better eye or having a field of vision of less than 20 degrees.

(3) Any person, who, through loss of limbs or motor function, is confined to a wheelchair, or requires assistance when pursuing normal day-to-day activities.

(4) Parents or guardians of persons under 18 years of age but otherwise eligible under (1), (2), or (3) or institutions devoted to the care or training of those persons.

(b) *Special Eligibility Showing.* The initial application from a person claiming eligibility under paragraph (a) shall be accompanied by a statement from a physician attesting to the condition of the applicant or the applicant's child (or ward in case of guardianship).

2. In § 90.53(a), Frequencies available, the Special Emergency Radio Service frequency table is amended as follows:

§ 90.53 Frequencies available.

Special Emergency Radio Service Frequency Table

Frequency or band	Class of station(s)	Limitations
* * * * *		
35.02	Mobile	26
* * * * *		
43.64	Base	4, 27
* * * * *		

4. In § 90.53(b), new paragraphs (26) and (27) are added as follows:

§ 90.53 Frequencies available.

* * * * *

(b)* * *

(26) This frequency is available in this service only to persons eligible under the provisions of § 90.38(a) for operation of digital transceivers having a maximum power output of three watts using F9Y emission. This frequency is also available in the Business Radio Service on a co-equal basis with the Special Emergency Radio Service users.

(27) After December 31, 1984, this frequency will be available only on a secondary basis to those licensees holding valid authorizations as of January 1, 1980. No new licensees will be granted in this service for one-way paging after that date. Between January 1, 1980, and December 31, 1984, existing stations and digital paging stations will be on a co-equal basis. This frequency is available on a primary basis after December 31, 1984, to persons eligible for station licenses under the provisions of § 90.38(a). Only F9Y emission and power not exceeding 10 watts will be authorized. Antennas having gain greater than 0 dBd will not be authorized.

5. In § 90.75, Business Radio Service, amend the Business Radio Service Frequency Table under paragraph (b) as follows:

(b) * * *

Business Radio Service Frequency Table

Frequency or band	Class of station(s)	Limitations
* * * * *		
35.02	do	4, 5, 22
* * * * *		

6. In § 90.75(c) Delete "Reserved" at paragraph (5) and insert the following:

(c) * * *

(5) This frequency is also available in the Special Emergency Radio Service for low power digital paging use on a co-equal basis.

* * * * *

7. In § 90.425 amend paragraph (d) by addition of subparagraph (6) as follows:

(d) * * *

(6) It is a digital paging station authorized in accordance with the provisions of § 90.38(a).

* * * * *

[FR Doc. 79-37167 Filed 12-3-79; 8:45 am]

BILLING CODE 6712-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1100

[No. 37231]

Office of Rail Public Counsel, Petition; Filing Requirements for Substantial Rail Rate Increases on Specific Commodities

AGENCY: Interstate Commerce Commission.

ACTION: Notice of denial of rulemaking request.

SUMMARY: The Commission has denied a petition to establish procedural rules and policies for the processing of rate increases proposing substantial changes for one or a limited group of commodities. Rules are not necessary in this area. The Commission has established in prior cases what its approach to these types of proceedings will be and internal procedures have been developed which should alleviate petitioner's concerns.

FOR FURTHER INFORMATION CONTACT: Richard Felder—(202) 275–7693.

SUPPLEMENTARY INFORMATION:

The Office of Rail Public Counsel filed a petition on July 30, 1979, requesting the Commission to institute a proceeding (1) to establish special procedural rules to govern rail tariff increases of substantial impact on specific commodities, and (2) to issue a policy statement on such increases.

Petitioner argues that in cases involving substantial rail rate increases on specific commodities, protesting shippers have been unable to submit crucial information which is in the possession of the railroads but which is not required to be disclosed by the railroads. To remedy this situation, petitioner proposes a set of procedural rules that would require the railroads to submit additional detailed traffic and cost data in such cases. Petitioner also proposes a policy statement that would encourage Administrative Law Judges to assume a stronger managerial role in presiding over such cases.

We deny the request to institute the proceeding. We believe that no further rules are needed in such cases. A new set of formal rules could create unduly rigid filing requirements and might inhibit rate flexibility.

The Commission's Administrative Law Judges are aware of the importance and complexity of these cases. Prehearing Conferences can be used to define the scope of the proceeding and determine what cost evidence should be presented.

We contemplate that further discussion of the manner in which we intend to approach these cases will be a part of the decision to be issued shortly in No. 37063, *Increased Rates on Coal, L&N RR, October 31, 1978.*

It is ordered:

The Office of Rail Public Counsel's petition is denied.

Dated: November 26, 1979.

By the Commission, Chairman O'Neal, Vice Chairman Stafford, Commissioners, Gresham, Clapp, Christian, Trantum, Gaskins and Alexis. Vice Chairman Stafford was absent and did not participate in the disposition of this proceeding.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-37160 Filed 12-3-79; 8:45 am]

BILLING CODE 7035-01-M

Notices

Federal Register
Vol. 44, No. 234
Tuesday, December 4, 1979

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.

Advisory Council on Historic Preservation; Public Information Meeting

Notice is hereby given pursuant to § 800.6(b)(3) of the Council's regulations, "Protection of Historic and Cultural Properties" (36 CFR Part 800), that on December 18, 1979, at 7:30 p.m., a public information meeting will be held at the Chester Redshaw School, 216 Livingston Avenue, New Brunswick, New Jersey.

The meeting is being called by the Executive Director of the Council in accordance with § 800.6(b)(3) of the Council's regulations. The purpose of the meeting is to provide an opportunity for representatives of national, State, and local units of government, representatives of public and private organizations, and interested citizens to receive information and express their views concerning the proposed Hotel-Conference Center, an undertaking assisted by the Department of Housing and Urban Development that will adversely affect the Hiram Market Historic District, New Brunswick, New Jersey, a property eligible for the National Register of Historic Places. Consideration will be given to the undertaking, its effects on National Register or eligible properties, and alternate courses of action that could avoid, mitigate, or minimize any adverse effects on such properties.

The following is a summary of the agenda of the meeting:

I. An explanation of the procedures and purpose of the meeting by a representative of the Executive Director of the Council.

II. A description of the undertaking and an evaluation of its effects on the property by the City of New Brunswick.

III. A statement by the New Jersey State Historic Preservation Officer.

IV. Statements from local officials, private organizations, and the public on the effects of the undertaking on the property.

V. A general question period.

Speakers should limit their statement to 5 minutes. Written statements in furtherance of oral remarks will be accepted by the Council at the time of the meeting. Additional information regarding the meeting is available from the Executive Director, Advisory Council on Historic Preservation, 1522 K Street, NW, Washington, D.C. 20005, 202–254–3967.

Robert R. Garvey,
Executive Director.
November 28, 1979.
[FR Doc. 79-37181 Filed 12-3-79; 8:45 am]
BILLING CODE 4310-10-M

DEPARTMENT OF AGRICULTURE

Forest Service

Enhancement, Protection and Management of Cultural Resources

AGENCY: Forest Service, USDA.

ACTION: Extension of Public Comment Period.

SUMMARY: The Forest Service published proposed policy on Enhancement, Protection and Management of Cultural Resources as Part VI of 44 FR 182, September 18, 1979 (P. 54268). Comments were due November 19, 1979. Because some interested parties did not receive relevant background data in sufficient time to fully analyze the proposal, the comment period is hereby extended to December 10, 1979.

DATE: Comments due December 10, 1979.

ADDRESS: Send comments to Chief, Forest Service, P.O. Box 2417, Room 4236, South Building, Washington, D.C. 20013

FOR FURTHER INFORMATION CONTACT: Dr. Janet Friedman, Cultural Resource Specialist, USDA, Forest Service, Room 4236, South Building, Washington, D.C. 20013 (447–3093).

R. Max Peterson,
Chief, Forest Service.
[Doc. 79-37191 Filed 12-3-79; 8:45 am]
BILLING CODE 3410-11-M

Office of the Secretary

Privacy Act of 1974; Systems of Records; Annual Publication

Pursuant to 5 U.S.C. 552a(e)(4), the Department of Agriculture hereby republishes its annual notice of the existence and character of the systems of records currently maintained pursuant to the Privacy Act of 1974. The last such Department of Agriculture annual republication was at 43 FR 51268 (November 2, 1978). The full text of the Department's systems of records was published at that time.

Since that time, the following additions, deletions, and revisions have been published:

43 FR 60628 (12/28/78)—Publication of FS-47, Placement Availability System;
44 FR 5171 (1/25/79)—Revision of OIG 1-6;
44 FR 36214 (6/21/79)—Publication of FS-48, YCC Long Term Benefit Evaluation;
44 FR 40367 (7/10/79)—New routine use added to ASCS-15, Farmers' Name and Address Master File;
44 FR 40909 (7/13/79)—Deletion of ESCS-6, Director's Study.

The above-cited **Federal Register** notices are printed in full below.

November 27, 1979.

Bob Bergland,
Secretary.

USDA/FS-47

SYSTEM NAME:

Forest Service Placement Availability System, USDA/FS.

SYSTEM LOCATION:

The records in this system are maintained in the Forest Service Headquarters Office in Washington, D.C., Regional Offices, and Research Station Offices as listed in 36 CFR 200.2, Subpart A.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Permanent full-time Forest Service employees in two-grade interval series, grades GS–9 through GS–14, in organizational units which have a Placement Availability System.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system includes information on above employees' availability for lateral reassignment (geographic availability, functional specialities for which available, reasons for desired move, and supervisor's comments).

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

5 CFR 335.102.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records may be stored in the Fort Collins Computer Center (FCCC) or manually in file folders.

RETRIEVABILITY:

Records are indexed by last name, social security number, position, organizational unit, category of availability, and category of organizational interest.

SAFEGUARDS:

Records are kept in either locked filing cabinets or on tapes which are accessible by special code.

RETENTION AND DISPOSAL:

Records will be maintained on individuals in the Forest Service or organizational units which elect to have a Placement Availability System. Records may be maintained on employees who have voluntary applications on file for lateral reassignment to organizational units which elect a Placement Availability System. Records will be destroyed on individuals who leave organizational units which have a Placement Availability System.

SYSTEM MANAGER(S) AND ADDRESS:

Director of Personnel Management, Forest Service, U.S. Department of Agriculture, Room 910 RP–E, P.O. Box 2417, Washington, D.C. 20013, or the appropriate Regional Personnel Officer or the appropriate Research Station Deputy Director for Administrative Support Services.

NOTIFICATION PROCEDURE:

Any employee may request information regarding the system of records, or information as to whether the system contains records pertaining to him or her from the system manager. A request for information should contain the individual's name and social security number and organizational unit.

RECORD ACCESS PROCEDURES:

Use same procedures as for requesting notification.

CONTESTING RECORD PROCEDURES:

Individual records may be amended or updated at any time, as the individual employee desires. Any part of an employee's record may be contested by that individual. The servicing personnel office will provide procedural advice.

RECORD SOURCE CATEGORIES:

The information in the records is furnished by the individual employee, and/or the employee's immediate supervisor.

USDA/OIG–1

SYSTEM NAME:

Employee Records, USDA/OIG.

SYSTEM LOCATION:

In the Headquarters Office in the Agriculture Administration Building, 14th and Independence Avenue, S.W., Washington, D.C. 20250, and in the following U.S. Department of Agriculture, Office of Inspector General, Regional Offices and suboffices:

OIG Regional Offices

26 Federal Plaza, Room 1707, New York, New York 10007.
8930 Ward Parkway, P.O. Box 205, Kansas City, Missouri 64141.
555 Battery Street, Room 522, San Francisco, California 94111.
101 South Main, Room 324, Temple, Texas 76501.
422 Federal Center Building, Hyattsville, Maryland 20782.
1 North Wacker Drive, Room 800, Chicago, Illinois 60606.
1447 Peachtree Street, N.W., Room 901, Atlanta, Georgia 30309.

OIG/Audit Suboffices

Federal Building, Harrisburg, Pennsylvania 17108.
Federal Building, Marlboro, Massachusetts 01752.
Federal Building, Syracuse, New York 13260.
Federal Office Building, Hato Rey, Puerto Rico 00917.
Federal Building, Little Rock, Arkansas 72201.
P.O. Box 29383, New Orleans, Louisiana 70189.
P.O. Box 16393, Jackson, Mississippi 39206.
P.O. Box 15067, Nashville, Tennessee 37215.
310 New Bern Avenue, Raleigh, North Carolina 27601.
333 Waller Avenue, Lexington, Kentucky 40504.
Box 14153 Main Post Office, St. Louis, Missouri 63178.
167 Federal Building, Des Moines, Iowa 50309.
276 Federal Building, Lincoln, Nebraska 68508.
571 Federal Building, St. Paul, Minnesota 55101.
200 North High Street, Columbia, Ohio 43215.
5610 Crawfordsville Road, Indianapolis, Indiana 46224.
2490 West 26th Avenue, Denver, Colorado 80211.
1711 Federal Building, Portland, Oregon 97204.
P.O. Box 1363, Huron, South Dakota 57350.
135 South State Street, Salt Lake City, Utah 84111.
24,000 Avila Road, Laguna Niguel, California 92677.

OIG/Investigation Suboffices

U.S. Court House, Hato Rey, Puerto Rico 00918.
600 Dekalb Pike, King of Prussia, Pennsylvania 19406.
310 New Bern Avenue, Raleigh, North Carolina 27611.
4004 Hillsboro Road, Nashville, Tennessee 37215.
5305 Executive Place, Jackson, Mississippi 39206.
200 North High Street, Columbia, Ohio 43215.
2490 West 26th Avenue, Denver, Colorado 80211.
P.O. Box 1363, Huron, South Dakota 57350.
100 Centennial Mall North, Lincoln, Nebraska 68508.
24,000 Avila Road, Laguana Niguel, California 92677.
511 Northwest Broadway, Portland, Oregon 97209.
522 N. Central Avenue, Phoenix, Arizona 85004.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

OIG temporary and permanent employees, former employees of OIG and predecessor offices, and applicants for employment.

CATEGORIES OF RECORDS IN THE SYSTEM:

These records show personnel management and work-related information, including position, title, grade, pay rate, pay, temporary and permanent address, phone number, performance evaluations, promotions, travel information, accident reports and related information, activity reports, participation in savings and contribution programs, availability for employment, for assignment, or for transfer, qualifications, awards, hours worked, issuance of credentials, passports, and other identification, assignment and accountability of property and other things of value, parking space assignments, training and development, and special assignments.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub. L. 95–452, 5 U.S.C. 301, 7 CFR 2.33.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

To other agencies in the Department and Executive Branch agencies, such as the Civil Service Commission, as necessary, for proper personnel actions.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on computer and in file folders, notebooks, and card file boxes.

RETRIEVABILITY:

By name of individual employee.

SAFEGUARDS:

Available on official need-to-know basis. Kept in locked offices after office hours.

RETENTION AND DISPOSAL:

Records are retained as long as needed and then discarded. Personal information that might be considered derogatory or embarrassing is burned when no longer needed.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Personnel Management Staff, OIG, U.S. Department of Agriculture, Washington, D.C. 20250.

NOTIFICATION PROCEDURE:

Inquiries should be addressed to Director, Policy, Liaison and Information Staff, OIG, U.S. Department of Agriculture, Washington, D.C. 20250.

RECORD ACCESS PROCEDURES:

To gain access to information in the system, send request to Director, Policy Liaison and Information Staff, OIG, USDA, Washington, D.C. 20250.

CONTESTING RECORD PROCEDURES:

To contest information in this system, send request to Director, Policy Liaison and Information Staff, OIG, USDA, Washington, D.C. 20250.

RECORD SOURCE CATEGORIES:

The primary information is furnished by the individual employee. Additional information is provided by supervisors, coworkers, references, and others.

USDA/OIG–2

SYSTEM NAME:

Intelligence Records, USDA/OIG.

SYSTEM LOCATION:

In the Headquarters Office in the Agriculture Administration Building, 14th and Independence Avenue, S.W., Washington, D.C. 20205, and in the OIG offices listed in the system of records designated USDA/OIG–1.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Suspects and unpaid informants.

CATEGORIES OF RECORDS IN THE SYSTEM:

Names, occupations, other information about suspects and allegations against them; and types of information previously furnished by or to be expected from informants.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub. L. 95–452, 5 U.S.C. 301, 7 CFR 2.33.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Routine uses for law enforcement purposes will include referral to the appropriate agency, whether Federal, State local or foreign, charged with the responsibility of investigating or prosecuting a violation of law or of enforcing or implementing the statute, rule, regulation or order issued pursuant thereto, of any record within this system when information available indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by rule, regulation, or order issued pursuant thereto.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Stored on sheets of paper and index cards.

RETRIEVABILITY:

Retrievable by name of individual subject.

SAFEGUARDS:

Available on an official need-to-know basis and kept in locked storage when not in use.

RETENTION AND DISPOSAL:

Kept indefinitely and continually updated; out-of-date material is burned.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Security and Special Investigations Division, Office of the Inspector General, Washington, D.C. 20250. Inquiries and requests should be addresed to: Director, Policy, Liaison and Information Staff, USDA, OIG, Washington. D.C. 20250.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

This system has been exempted from the provisions of sections (c)(3), (d), (e)(1), (e)(4) (G), (H), and (I) and (f) pursuant to 5 U.S.C. 552a(k)(2) as investigatory material compiled for law enforcement purposes. This exemption is contained in 7 CFR 1.123.

USDA/OIG–3

SYSTEM NAME:

Investigative Files and Subject/Title Index, USDA/OIG.

SYSTEM LOCATION:

In the Headquarters Office in the Agriculture Administration Building, 14th and Independence Avenue, S.W., Washington, D.C. 20250, and in the OIG Regional and Investigation Suboffices listed in the system of records designated USDA/OIG–1.

Except for inadvertent errors, all entries in regional office indexes are duplicated in the Headquarters index. Thus the Headquarters index is the only complete index in OIG. The Headquarters files also contain a copy of every investigative report, but not the correspondence in all cases. Older investigative files may be stored in Federal Records Centers or on microfiche. Therefore, delays in retrieving this material can be expected.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The individual names in the OIG index fall into one or more of the following categories:

Subjects. These are applicants for OIG employment or individuals against whom allegations of wrongdoing have been made. In some instances, these individuals have been the subjects of investigations conducted to establish whether allegations were true. In other instances, the allegations were deemed too frivolous or indefinite to warrant inquiry.

Principals. These are individuals who are not named subjects of investigative inquiries, but may be responsible for violations. For example, the president of a firm alleged to have violated laws or regulations would likely be individually listed in the OIG index.

Complainants. These are individuals who allege wrongdoing, mismanagement, or unfair treatment relating to USDA employees and/or programs.

Others. These are all other individuals closely connected with a matter of investigative interest or whose names have been checked through the index to determine whether they were of record. Among these names are those of people who are connnected with a matter only in that they have shown unusual interest in having allegations investigated or in learning the results of investigation. Also included in the index are the names of persons on the Department of Justice crime list.

CATEGORIES OF RECORDS IN THE SYSTEM:

The OIG Subject/Title Index and Investigative Files consist of:

1. Index cards and/or a microfiche index filed alphabetically by the names of individuals, organizations, and firms with a separate card or line items for each; dates of entries made into the index or dates of materials containing information about the named subjects; and identification of the OIG file or files containing information on that subject.

2. Files containing bound sheets of paper or microfiche of such sheets from investigative and other reports, correspondence, and informal notes and notations concerning (a) one investigative matter or (b) a number of incidents of the same sort of alleged violation or irregularity.

If such information was available when an index card or line item was made, the card or microfiche concerning an individual will include the individual's address, date of birth, and Social Security number.

3. Where investigation is being or will be conducted, but has not been completed, various case management records, investigator's notes, statements of witnesses, and copies of records. These are contained on index slips or cards and sheets of paper located in an OIG office or in the possession of the OIG investigator. Certain management records are retained after the investigative report is released as a means of following action taken on the basis of the OIG investigative report.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub. L. 95–4525, U.S.C. 301, 7 CFR 2.33.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Routine use for law enforcement purposes will include referral to the appropriate agency, whether Federal, State, local or foreign, charged with the responsibility for investigating or prosecuting a violation of law or or enforcing or implementing the statute, rule, regulation or order issued pursuant thereto, or any record within this system when information available indicates a violation or potential violation of law, whether civil, criminal or regulatory in nature, and whether arising by general statute or particular program statute, or by rule, regulation or order issued pursuant thereto.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

The OIG Subject/Title Index consists of 3 inch by 5 inch cards or microfiche line items stored cabinets, in steel cabinets. The investigative files are stored in steel lektriever cabinets, on microfiche sheets, or in Federal Records Centers.

RETRIEVABILITY:

The subject cards or line items are arranged alphabetically, and each card or line item identifies one or more OIG investigative case files or administrative files arranged numerically by file number. Iniformation in investigative or administrative files concerning individuals not indexed is considered irretrievable.

SAFEGUARDS:

These records are available within USDA and to others in the Executive Branch only upon proper identification and on a need-to-know basis. These records are kept in limited-access areas during duty hours and in locked offices at all other times.

RETENTION AND DISPOSAL:

The cards or line items are kept indefinitely and investigative case files are maintained for 15 years. However, certain investigative case files of unusual significance are kept indefinitely. Administrative files are kept for five years.

SYSTEM MANAGERS(S) AND ADDRESS:

Director, Management and Budget Staff, Office of the Inspector General U.S. Department of Agriculture, Washington, D.C. 20250.

RECORD ACCESS PROCEDURES:

To request acess to information this system, write to Direrctor, Policy, Liaison and Information Staff, Office of Inspector General, U.S. Department of Agriculture, Washington, D.C. 20250.

CONTESTING RECORD PROCEDURE:

To contest information in this system, send request to Director, Policy, Liaison and Information Staff, Office of Inspector General, U.S. Department of Agriculture, Washington, D.C. 20250 .

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

This system has been exempted from the provisions of sections (c)(3), (d), (e)(1), (e)(4)(G), (H), and (I) and (f) pursuant to 5 U.S.C. 552a (k)(2) and (k)(5) as investigatory material compiled for law enforcement purposes or compiled solely for determining suitability, eligibility or qualifications for Federal civilian employment. This exemption is contained in 7 CFR 1.123.

USDA/OIG–4

SYSTEM NAME:

Liaison Records, USDA/OIG.

SYSTEM LOCATION:

Headquarters Offices in Agriculture buildings at 14th and Independence Avenue, S.W., Washington, D.C. 20250, and in the OIG offices listed in the system of records designated USDA/OIG–1.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Employees or officials of Federal, State, and local governmental agencies.

CATEGORIES OF RECORDS IN THE SYSTEM:

Such information as name, title, address, phone number, and type of assistance previously given or interest previously shown or expected.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub. L. 95–452, 5 U.S.C. 301, 7 CFR 2.33.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosed to other investigative agencies (e.g., FBI, Secret Service, IRS) to coordinate investigative efforts or for those agencies to use in their independent investigations and to facilitate referral to OIG investigative information to other Executive Agencies that have an official interest.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM.

STORAGE:

Index cards and sheets of paper.

RETRIEVABILITY:

By name of individual or by name of agency.

SAFEGUARDS:

Information is usually obtained from public records or previous contacts and is generally available to OIG employees and others on request. Records are in the custody of OIG employees during working hours and in locked offices at other times.

Retention and disposal:

Information is kept indefinitely and disposed of when updated. Out-of-date information is discarded.

SYSTEM MANAGER(S) AND ADDRESS:

Directors of the offices indicated in "System location."

NOTIFICATION PROCEDURE:

Inquiries and requests should be addressed to Director, Policy, Liaison and Information Staff, Office of the Inspector General, U.S. Department of Agriculture, Washington, D.C. 20250.

RECORD ACCESS PROCEDURES:

To gain access to information in this system, send request to Director, policy, Liaison and Information Staff, OIG, U.S. Department of Agriculture, Washington, D.C. 20250.

CONSTESTING RECORD PROCEDURES:

To contest information in this system, send request to Director, Policy, Liaison and Information Staff, OIG, U.S. Department of Agriculture, Washington, D.C. 20250.

RECORD SOURCE CATEGORIES:

Public documents and directories and previous contacts with individuals listed.

USDA/OIG–5

SYSTEM NAME:

Management Information and Data Analysis System, USDA/OIG.

SYSTEM LOCATION:

Computer files are maintained on the Computer Sciences Infonet System with main offices at 650 North Sepulveda, El Segundo, California. Source documents and printouts are kept in OIG Headquarters, U.S. Department of Agriculture, 14th and Independence Avenue, S.W., Washington, D.C. 20250 and in the OIG regional offices listed in the system of records designated as USDA/OIG–1 (with the exception of the New York Regional Office).

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

OIG professional audit employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

The Management Information and Data Analysis System provides audit management officials with a wide range of information on audit operations, including job performance of OIG professional audit personnel in grade GS–13 and below. The system identifies individual audit assignments of employees and provides information on their use of direct and indirect time; significant dates relating to each audit such as starting date, exit conference date, and report release date; the number and significance of audit findings and the identity of all the professionals who participated in the assignment.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub. L. 95–452, 5 U.S.C. 301; 7 CFR 2.81.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Provided upon request to the General Accounting Office for reviewing OIG audit operations. Disclosure may also be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Computer discs and/or magnetic tape.

RETRIEVABILITY:

Information in the system can be retrieved by OIG Headquarters and regions. Information can be retrieved by audit report number, employee Social Security number, or geographic location.

SAFEGUARDS:

Normal computer security is maintained over access to discs and magnetic tapes. printouts are available within USDA as necessary and are kept under lock and key when not in use. Source documents are kept in file cabinets in the offices listed above.

RETENTION AND DISPOSAL:

Discs and/or magnetic tapes are cleared, retired, or destroyed, when no longer useful, in accordance with General Services Administration and USDA retirement and/or destruction schedules.

SYSTEM MANAGER(S) AND ADDRESS:

Assistant Inspector General for Audits, Office of the Inspector General, U.S. Department of Agriculture, Washington, D.C. 20250.

NOTIFICATION PROCEDURE:

Any individual may request information regarding this system of records, or information as to whether the system contains records pertaining to him, from the Director, Policy, Liaison and Information Staff, USDA-OIG, Washington, D.C. 20250. A request for information pertaining to an individual should contain: Name, address, and particular information requested.

RECORD ACCESS PROCEDURES:

Any individual may obtain information as to the procedures for gaining access to a record in the system which pertains to him by submitting a written request to the Director, Policy, Liaison and Information Staff, OIG, U.S. Department of Agriculture, Washington, D.C. 20250.

CONTESTING RECORD PROCEDURES:

Same as access procedures described above.

RECORD SOURCE CATEGORIES:

Information in the system comes entirely from OIG audit employees.

USDA/OIG-6

SYSTEM NAME:

Audit Information System, USDA/OIG.

SYSTEM LOCATION:

Records included in this system may be located at audit sites throughout the United States or at any of the Departmental Computer Centers. The Departmental Computer Centers are: (1) Washington Computer Center, 12th and Independence Avenue, S.W., Washington, D.C. 20250; (2) New Orleans Computer Center, P.O. Box 60900, New Orleans, Louisiana 70160; (3) Kansas City Computer Center, P.O. Box 205, Kansas City, Missouri 64141; (4) St. Louis Computer Center, 1520 Market Street, Room 3441, St. Louis, Missouri 63103; (5) Fort Collins Computer Center, 3825 East Mulberry Street, Fort Collins, Colorado 80521.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system employs temporary data sets, computer printouts, and other audit records obtained from USDA agencies, non-Federal sources, and Federal agencies other than USDA. Individuals covered by these records are participants in programs administered and/or funded by the Department of Agriculture; employees of USDA and other Federal, State, county, and municipal agencies; and officials and employees of contractors, grantees, and cooperators that conduct business related to USDA programs.

CATEGORIES OF RECORDS IN THE SYSTEM:

The system may contain, for short periods of time, various categories of records relating to administration of, or individual participation in, USDA programs. For example, the categories of records may relate to the Department's farm, food, loan and research programs and to pay roll records of USDA or other governmental employees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Pub. L. 95–452, 5 U.S.C. 301, 7 CFR 2.33.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Records are routinely used for analysis during the course of Office of Inspector General (OIG) audits. To facilitate this analysis, USDA, other Federal, State, or other governmental computer tapes containing program participation or employement information may be matched against themselves or each other to find duplications that indicate possible improper or illegal participation in USDA programs. Matching may be conducted by OIG, other USDA agencies, other Federal agencies, and/or State, county, or municipal agencies. The computer printouts of duplicates may be furnished to OIG auditors and investigators, the non-Federal entity responsible for operating the program, other Executive Branch audit agencies, the General Accounting Office, the Department of Justice, other law enforcement agencies, and the Congress.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information is stored electronically on computer direct access storage devices or magnetic tape and in computer printouts and other audit records.

RETRIEVABILITY:

Electronically stored information may be retrievd using standard audit software analysis and retrieval packages and is limited only by the data elements maintained in the data set. This information may be transmitted and received using standard teleprocessing procedures. Data elements may include such information as an individual's name, address, social security numbers, employee identification, case or farm number, and specific information about the individual's program participation or employment. Information located in computer printouts and other audit records may be retrieved manually while audits are in process. After an audit is completed, information about individuals can only be retrieved by first identifying the audit involved (by type, location and time conducted) and then retrieving the information from audit work materials by mechanical or electronic search. If individual participation was investigated, personal privacy information about that individual may be retrievable, by name, from system USDA/OIG–3, described above.

SAFEGUARDS:

Normal computer security is maintained over access to electronically encoded data. Computer printouts and other audit records are protected in accordance with the sensitivity of data contained therein.

RETENTION AND DISPOSAL:

Electronically encoded data is seldom retained for more than six months. It is then destroyed either by degaussing or overwriting the computer media. Computer printouts and manually prepared audit records may be incorporated into audit files where they are retrievable only by audit number or report title. Audit files are retained in accordance with General Services Administration retirement and/or destruction schedules. Computer printouts not incorporated into audit files are destroyed.

SYSTEM MANAGER(S) AND ADDRESS:

The system managers are the USDA Regional Inspectors General for Audits in whose geographical areas the audit sites and Departmental Computer Centers are located. These are as follows: (1) Regional Inspector General for Audits, Northeast Region, OIG, USDA, Room 422, Federal Building, Hyattsville, Maryland 20782 (Washington Computer Center); (2) Regional Inspector General for Audits, Southeast Region, OIG, USDA, 1447 Peachtree Street, N.E., Room 900, Atlanta, Georgia 30309; (3) Regional Inspector General for Audits, Midwest Region, OIG, USDA, 1 North Wacker Drive, Chicago, Illinois 60606; (4) Regional Inspector General for Audits, Southwest Region, OIG, USDA, Federal Office Building—Room 324, 101 South Main Street, Temple, Texas 76501 (New Orleans Computer Center); (5) Regional Inspector General for Audits, Great Plains Region, OIG, USDA, 8930 Ward Parkway, P.O. Box 205, Kansas City, Missouri 64141 (Kansas City, Fort Collins, and St. Louis Computer Centers); (6) (Regional Inspector General for Audits, Western Region, OIG, USDA, Room 522 Customs House, 555 Battery Street, San Francisco, California 94111.

NOTIFICATION PROCEDURE:

Any individual may request information contained in this system of records or information as to whether the system contains records pertaining to that individual by contacting the Director, Policy, Liaison and Information Staff, OIG, USDA, Washington, D.C. 20250. The individual is reminded that this system of records is temporary and usually is accessible only while an audit of a particular program or activity is in process. The period of accessibility normally ranges from one month to approximately six months, depending on the type of audit and the use made of the information. Any request for information pertaining to an individual should contain that person's name, address, the USDA program the individual is participating in, any pertinent identification number such as a case number, and the particular information requested. Proof of identity and/or authorization to access will be required.

RECORD ACCESS PROCEDURES:

Any individual may obtain information as to the procedures for gaining access to a record in the system which pertains to that person by submitting a written request to the Director, Policy, Liaison and Information Staff, OIG, U.S. Department of Agriculture, Washington, D.C. 20250.

CONTESTING RECORD PROCEDURES:

These inquiries also should be sent to the Director, Policy, Liaison and Information Staff, OIG, U.S. Department of Agriculture, Washington, D.C. 20250.

RECORD SOURCE CATEGORIES:

Information contained in this system of records is obtained mainly from USDA agencies and State and local governments that administer USDA programs on a cooperative basis and may be obtained from other grantees and program participants and other Federal agencies.

Information generally relates to a USDA program or activity which is being audited. Upon conclusion of the audit, the information is either destroyed, returned to the originator, or stored in an audit file from which information about individuals cannot be retrieved without manual and/or electronic search.

USDA/FS–48

SYSTEM NAME:

YCC Long-term Benefit Evaluation, USDA/FS.

SYSTEM LOCATION:

Rocky Mountain Forest and Range Experiment Station, 240 West Prospect Street, Fort Collins, CO 80521.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Former YCC enrollees and their parents or guardians, unsuccessful applicants to the YCC program and their parents or guardians, and indivuals in communities local to YCC camps.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name and address of above persons, signed statement of person's willingness to participate in the study, identification number for each person (not social security number), responses on questionnaires completed at each phase of the study by respondents. Questionnaires will solicit information from respondents on the benefits of the YCC program to the enrollees, to the parents, to the community, and to society in general. This information will pertain to the following broad classes of benefits:

a. Increased awareness and appreciation of the environment.

b. Improved work habits and work skills.

c. Improved ability to get along with others.

d. Increased self-confidence.

e. Improvement in the enrollee's basic orientation to life (greater awareness of and direction toward life goals, more physically fit, etc.).

f. Other related benefits of lesser significance.

Questionnaires will also solicit demographic information (race, sex, age, education, etc.) from enrollees.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

16 U.S.C. 1701–1706.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Disclosure may be made to Colorado State University and the U.S. Department of the Interior. Disclosure may be made to a Congressional Office from the records of an individual in response to an inquiry from the Congressional Office made at the request of that individual.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Information will be kept on keypunch cards or data tapes.

RETRIEVABILITY:

Names and addresses of respondents will be kept for the purpose of mailing questionnaires only. An ID number will be assigned to each individual and will be used to determine who has or has not returned the questionnaire and to trace the changes in responses. Names and/or addresses of the respondents will not be associated with the responses on the questionnaires in any way.

SAFEGUARDS:

The information on respondents obtained in the study is *not* potentially damaging, but all information will be kept in a small locked room. People who will have access to the information will be those directly involved with the evaluation study; the two principal investigators, the project director, two research assistants and the computer programmer and keypuncher. All personnel involved with the study will be instructed on the ge a04de3.205proper handling of the data.

RETENTION AND DISPOSAL:

The names and addresses will be destroyed by December 30, 1983. The remaining statistical data will be maintained indefinitely.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Human Resource Programs, USDA, Forest Service, 12th and Independence, Washington, D.C. 20013.

NOTIFICATION PROCEDURE:

Any individual may request information regarding the system of records, or information as to whether the system contains records pertaining to him by contacting the system manager.

RECORD ACCESS PROCEDURES:

To obtain information on the procedure for obtaining access to the records, write to system manager using the above address.

CONTESTING RECORD PROCEDURES:

Use the same procedures as for record access.

RECORDS SOURCE CATEGORIES:

Names and addresses of enrollees from lists of enrollees at each camp; parents of enrollees from the enrollees whose names are obtained from the camp lists; unsuccessful applicants maintained by YCC administrators in Washington, D.C. and from lists of unsuccessful applicants maintained by agencies in those states not included in the Washington, D.C. list; parents of unsuccessful applicants from the unsuccessful applicants; individuals in communities near YCC camps from those involved in the YCC program and others who would be aware of the people in the communities local to YCC camps who are knowledgeable about the program and could provide valuable information on the program's benefits; other categories are self-explanatory.

USDA/ASCS—15

SYSTEM NAME:

Farmer's Name and Address Master File (Automated) USDA/ASCS.

SYSTEM LOCATIONS:

Management Field Office, ASCS-USDA, 8930 Ward Parkway, Kansas City, Missouri 64114.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

All known farmers who reside in area served by the local county ASCS office.

CATEGORIES OF RECORDS IN THE SYSTEM:

Contains names and addresses and zip codes of all farmers and other information, such as, social security or producer identification number, race code, State and county code on farmers who participate.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

7 U.S.C. 135B, 450k, 1281–1393, 1421–1449, 1781–1787; 15 U.S.C. 714b and c; 16 U.S.C. 590a–590q, 1301–1311; 26 U.S.C. 6109.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

Furnished to (1) Internal Revenue Service to report total annual payments to each producer; (2) approved cooperative Marketing Associations for price support loan eligibility; (3) State and county taxing authorities and (4) Commodity Promotion Boards where producer funds are withheld by ASCS Disclosure may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual. Referral to Individual Congressmen, upon their request to provide information to their farmer constituency.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained on mag-tape by the Kansas City Computer Center at the address shown above.

RETRIEVABILITY:

Records are indexed by the producer identification number of the individual farmer, in State and county sequence.

SAFEGUARDS:

Records are kept in a fire proof vault in a secured area of Government office building.

RETENTION AND DISPOSAL:

Records of current producers are maintained indefinitely. Additions, deletions and corrections are made periodically.

SYSTEM MANAGER(S) AND ADDRESS:

Deputy Administrator, Management, ASCS, USDA, Washington, D.C. 20250.

NOTIFICATION PROCEDURE:

Any individual may request information regarding this system of records, or information as to whether the system contains records pertinent to him, from the Director, Management Field Office, Kansas City, Missouri 64114, telephone 816–926–6502. A request for information pertaining to an individual should contain: name, address, producer idenification number(s) and the ASCS county office(s) where the farm records are maintained.

RECORD ACCESS PROCEDURES:

Any individual may obtain information as to the Procedures for gaining access to a record in the system which pertains to him, by submitting a written request to the official referred to in the preceding paragraph.

CONTESTING RECORD PROCEDURES:

Same as Records Access Procedure.

RECORD SOURCE CATEGORIES:

Directly from individual and from documents submitted by the ASCS county office.

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BILLING CODE 3410–01–M

Rural Electrification Administration

Western Illinois Power Cooperative, Jacksonville, Ill.; Proposed Loan Guarantee

Under the authority of Pub. L. 93–32 (87 Stat. 65) and in conformance with applicable agency policies and procedures as set forth in REA Bulletin 20–22 (Guarantee of Loans for Bulk Power Supply Facilities), notice is hereby given that the Administrator of REA will consider (a) providing a guarantee supported by the full faith and credit of the United States of America for a loan in the approximate amount of $2,783,000 to Western Illinois Power Cooperative of Jacksonville, Illinois, and (b) supplementing such a loan with an insured REA loan at 5 percent interest in the approximate amount of $2,764,000 at this cooperative.

These loans will be used to finance a construction program consisting of 58 miles of 69 kV transmission lines, three 69 kV distribution substations, two 138/69 kV transmission substations, and miscellaneous transmission, generation and headquarters improvements.

Legally organized lending agencies capable of making, holding and servicing the loan proposed to be guaranteed may obtain information on the proposed program, including the engineering and economic feasibility studies and the proposed schedule for the advances to the borrower of the guaranteed loan funds from Mr. Donald B. Bringman, Manager, Western Illinois Power Cooperative, Inc., P.O. Box 609, Jacksonville, Illinois 62651.

In order to be considered, proposals must be submitted January 3, 1980 to Mr. Bringman. The right is reserved to give such consideration and make such evaluation or other disposition of all proposals received, as Western Illinois Power Cooperative, Inc., and REA deem appropriate. Prospective lenders are advised that the guaranteed financing for this project is available from the Federal Financing Bank under a standing agreement with the Rural Electrification Administration.

Copies of REA Bulletin 20–22 are available from the Director, Office of Information and Public Affairs, Rural Electrification Administration, U.S. Department of Agriculture, Washington, D.C. 20250.

Dated at Washington, D.C., this 26th day of November, 1979.

Robert W. Feragen,

Administrator, Rural Electrification Administration.

[FR Doc. 79–37030 Filed 12–3–79; 8:45 am]

BILLING CODE 3410–15–M

Soil Conservation Service

Pine Valley Watershed, Oregon; Deauthorization of Federal Funding

AGENCY: Soil Conservation Service, Department of Agriculture.

ACTION: Notice of Deauthorization of Federal Funding.

FOR FURTHER INFORMATION CONTACT: James W. Mitchell, Director, Watersheds Division, Soil Conservation Service, U.S. Department of Agriculture, P.O. Box 2890, Washington, D.C. 20013 (202–447–3527).

NOTICE: Pursuant to the Watershed Protection and Flood Prevention Act, Pub. L. 83–566, and the Soil Conservation Service Guidelines (7 CFR 622), the Soil Conservation Service gives notice of the deauthorization of Federal funding for the Pine Valley Watershed project, Baker County, Oregon, effective on November 13, 1979.

(Catalog of Federal Domestic Assistance Program No. 10.904, Watershed Protection and Flood Prevention Program, Pub. L. 83–566, 16 U.S.C. 1001–1008)

Dated: November 27, 1979.

Edward E. Thomas,

Assistant Administrator for Land Resources.

[FR Doc. 79–37222 Filed 12–3–79; 8:45 am]

BILLING CODE 3410–16–M

CIVIL AERONAUTICS BOARD

[Docket No. 36115]

South Pacific Island Airways Fitness Investigation; Postponement of Hearing

Notice is hereby given that the hearing in the proceeding previously scheduled to be held on December 20, 1979 (44 FR 64101, November 6, 1979) on the application of the South Pacific Island Airways filed in Docket 36115, is postponed indefinitely.

By telegram dated November 21, 1979, the applicant requested that a delay of 90 days from the scheduled hearing date be granted to enable the carrier to prepare its presentation based upon present market conditions, an evaluation of increased fare changes being proposed by the incumbent carrier, and the essential air service order recently issued by the Board for American Samoa. Since the postponement reqested by the applicant will necessitate a re-assignment to another judge, the rescheduling shall be contingent upon the receipt of a further request from the applicant for scheduling of the hearing.

Accordingly, the applicant is directed to advise the Chief Administrative Law Judge when it is ready to proceed; and, at that time, submit and circulate its exhibit materials and request that its application be rescheduled for hearing.

Dated at Washington, D.C., November 28, 1979.

Frank M. Whiting,

Administrative Law Judge.

[FR Doc. 79–37257 Filed 12–3–79; 8:45 am]

BILLING CODE 6320–01–M

[Order 79–11–187; Docket 34941]

Bahamasair Holdings, Ltd.; Application

AGENCY: Civil Aeronautics Board.

ACTION: Notice of Order to Show Cause, Order 79–11–187, on the Application of Bahamasair Holdings Limited, Docket 34941.

SUMMARY: The Board proposes to approve the following application:

Applicant: Bahamasair Holdings Limited.

Application Date: March 6, 1979. Docket 34941.

Authortiy Sought: Renew its foreign air carrier permit to operate scheduled

services, as well as charters, between The Bahama Islands and the coterminal points Miami, Palm Beach, Fort Lauderdale and Tampa, Florida; and to amend its permit to add the coterminal points Atlanta, Georgia; Chicago, Illinois; Detroit, Michigan; and Dallas, Texas.

OBJECTIONS: All interested persons having objections to the Board's tentative findings and conclusions that this authority should be granted, as described in the order cited above, shall, No Later Than, December 26, 1979, file a statement of such objections with the Civil Aeronautics Board (20 copies) and mail copies to the applicant, the Department of Transportation, the Department of State, and the Ambassador of The Bahamas in Washington, D.C. A statement of objections must cite the docket number and must include a summary of testimony, statistical data, or other such supporting evidence.

If no objections are filed, the Secretary of the Board will enter an order which will, subject to disapproval by the President, make final the Board's tentative finding and conclusions and issue the proposed permit or certificate.

ADDRESSES FOR OBJECTIONS: Docket 34941, Docket Section, Civil Aeronautics Board, Washington, D.C. 20428. George U. Carneal, Hogan & Hartson, 815 Connecticut Avenue, N.W., Washington, D.C. 20006, (202) 331–4500.

To Get a Copy of the Complete Order, request it from the C.A.B. Distribution section, Room 516, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428. Persons outside the Washington metropolitan area may send a postcard request.

FOR FURTHER INFORMATION CONTACT: C. Robert Mallalieu, Negotiations Division of the Bureau of International Aviation, Civil Aeronautics Board; (202) 673–5044.

By the Civil Aeronautics Board, November 28, 1979.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37256 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

[Docket 33068]

Transpacific Low Fare Route Investigation

The Administrative Law Judge's Recommended Decision in this case was served on November 23, 1979. The Board has already taken discretionary review on its own initiative. Order 78–7–114. Briefs to the Board will be due on December 21, 1979.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37255 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

[Docket 37114; Order 79–11–17]

Trans World Airlines, Inc.; Transatlantic Arbitrary Fare Increases; Order of Suspension and Investigation

Adopted by the Civil Aeronautics Board in its office in Washington, D. C. on the 19th day of November, 1979.

By tariff revisions filed October 1, 1979 for effect November 30, 1979, Trans World Airlines, Inc. (TWA) proposes an 11 percent increase in its arbitrary fares, used to construct through international fares between U.S. interior points and transatlantic points over the New York gateway.[1] In support of its request, the carrier states that the Board has approved a cumulative increase of 11.93 percent in domestic fares since May of this year and, inasmuch as the arbitraries typically are related to currently effective U.S. domestic fares, the increases are justified.

We have decided to suspend the proposed increase in TWA's arbitrary fares.

Our policy objective for several years has been to seek an international fares situation in which competitive forces operate, with minimal intervention by governments, to provide consumers with as many price/quality options as possible. This can only be achieved by injecting more competition into the market. We have authorized a number of U.S. and foreign carriers to provide new direct transatlantic services not only from the traditional New York gateway but also from interior points not traditionally considered gateways. To illustrate, new direct transatlantic services are now in place between Dallas-Fort Worth and Houston, on the one hand, and Belgium, Germany, France the Netherlands and the United Kingdom, on the other, as well as between Atlanta and Belgium, France and the United Kingdom.

Against this background, we must now question whether traditional methods of constructing through international fares from interior U.S. points, as typified in the TWA proposal before us, now operate to the best interests of the traveling public. We acknowledge that in the past, use of an arbitrary (or proportional) fare has produced a through fare that often is lower than that produced under a strict combination of fares principle; however, this has usually been in cases where either the most direct routing is via the New York gateway or the fare from the nearest U.S. point with direct international service is in itself constructed by use of an arbitrary fare. But with the fundamental changes now occurring in transatlantic service patterns as a result of our procompetitive policy, there is every indication that TWA's proposal, by limiting construction to the New York gateway, stiffles competition and has the effect of charging many of its interior point passengers excessive prices as illustrated below.

Presently, TWA offers non-stop transatlantic services from Boston, Chicago, Los Angeles, Philadelphia and Washington, D.C., as well as from New York, and direct, on-line services from other U.S. cities. Yet while offering these services, a large proportion of TWA's fares from these points are still constructed over New York by means of arbitrary fares. Thus, using TWA's partially unbundled normal economy fares in conjunction with the proposed arbitrary fares, a passenger from Chicago traveling on the carrier's non-stop services to London pays a fare per mile that is over 14 percent greater than his New York-London counterpart.

Moreover, there is every indication TWA's present construction techniques unduly penalize its off-line interior point passengers as well. Were fares to its interior points receiving direct services established at levels equal to the fare per mile paid at New York,[2] these off-line passengers would benefit from the lowest combination of sector fares over the nearest gateway. For example, a passenger from Billings, Montana, traveling to London and paying a fare equal to the sum of the local fare to Chicago and a Chicago-London fare established in accordance with the above principle, would pay a per mile fare seven percent lower than that resulting from the traditional construction over New York.

In view of these circumstances, we believe TWA's present system of arbitrary fares is due for reform. These fares we believe, should reflect the realties of the marketplace, taking into consideration direct services to interior cities, and not limit construction to a single traditional gateway. Indeed, several carriers have already filed such fares in a few transatlantic markets.

[1] Tariff C.A.B. No. 339, Airline Tariff Publishing Co., Agent.

[2] A generous assumption, actually, since pricing theory holds that per mile fares should vary inversely with distance over the range of a given aircraft type.

Delta and Sabena have proportional fares on file for service over Atlanta; Braniff, for service over Dallas-Fort Worth; and British Caledonia, for service over Houston. We are encouraged by this trend which offers passengers the lowest possible fares and fosters competition among carriers for interior U.S. point traffic. We urge TWA, as well as other carriers, to file point-to-point fares for those cities receiving such direct service, and if competitive circumstances dictate, proportional fares for use in constructing through fares from other interior points over the nearest point receiving direct service. Meanwhile, because TWA's present proposal has the effect of charging its passengers from interior U.S. points receiving non-stop service to Europe excessive fares, we will suspend, pending investigation, its proposed arbitraries insofar as they are used to construct fares between Boston, Chicago, Los Angeles, and Philadelphia, on the one hand, and London, on the other; between Boston and Washington, D.C., on one hand, and Paris, on the other; and between Boston and Rome.

Accordingly, pursuant to sections 102, 204(a), 403, 801 and 1002(j) of the Federal Aviation Act, as amended:

1. We shall institute an investigation to determine whether the fares and provisions set forth in Appendix A hereof, and rules and regulations or practices affecting such fares and provisions, are or will be unreasonable, unjustly discriminatory, unduly preferential, unduly prejudicial or otherwise unlawful; and if we find them to be unlawful, to act appropriately to prevent the use of such fares, provisions or rules, regulations, or practices;

2. Pending hearing and decision by the Board, we hereby suspend the tariff provisions specified in Appendix A and defer their use from November 30, 1979, to and including November 29, 1980, unless otherwise ordered by the Board, and shall permit no changes to be made therein during the period of suspension except by order or special permission of the Board;

3. We shall submit this order to the President[3] and it shall become effective on November 30, 1979 and

4. We shall file a copy of this order in the aforesaid tariff and serve it on Trans World Airlines, Inc.

We shall publish this order in the Federal Register.

[3] We submitted this order to the President on November 19, 1979.

By the Civil Aeronautics Board.[4]

Phyllis T. Kaylor

Secretary.

Appendix A

Transatlantic Passenger Fares Tariff No. IPF-1, C.A.B. No. 339 Issued by Airline Tariff Publishing Co., Agent

In Supplement No. 10, all arbitraries:

1. Between Boston, Chicago, Los Angeles and Philadelphia, on the one hand, and New York, on the other, insofar as they apply to construct through fares to and from, London, United Kingdom;

2. Between Boston and Washington, D.C., on the one hand, and New York, on the other, insofar as they apply to construct through fares to and from Paris, France;

3. Between Boston and New York, insofar as they apply to construct through fares to and from Rome, Italy.

[FR Doc. 79-37258 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF COMMERCE

Industry and Trade Administration

Brown University; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666—11th Street NW. (Room 735) Washington, D.C.

Docket number: 79-00155. Applicant: Brown University, Providence, RI 02912. Article: TE-280 High Pressure Carbon Dioxide Laser Amplifier. Manufacturer: Lumonics Research Ltd., Canada. Intended Use of Article: The article is intended to be used to amplify short pulses of ten micrometer laser radiation during the investigation of the temporal modification of ultrashort laser pulses in high pressure gas laser amplifiers.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides a carbon dioxide pressure of 10 atmospheres in a tunable laser. The National Bureau of Standards advises in its memorandum dated November 6, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-37170 File 12-3-79; 8:45 am]

BILLING CODE 3510-25-M

[4] All members concurred.

California Institute of Technology; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666-11th Street NW. (Room 735) Washington, D.C.

Docket number: 79-00387. Applicant: California Institute of Technology, 1201 E. California Street, Pasadena, CA 91125. Article: Ion Microanalyzer System, Model IMS-3F and Accessories. Manufacturer: CAMECA, France. Intended use of article: The article is intended to be used to analyze mineralogically and chemically complex rock samples from the moon and other extraterrestrial sources and the earth. The rock samples are comprised mainly of electrically nonconducting silicate minerals. It will be used to measure precise isotopic rations and chemical abundances of trace elements in selected microscopic volumes (10-1000μ^3) of individual mineral crystals in the rock sample.

The objective of the measurements is to study the history and conditions of formation and metamorphism of lunar and other extraterrestrial samples and terrestrial rock samples. In addition, the article will be used to acquaint students with available analytical instruments

which are used to solve problems in the earth sciences and to provide training in methods of research as well as to also provide a sound understanding of the newly developed ion microprobe instrumentation as a basis for future research careers.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides a resolving power of 5000 (10% valley) with a high vacuum of at least 10^{-8} torr.

The National Bureau of Standards advises in its memorandum dated November 9, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Program Staff.

[FR Doc. 79-37171 Filed 12-3-79; 8:45 am]

BILLING CODE 3510-25-M

Johns Hopkins University; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666—11th Street NW. (Room 735) Washington, D.C.

Docket number: 79-00357. Applicant: The Johns Hopkins University, The Good Samaritan Hospital, Section of Orthopaedics, Charles and 31st Streets, Baltimore, Md. 21218. Article: Microtome, Model 1140 and Accessories. Manufacturer: Waldemar Jung GmbH, West Germany. Intended use of article: The article will be used in research to study cellular detail and micro vasculature of bone altered by experimentally produced ischemia on dog models.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article cuts undecalcified bone to one micron thickness. The Department of Health, Education, and Welfare advises in its memorandum dated November 1, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-37172 Filed 12-3-79; 8:45 am]

BILLING CODE 3510-25-M

Massachusetts Institute of Technology; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666-11th Street, N.W. (Room 735) Washington, D.C.

Docket number: 79-00339. Applicant: Massachusetts Institute of Technology, 77 Massachusetts Avenue, Cambridge, Massachusetts 02139. Article: Interferometer Mirrors. Manufacturer: Optical Surfaces Ltd., United Kingdom. Intended use of article: The article is intended to be used as the primary component for an in-house build Spherical Fabry-perot spectrometer which will be used to measure the Brillouin spectrum of laser light which has been scattered from thermal fluctuations in matter. The system studies will be superfluid helium. The objective of the experiments is to investigate dynamic critical phenomena near the superfluid to normal fluid phase transition. This research will be carried out as part of the graduate training of students at MIT.

Comments: No comments have been received with respect to this application. Decision: Application approved. No intrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides a sphericity of lambda/100. The National Bureau of Standards advises in its memorandum dated November 6, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-37173 Filed 12-3-79; 8:45 am]

BILLING CODE 3510-25-M

Tri-State University; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666 11th Street, N.W. (Room 735) Washington, D.C.

Docket number: 79-00211. Applicant: Tri-State University, Angola, Indiana 46703. Article: Centrifugal Pump Test Set. Manufacturer: Plint and Partners, Ltd., United Kingdom. Intended use of Article: The article is intended to be used for educational purposes in the courses:

CE 304 Hydraulic Engineering I—To expose all civil engineering students to basic design concepts in hydraulic engineering including

the selection of centrifugal pumps in the design of pipe systems, and

CE 404 Hydraulic Engineering II—Application of hydraulic engineering design concepts of hydrology as applied to drainage systems and the detailed analysis of the operating characteristics of centrifugal pumps and turbines.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article is capable of studying the various factors that effect efficiency in centrifugal pumping. The National Bureau of Standards advises in its memorandum dated November 7, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-37174 Filed 12-3-79; 8:45 am]

BILLING CODE 3510-25-M

University of California, Livermore; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-freee entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666-11th Street, N.W. (Room 735) Washington, D.C.

Docket number: 79-00362. Applicant: University of California—Lawrence Livermore Laboratory, P.O. Box 5012, Livermore, CA 94550. Article: IMACON Model 790 Streaking and Framing Camera with Extra Large S-20 Photocathode and Accessories. Manufacturer: John Hadland, United Kingdom. Intended use of article: The article is intended to be used for interferometric measurements of free surface velocity of shocked surfaces, fast multiframe photography of rapid events studied in surface fluff ejection, and high-speed intensified flash x-ray diagnostics. Experiments will be conducted to measure the thermodynamic properties of materials under shock-loading conditions, and to measure very high time resolution velocity histories and surface qualities under high magnification. In addition, the article will be used to understand more fully the thermodynamic properties of matter at high pressure and temperature.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article provides resolution of at least 12 frames per event. The National Bureau of Standards advises in its memorandum dated October 31, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-37175 Filed 12-3-79 8:45 am]

BILLING CODE 3510-25-M

University of Washington; Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Public Law 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (15 CFR 301).

A copy of the record pertaining to this decision is available for public review between 8:30 A.M. and 5:00 P.M. at 666-11th Street, N.W. (Room 735) Washington, D.C.

Docket number: 70-00215. Applicant: University of Washington, Quaternary Research Center, Seattle, Washington 98195. Article: Automated Sample Preparation Unit, Model MM5020 and Accessories. Manufacturer: VG Micromass Ltd., United Kingdon. Intended use of article: The article will be used in conjunction with a mass spectrometer that is being used to analyze $^{18}/O^{16}O$ ratios in ice cores from Antarctica to provide information about major climatic fluctuations. A study of past climatic variations is critical to understanding and predicting future long-term global climatic changes. The article will also be used to study the $^{13}/C^{12}C$ ration in tree rings in research designed to assist in determinations of the proportion of CO^2 in the atmosphere that results from fossil fuel combustion. In addition, the article will be used to train students in the isotope ratio mass spectrometry techniques.

Comments: No comments have been received with respect to this application. Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States. Reasons: The foreign article has the capability to process a large number of time perishable samples (96) within a 24 hour period. The National Bureau of Standards advises in its memorandum dated November 13, 1979 that (1) the capability of the foreign article described above is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or aparatus of equivalent scientific value to the foreign article for the applicant's intended use.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-37176 Filed 12-3-79; 8:45 am]

BILLING CODE 3510-25-M

Application for Duty-Free Entry of Scientific Articles; Correction

In the Notice of Application for Duty-Free of Scientific Articles appearing at pages 67486 and 67487 in the **Federal Register** of Monday, November 26, 1979, the following amendment is hereby made to include a description of the article:

Docket Number: 80–00002. Applicant: Harvard Medical School, Purchasing Department, 75 Mount Auburn Street, Cambridge, Massachusetts 02138. Article: Mass Spectrometer, MAT 312 and Accessories. Intended use of Article: The article is intended to be used for biomedical research of the interplay of cells with their environment. In pursuing this research it will be necessary to relate the pathophysiological consequences to known modifications of the interacting compound, i.e. the carbohydrate and glycoconjugate structures, on biosurfaces. Specific projects will include investigations of the following: (1) Heparin Structure, (2) Metabolism and function of membrane derived oligosaccharides, (3) Glycoconjugate studies, (4) Structural studies of lipid-linked oligosaccharides, (5) Development studies in glycoconjugate analysis. Application Received by Commissioner of Customs: October 18, 1979.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppa,

Director, Statutory Import Programs Staff.

[FR Doc. 79-37177 Filed 12-3-79; 8:45 am]

BILLING CODE 3510-25-M

Travel Service

Travel Advisory Board; Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. (App. 1976) notice is hereby given that the Travel Advisory Board of the U.S. Department of Commerce will meet on January 3, 1980, at 1:00 p.m., in Room 4830 of the Main Commerce Building, 14th Street and Constitution Avenue, NW., Washington, D.C. 20230.

Established in July 1968, the Travel Advisory Board consists of senior representatives of 15 U.S. travel industry segments who are appointed by the Secretary of Commerce.

Members advise the Secretary of Commerce and Assistant Secretary of Commerce for Tourism on policies and programs designed to accomplish the purpose of the International Travel Act of 1961, as amended, and the Act of July 19, 1940, as amended. A detailed agenda for the meeting will be published in the **Federal Register** in advance of the meeting.

A limited number of seats will be available to observers from the public and the press. The public will be permitted to file written statements with the Committee before or after the meeting. To the extent time is available, the presentation of oral statements is allowed.

Sue Barbour, Travel Advisory Board Liaison Officer, the United States Travel Service, Room 1858, U.S. Department of Commerce, Washington, D.C. 20230 (telephone 202/377–4752) will respond to public requests for information about the meeting.

Jeanne Westphal,

Acting Assistant Secretary for Tourism, Department of Commerce.

[FR Doc. 79-37179 Filed 12-3-79; 8:45 am]

BILLING CODE 3510-11-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Import Restraint Levels for Certain Cotton Textile Products From Pakistan

November 28, 1979.

AGENCY: Committee for the Implementation of Textile Agreements.

ACTION: (1) Increasing the import level for other cotton manufactures, such as towels, tablecloths and pillows in Category 369 (except T.S.U.S.A. 366.1855), by 5 million square yards equivalent to 24 million square yards equivalent (5, 217,391 pounds) during the agreement year which began on January 1, 1979; and (2) controlling imports of cotton nightwear in Category 351 at the adjusted level of 6,647 dozen during the agreement year which began on January 1, 1979.

(A detailed description of the textile categories in terms of T.S.U.S.A. numbers was published in the **Federal Register** on January 4, 1978 (43 FR 884), as amended on January 25, 1978 (43 FR 3421), March 3, 1978 (43 FR 8828), June 22, 1978 (43 FR 26773), September 5, 1978 (43 FR 39408), January 2, 1979 (44 FR 94), March 22, 1979 (44 FR 17545), and April 12, 1979 (44 FR 21843)).

SUMMARY: Under the terms of the Bilateral Cotton Textile Agreement of January 4 and 9, 1978, as amended, between the Governments of the United States and Pakistan, agreement has been reached to increase the level established for cotton textile products in Category 369 (except T.S.U.S.A. 366.1855) by 5 million square yards equivalent during the agreement year that began January 1, 1978. Also under the terms of the bilateral agreement, the United States Government has decided to control imports in Category 351 at the adjusted level of 6,647 dozen during the agreement year which began on January 1, 1979. The adjusted level reflects a deduction of 6,815 dozen which represents 1978 overshipments.

EFFECTIVE DATE: December 4, 1979.

FOR FURTHER INFORMATION CONTACT: Carl Ruths, International Trade Specialist, Office of Textiles, U.S. Department of Commerce, Washington, D.C. 20230 (202/377–5423).

SUPPLEMENTARY INFORMATION: On January 21, 1979 a letter dated December 27, 1978 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs was published in the **Federal Register** (44 FR 92), which established import restraint levels for certain specified categories of cotton textile products, produced or manufactured in Pakistan and exported to the United States during the twelve-month period which began on January 1, 1979 and extends through December 31, 1979. A further letter dated August 14, 1979 was published in the **Federal Register** on August 17, 1979 (44 FR 48314) which established a level of restraint for Category 369 (except T.S.U.S.A. 366.1855) during the same twelve-month period.

In the letter published below the Commissioner of Customs is directed, in accordance with the provisions of the bilateral agreement, to increase the level previously established for Category 369 (except T.S.U.S.A. 366.1855) to 5,217,391 pounds, and to control imports in Category 351 at the adjusted level of 6,647 dozen, both during the twelve-month period that began on January 1, 1979.

Paul T. O'Day,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

Commissioner of Customs,
Department of the Treasury,
Washington, D.C. 20229.

Dear Mr. Commissioner: This directive further amends, but does not cancel, the directive issued to you on December 27, 1978 by the Chairman, Committee for the Implementation of Textile Agreements, concerning imports into the United States of certain cotton textile products, produced or manufactured in Pakistan.

Under the terms of the Arrangement Regarding International Trade in Textiles done at Geneva on December 20, 1973, as extended on December 15, 1977; pursuant to the Bilateral Cotton Textile Agreement of January 4 and 9, 1978, as amended, between the Governments of the United States and Pakistan; and in accordance with the provisions of Executive Order 11651 of March 3, 1972, as amended by Executive Order 11951 of January 6, 1977, you are directed, effective on December 4, 1979, to increase the twelve-month level of restraint established for cotton textile products in Category 369

(except T.S.U.S.A. 366.1855) to 5,217,391 pounds.[1]

Pursuant to the foregoing authorities, you are further directed to prohibit, effective on December 4, 1979 and for the twelve-month period beginning on January 1, 1979 and extending through December 31, 1979, entry for consumption or withdrawal from warehouse for consumption of cotton textile products in Category 351 in excess of 6,647 dozen.[2]

Textile products in Category 351 which have been exported to the United States prior to January 1, 1979 shall not be subject to this directive.

Textile products in Category 351 which have been released from the custody of the U.S. Customs Service under the provisions of 19 U.S.C. 1448(b) or 1484(a)(1)(A) prior to the effective date of this directive shall not be denied entry under this directive.

A detailed description of the textile categories in terms of T.S.U.S.A. numbers was published in the Federal Register on January 4, 1978 (43 FR 884), as amended on January 25, 1978 (43 FR 3421), March 3, 1978 (43 FR 8828), June 22, 1978 (43 FR 26773), September 5, 1978 (43 FR 39408), January 2, 1979 (44 FR 94), March 22, 1979 (44 FR 17545), and April 21, 1979 (44 FR 21843).

[1] The level of restraint has not been adjusted to reflect any imports after December 31, 1978.

[2] Imports during the January–September period of 1979 have amounted to 5,368 dozen.

In carrying out the above directions, entry into the United States for consumption shall be construed to include entry for consumption into the Commonwealth of Puerto Rico.

The action taken with respect to the Government of Pakistan and with respect to imports of cotton textile products from Pakistan has been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. Therefore, the directions to the Commissioner of Customs, being necessary to the implementation of such actions fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the Federal Register.

Sincerely,

Paul T. O'Day,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 79-37178 Filed 12-3-79; 8:45 am]

BILLING CODE 3510-25-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

SIPC; Action Taken on Consent Order

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of action taken on consent order.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives Notice that a Consent Order was entered into between the Office of Enforcement, ERA, and the firm listed below during the month of October 1979. The Consent Order represents resolutions of outstanding compliance investigations or proceedings by the DOE and the firm which involves a sum of less than $500,000. This Consent Order is concerned exclusively with payment of the refunded amounts to injured parties for alleged overcharges made by the specified companies during the time periods indicated below through direct refunds or rollbacks of prices.

For further information regarding this Consent Order, please contact Mr. Herbert M. Heitzer, District Manager of Enforcement, 1421 Cherry Street, Philadelphia, Pennsylvania 19120, telephone number (215) 597–2633.

Firm name and address	Refund amount	Product	Period covered	Recipients of refund
SIPCO, 2541 Richmond Terrace, Staten Island, N.Y. 10303	$35,000	No. 2 fuel oil	Nov. 1, 1973, to Apr. 30, 1974	275-gallon tank, homeowner class of purchaser.

Issued in Philadelphia on the 15th day of November 1979.

Herbert M. Heitzer,

District Manager of Enforcement.

[FR Doc. 79-37124 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

First Stop Service Station, Inc.; Proposed Remedial Order

Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration (ERA) of the Department of Energy hereby gives notice of a Proposed Remedial Order which was issued to Franklin Babbitt, d.b.a. First Stop Service Station, Inc., Long Island. This Proposed Remedial Order charges Franklin Babbitt with pricing violations in the amount of $558, connected with the retail sale of gasoline during the time period September 17, 1979 through October 3, 1979.

A copy of the Proposed Remedial Order, with confidential information deleted, may be obtained from Edward F. Momorella, Program Manager for Product Retailers, Department of Energy, Northeast Enforcement District, 1421 Cherry Street, 10th Floor, Philadelphia, Pa. 19102. On or before December 19, 1979, any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, 2000 "M" Street NW., Washington, D.C. 20461, in accordance with 10 CFR 205.193.

Issued in Philadelphia, Pennsylvania, on the 15th day of November 1979.

Herbert M. Heitzer,

District Manager, Office of Enforcement, Northeast District.

[FR Doc. 79-37128 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

Hancock Exxon Service Station; Proposed Remedial Order

Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration (ERA) of the Department of Energy hereby gives notice of a Proposed Remedial Order which was issued to Forest Mason D/B/A Hancock Exxon, Quincy, Massachusetts. This Proposed Remedial Order charges Forest Mason with discriminatory business practices connected with the retail sale of gasoline during the time period August 10, 1979 through September 18, 1979.

A copy of the Proposed Remedial Order, with confidential information deleted, may be obtained from Edward F. Momorella, Program Manager for Product Retailers, Department of Energy, Northeast Enforcement District, 1421 Cherry Street, 10th Floor, Philadelphia, Pa. 19102. On or before December 19, 1979, any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, 2000 "M" Street NW., Washington, D.C. 20461, in accordance with 10 CFR 205.193.

Issued in Philadelphia, Pennsylvania, on the 15th day of November 1979.

Herbert M. Heitzer,

District Manager, Office of Enforcement, Northeast District.

[FR Doc. 79-37129 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

Harmar Marina; Proposed Remedial Order

Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration (ERA) of the Department of Energy hereby gives notice of a Proposed Remedial Order which was issued to Harmar Marina, Harmarville, Pa. This Proposed Remedial Order charges Harmar Marina with pricing violations in the amount of $456.00, connected with the retail sale of gasoline during the time period August 1, 1979 through August 29, 1979.

A copy of the Proposed Remedial Order, with confidential information deleted, may be obtained from Edward F. Momorella, Program Manager for Product Retailers, Department of Energy, Northeast Enforcement District, 1421 Cherry Street, 10th Floor, Philadelphia, Pa. 19102. On or before December 19, 1979, any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, 2000 "M" Street NW., Washington, D.C. 20461, in accordance with 10 CFR 205.193.

Issued in Philadelphia, Pennsylvania, on the 15th day of November 1979.

Herbert M. Heitzer,

District Manager, Office of Enforcement, Northeast District.

[FR Doc. 79-37127 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

Hilgton's Exxon; Proposed Remedial Order

Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration (ERA) of the Department of Energy hereby gives notice of a Proposed Remedial Order which was issued to William R. Hilgton D/B/A Hilgton's Exxon, West Chester, Pa. This Proposed Remedial Order charges William Hilgton with pricing violations in the amount of $444, connected with the retail sale of gasoline during the time period August 1, 1979 through August 28, 1979.

A copy of the Proposed Remedial Order, with confidential information deleted, may be obtained from Edward F. Momorella, Program Manager for Product Retailers, Department of Energy, Northeast Enforcement District, 1421 Cherry Street, 10th Floor, Philadelphia, Pa. 19102. On or before December 19, 1979, any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, 2000 "M" Street NW., Washington, D.C. 20461, in accordance with 10 CFR 205.193.

Issued in Philadelphia, Pennsylvania, on the 15th day of November 1979.

Herbert M. Heitzer,

District Manager, Office of Enforcement, Northeast District.

[FR Doc. 79-37125 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

Kammerman Marina; Proposed Remedial Order

Pursuant to 10 CFR 205.192(c), the Economic Regulatory Administration (ERA) of the Department of Energy hereby gives notice of a Proposed Remedial Order which was issued to Roger Gros D/B/A Kammerman Marina, Atlantic City, New Jersey. This Proposed Remedial Order charges Roger Gros with pricing violations in the amount of $1,047, connected with the retail sale of gasoline during the time period August 1, 1979 through September 24, 1979.

A copy of the Proposed Remedial Order, with confidential information deleted, may be obtained from Edward F. Momorella, Program Manager for Product Retailers, Department of Energy, Northeast Enforcement District, 1421 Cherry Street, 10th Floor, Philadelphia, Pa. 19102. On or before December 19, 1979, any aggrieved person may file a Notice of Objection with the Office of Hearings and Appeals, 2000 "M" Street NW., Washington, D.C. 20461, in accordance with 10 CFR 205.193.

Issued in Philadelphia, Pennsylvania, on the 15th day of November 1979.

Herbert M. Heitzer,

District Manager, Office of Enforcement, Northeast District.

[FR Doc. 79-37128 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

San Diego Gas & Electric; Application for Authority To Export Electric Energy and To Supersede Prior Authorization

AGENCY: Department of Energy, Economic Regulatory Administration.

ACTION: Notice of Application for Authority to Export Electric Energy and to Supersede Prior Authorization: San Diego Gas & Electric.

SUMMARY: San Diego Gas & Electric has filed an application with the Economic Regulatory Administration for authority to export electric energy to Mexico and to supersede prior authorization.

FOR FURTHER INFORMATION CONTACT:

James M. Brown, Jr., System Reliability and Emergency Response Branch, Department of Energy, Room 4110, 2000 M Street NW., Washington, D.C. 20461, (202) 254-8247.

Lise Courtney M. Howe, Office of General Counsel, Department of Energy, Room 5E-064, Forrestal Building, 1000 Independence Avenue SW., Washington, D.C. 20585, (202) 254-2900.

SUPPLEMENTARY INFORMATION: On November 8, 1979 San Diego Gas & Electric (SDG&E) filed an application with the Economic Regulatory Administration (ERA) for authority to export electric energy to Mexico pursuant to section 202(e) of the Federal Power Act. SDG&E requests authority to export approximately 40-50 MW of electric energy to the Comision Federal de Electricidad (CFE) if emergencies occur on the CFE system; similarly, SDG&E also may receive up to 32 MW from CFE. In either instance, the area receiving emergency service will be isolated from the remainder of the receiving party's system.

Applicant states that the export of emergency energy under this agreement will not impair the sufficiency of electric supply to SDG&E 's customers in the United States pursuant to section 202(e) of the Federal Power Act.

SDG&E wishes to supersede the prior authorization for emergency exports to CFE of up to 60 MW of power, which was issued on December 29, 1970 in Docket E-7545 by the Federal Power Commission (FPC).

Applicant proposes to export the electric energy via existing transmission facilities which were authorized by the FPC in Docket No. E-7544.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the System Reliability and Emergency Response Branch, Economic Regulatory Administration, Room 4110, 2000 M Street NW., Washington, D.C. 20461, an accordance with sections 1.8 or 1.10 of the Rules of Practice and Procedure (18 C.F.R. 1.8, 1.10).

Any such petitions and protests should be filed on or before December 31, 1979. Protests will be considered by ERA 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 petition to intervene. Copies of this application are on file with ERA and will, upon request, be made available for public inspection and copying at the ERA Docket Room, Room B-120, 2000 M Street, NW., Washington, D.C., and at the System Reliability and Emergency Response Branch, Room 4110, 2000 M Street NW., Washington, D.C.

Dated: November 28, 1979.

Jerry L. Pfeffer,

Acting Assistant Administrator for Utility Systems, Economic Regulatory Administration.

[FR Doc. 79-37130 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket No. CP75-123]

Arkansas Louisiana Gas Co.; Petition To Amend

November 30, 1979.

Take notice that on October 24, 1979, [1] Arkansas Louisiana Gas Company (Arkla), P.O. Box 21734, Shreveport, Louisiana 71151, filed in Docket No. CP75-123 a petition to amend the order issued February 12, 1975,[2] as amended, in the instant docket so as to authorize the addition of delivery points to facilitate the exchange arrangement between Arkla and Natural Gas Pipeline Company of America (Natural), all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Arkla states that by order issued February 12, 1975, in its Docket No. CP75-123, Arkla and Natural were authorized to carry out a gas exchange arrangement and to construct and operate facilities to that end, pursuant to an exchange agreement between the two parties dated July 5, 1974, as amended. Arkla states that the exchange agreement was amended on August 3, 1978, by adding two new delivery points from Natural to Arkla.

It is stated that the parties have, on June 22, 1979, again amended the exchange agreement to provide that Arkla would deliver and Natural would receive such daily volumes of gas, not to exceed 10,000 Mcf, as Arkla may have available and tender from time to time at the following delivery point:

At the existing point of interconnection in the systems of the two parties located in Section 65, Block A-7, H&GN Survey, Wheeler County, Texas.

Natural would deliver, or cause to be delivered, daily volumes equal in thermal content to the volumes Natural receives at the Arkla delivery point and Arkla would receive such volumes at the following points of delivery:

(a) At the Gamble Unit #1 Well, Roger Mills County, Oklahoma;

(b) at the Clyde Tice #1-28 Well, Roger Mills County, Oklahoma;

(c) at the Hartley #1-8 Well, Roger Mills County, Oklahoma;

(d) at the existing point of interconnection of the pipeline systems of Arkla and Natural located in Section 33, Township 11 North, Range 25 West, Beckham County, Oklahoma, such point being a balancing delivery point.

Natural, it is stated, would own and operate the measurement facilities at delivery points in Grady County, Oklahoma, in Beckham County, Oklahoma, and in the Section 65, Block A-7, H&GN Survey Wheeler County, Texas, with the understanding that no new facilities would be required for the Roger Mills County, Oklahoma, delivery points.

Arkla further proposes to add further wells and balancing points which may be attached to either party's system in a specified area of interest in western Oklahoma and the panhandle area of Oklahoma and Texas.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37232 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[1] The application was initially tendered for filing on October 24, 1979; however, the fee required by Section 159.1 of the Regulations under the NGA (18 CFR 159.1), was not paid until October 26, 1979, thus filing was not completed until the latter date.

[2] This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Commission.

[Project No. 2943]

City of Columbus, Ohio; Application for Preliminary Permit

November 27, 1979.

Take notice that the City of Columbus, Ohio filed on August 14, 1979, an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. Section 791(a)-825(r)] for a proposed hydroelectric project to be known as the O'Shaughnessy Project, FERC No. 2943, located on the Scioto River in Delaware County, Ohio. Correspondence with the Applicant should be directed to: Robert C. Parkinson, Director, City of Columbus, Department of Public Service, 90 West Broad Street, Columbus, Ohio 43215.

Purpose of Project—Project energy would be utilized by the City of Columbus for municipal purposes.

Proposed Scope and Cost of Studies under Permit—The Applicant seeks issuance of a preliminary permit for a period of 36 months. Applicant proposes to develop preliminary designs, collect hydraulic data, perform field surveys, and prepare an application for FERC license, including an environmental report. Applicant estimates that the cost of work to be performed, including studies under the permit, would be $52,000.

Project Description—The proposed project would utilize the existing O'Shaughnessy Dam and Reservoir on the Scioto River which at present are used for water supply and recreation. The project would consist of: 1) The O'Shaughnessy Dam, a compacted earth-fill dam with an 879-foot-long uncontrolled concrete gravity spillway section topped by flashboards three feet in height; 2) a reservoir with a gross storage capacity of 16,900 acre-feet; 3) a single room powerhouse with an installed capacity of approximately 5,100 kW, located approximately 300 feet downstream from the dam; 4) a penstock approximately 300 feet long connecting the proposed powerhouse with the existing bulkheaded power gate chamber and vaulted conduit; and 5) appurtenant facilities. Average head at the project would be 65 feet. Applicant estimates the annual generation would average 14,000,000 kWh.

Purpose of Preliminary Permit—A preliminary permit does not authorize construction. A permit, if issued, gives the Permittee, during the term of the permit, the right of priority of application for license while the Permittee undertakes the necessary studies and examinations to determine the engineering, economic, and environmental feasibility of the proposed project, the market for the power, and all other necessary information for inclusion in an application for a license.

Agency Comments—Federal, State, and local agencies that receive this notice through direct mailing from the Commission are invited to submit comments on the described application for preliminary permit. (A copy of the application may be obtained directly from the Applicant.) Comments should

be confined to substantive issues relevant to the issuance of a permit and consistent with the purpose of a permit as described in this notice. No other formal request for comments will be made. If any agency does not file comments within the time set below, it will be presumed to have no comments.

Protests, and Petitions to Intervene—Anyone desiring to be heard or to make any protest about this application should file a petition to intervene or a protest with the Federal Energy Regulatory Commission, in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR, Section 1.8 or Section 1.10 (1978). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in § 1.10 for protests.

In determining the appropriate action to take, the Commission will consider all protests filed, but a person who merely files a protest does not become a party to the proceeding. To become a party or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules.

Any protest, petition to intervene, or agency comments must be filed on or before January 24, 1980. The Commission's address is: 825 North Capitol Street, N.E., Washington, D.C. 20426.

The application is on file with the Commission and is available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37233 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No, CP71-68, et al.]

Consolidated System LNG Co., et al.; Petition To Amend

November 30, 1979.

Take notice that on November 7, 1979, Consolidated System LNG Corporation (Consolidated LNG), 445 West Main Street, Clarksburg, West Virginia 26301, Columbia LNG Corporation (Columbia LNG), 20 Montchanin Road, Wilmington, Delaware 19807, and Southern Energy Company, P.O. Box 2563, Birmingham, Alabama 35202, filed in Docket No. CP71-68, *et al.*, a petition to amend the orders issued pursuant to Section 3 of the Natural Gas Act on December 22, 1978, and February 16, 1979, in the instant dockets so as to extend the authorizations granted by said orders to June 30, 1980, all as more fully set forth in the petition to amend which is on file with with the Commission and open to public inspection.

Petitioners state that on October 5, 1972, the Federal Power Commission in Opinion No. 622-A authorized Applicants to import liquefied natural gas (LNG), said Opinion concomitantly approving contractual arrangements between El Paso Algeria Corporation (EL Paso Algeria), Petitioners LNG supplier, and Sonatrach, the Algerian national hydrocarbon company and El Paso Algeria's LNG supplier, as well as the contractual arrangement between Applicants and EL Paso Algeria.

Petitioners state further that due to delays encountered in the construction of LNG tankers in U.S. shipyards, EL Paso Algeria was temporarily unable to fulfill its shipping obligations under the aforementioned contracts. Subsequently, it is stated, EL Paso Algeria chartered three vessels from Sonatrach for a time period ending December 31, 1979, which was the authorization by the commission in the orders of December 22, 1978, and February 16, 1979.

Petitioners now state that EL Paso Algeria has recently informed them that (1) delivery of vessels will be further delayed for an as yet unknown but significant period, and (2) several months may be required to finalize and implement alternative means of fulfilling contractual obligations currently being studied. Thus, it is asserted, use of the Sonatrach vessels beyond December 31, 1979, is necessary.

Petitioners request the Commission to extend the authorizations granted by the orders of December 22, 1978, and February 16, 1979, to June 30, 1980.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). 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 petition to intervene in accordance with the Commissions Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37234 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Project No. 2232]

Duke Power Co.; Application for Change in Land Rights

November 27, 1979.

Take notice that an application was filed on August 10, 1979, under the Federal Power Act, 16 U.S.C. §§ 791a-825r, by Duke Power Company for a change in land rights, for the Catawba Development of FERC Project No. 2232 (Catawba Wateree). The project lands affected are located on the Catawba River (Lake Wylie) in Mecklenburg County. Correspondence with the Applicant on this matter should be addressed: Mr. John E. Lansche, Assistant General Counsel, Duke Power Company, Box 2178, Charlotte, North Carolina 28242.

Applicant requests Commission approval to grant a 170 foot long extension to an existing easement, which was approved by the Commission in an order issued September 27, 1977. This September 27, 1977 order granted an easement to the Charlotte Mecklenburg Board of Education for a sewage treatment plant effluent line which discharges into Lake Wylie. Applicant now seeks an additional easement (170 feet long by 30 feet wide). Applicant states that this extension of the existing easement is necessary because the existing underwater outfall would not be in a location suitable to the nearby residents or to the North Carolina Division of Health Services. As such Applicant requests the additional 170 feet of right of way in order to extend the underwater outfall 160 feet further into Lake Wylie.

Anyone desiring to be heard or to make any protest about this application should file a petition to intervene or a protest with the Federal Energy Regulatory Commission, in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR § 1.8 or § 1.10 (1979). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in § 1.10 for protests. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but a person who merely files a protest or comments does not become a party to the proceeding. To become a party, or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any comments, protests, or petition to intervene must be filed on or before January 7, 1980. The Commission's address is: 825 North Capitol Street, N.E., Washington, D.C. 20426. The application is on file with the

Commission and is available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37234 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-73]

El Paso Natural Gas Co.; Application

November 29, 1979.

Take notice that on November 9, 1979, El Paso Natural Gas Company (Applicant), P.O. Box 1492, El Paso, Texas 79978, filed in Docket No. CP80-73 an application pursuant to section 7(c) of the Natural Gas Act and § 157.7(g) of the Regulations thereunder (18 CFR 157.7(g)), for a certificate of public convenience and necessity authorizing the construction, and for permission and approval to abandon various field compression and related metering and appurtenant facilities, during the 12-month period commencing January 1, 1980, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to enable Applicant to act with reasonable dispatch in constructing and abandoning facilities which would not result in changing Applicant's system salable capacity or service from that authorized prior to the filing of the instant application.

Applicant states that the total cost of proposed construction and abandonment under § 157.7(g) would not exceed $3,000,000 and no single project would exceed $500,000. Applicant also states that said costs would be financed through use of internally generated funds.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.70). 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 petition 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 petition 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 permission and approval for the proposed abandonment are required by the public convenience and necessity. If a petition 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 dully given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37236 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-74]

El Paso Natural Gas Co.; Application

November 29, 1979.

Take notice the on November 9, 1979, El Paso Natual Gas Company (Applicant), P.O. Box 1492, El Paso, Texas 79978, filed in Docket No. CP80-74 an application pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of the Regulations thereunder (18 CFR 157.7(b)) for a certificate of public convenience and necessity authorizing the construction on a calendar year basis for an indefinite period, and operation of facilities to enable Applicant to take into its certificated main pipeline system natural gas which would be purchased from producers and other similar sellers thereof, all as more fully set forth in the application on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in connecting to its pipeline system supplies of natural gas which may become available from various producing areas generally coextensive with its pipeline system or with the systems of other pipeline companies which may be authorized to transport gas for the account of or exchange gas with Applicant.

Applicant states that the total cost of the proposed facilities would not exceed $20,000,000 with no single onshore project to exceed $2,500,000 and no single offshore project to exceed $3,500,000.

Applicant states that the Commission's Order No. 56 issued November 1, 1979, in Docket Nos. RM79-37 and RM79-43 provided in amended Section 157.7(b)(7)(ii) of the Regulations that applications for budget-type certificates under the new rules, by persons holding budget-type cetificates on the effective date of such order, should be filed at least sixty days before the lapse of the existing certificates. It is asserted that Applicant's existing budget-type certificate expires on December 31, 1979; however, as a result of the date of issuance of Order No. 56 and Applicant's subsequent receipt of such order, is is not possible for Applicant to comply with said sixty day advance filing requirement. Applicant requests waiver of the requirements of Section 157.7(b)(7)(ii) of the Regulations so as to permit the budget-type certificate requested herein to be made effective on January 1, 1980, and to continue in effect each calendar year thereafter until terminated by Applicant in accordance with Section 157.7(b)(3)(i)(L) of said Regulations or revoked by the Commission in accordance with Section 157.7(b)(5)(iii) of said Regulations.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of Commission's Rules of Practice (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it it 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 petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 petition 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 is required by the public convenience and necessity. If a petition 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37237 Filed 12-3-79 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CI80-33]

IGC Production Co.; Application for Abandonment

November 29, 1979.

Take notice that on October 26, 1979, IGC Production Co. of P.O. Box 7608, Boise, Idaho 83707 (Applicant) filed an application in Docket No. CI80-33 pursuan to section 7(b) of the Natural Gas Act for authorization to abandon a limited term gas sale to Northwest Pipeline Corporation (Northwest) from certain wells in the East Douglas Creek Field, Rio Blanco County, Colorado. Applicant states that gas from the East Douglas Creek Field is being sold to Northwest pending certification of the transportation service necessary for Northwest in Docket No. CP78-254 to transport said gas to Applicant's parent corporation, Intermountain Gas Company (Intermountain). Once transportation of the gas to Intermountain is certificated, Northwest will still he entitled to purchase up to 25% of the gas delivered for use as part of its general pipeline supply. The remainder will be sold by IGC to Intermountain.

Applicant further states that the limited term sale of gas to Northwest was necessitated by the need for funds to continue drilling in order to avoid the return of acreage under farmout agreements. While IGC always intended to sell the East Douglas Creek Field Gas to its parent Intermountain, the limited term sale permitted IGC to obtain the necessary drilling funds while making available to Intermountain a proportionate share of any volumes delivered to Northwest prior to certification of Northwest's transportation service.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 14, 1979 file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulation 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 persons wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37238 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-64]

Louisiana Nevada Transit Co.; Application

November 28, 1979.

Take notice that on November 7, 1979, Louisiana-Nevada Transit Company (Applicant), P.O. Box 8789, Denver, Colorado 80202, filed in Docket No. CP80-64 an application pursuant to Section 7(b) of the Natural Gas Act for permission and approval to abandon its transportation and sale of surplus gas on an interruptible basis to Arkansas Louisiana Gas Company (Arkla), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

On June 8, 1949, according to Applicant, the Commission authorized the construction and operation facilities for the transportation and sale of surplus gas on an interruptible basis to Arkla for resale, pursuant to a contract dated November 19, 1948. On February 21, 1952, Applicant filed a tariff revision designed to replace its existing Rate Schedules H-1 and NL-1 with a single Rate Schedule S-1, it is stated.

By letter dated August 17, 1955, Arkla terminated the November 19, 1948, contract effective as of November 19, 1955, it is stated. Applicant states that since the November 1948 agreement is no longer effective Applicant proposes to abandon the transportation and sale of gas to Arkla.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition 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 petition to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that permission and approval for the proposed abandonment are required by the public convenience and necessity. If a petition 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37239 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Dockets Nos. CP66-121, (CP66-110, et. al.), CP79-161]

Midwestern Gas Transmission Co.; Petition To Amend

November 30, 1979.

Take notice that on October 31, 1979, Midwestern Gas Transmission Company (Petitioner), P. O. Box 2511, Houston, Texas 77001, filed in Docket Nos. CP66-110, *et. al.*, a petition to amend the Commission's order of September 25, 1979, issued pursuant to Section 3 of the Natural Gas Act so as to authorize the importation of up to 600,000 Mcf of natural gas per day, to be purchased from TransCanada Gas Pipelines Limited (TransCanada), all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Petitioner states that by order issued by the Economic Regulatory

Administration (ERA) on August 9, 1979, at Docket No. CP79–04–NG and by order of the Commission issued September 25, 1979, in Docket Nos. CP66–110, *et. al.*, it was authorized to import an additional 114 Bcf of natural gas from Canada at a point on the United States-Canadian boundary near Emerson, Manitoba, until and including October 31, 1980, at daily volumes up to 350,000 Mcf. Petitioner further states that it in turn received authorization to resell to Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), Northern Natural Gas Company (Northern) and Natural Gas Pipeline Company of America (Natural), until and including October 31, 1980, up to 350,000 Mcf of gas on any day.

The natural gas to be imported by Petitioner is to be purchased from TransCanada and is to be exported from Canada by TransCanada under authority of export License GL–18 issued by the National Energy Board of Canada (NEB), it is stated.

Petitioner then states that pursuant to an October 2, 1979, petition to amend, the Commission granted temporary authorization on October 10, 1979, for Petitioner to import and sell for a period of sixty days up to 120,000 Mcf per day to Tennessee at an existing interconnection between the facilities of TransCanada and those of Tennessee near Niagara Falls, New York (Niagara Interconnection).

Petitioner asserts that it has been informed that TransCanada now expects to have from time to time daily quantities up to 600,000 Mcf of gas available for export from Canada. Consequently, Petitioner requests authorization to import and resell to Tennessee, Northern, and Natural up to 600,000 Mcf of natural gas on any day. Petitioner states that no change is requested in the total volumes of 114 Bcf to be imported by Petitioner up to and including October 31, 1979.

Petitioner asserts that the proposal would allow Petitioner, Tennessee, Natural, and Northern to take maximum advantage of the availability of natural gas from TransCanada as that availability is affected by TransCanada's system operation.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 14, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). 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 petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79–37240 Filed 12–3–79; 8:45 am]

BILLING CODE 6450–01–M

[Project No. 2360]

Minnesota Power & Light Co.; Application for Approval of an Exhibit R

November 27, 1979.

Take notice that on April 2, 1978, Minnesota Power and Light Company filed an application under the Federal Power Act, 16 U.S.C. Sections 791(a)–825(r) (1976), for approval of an Exhibit R (Recreation Plan) for its constructed St. Louis River Project, FERC No. 2360. The project is located on the St. Louis, Cloquet, Whiteface, Skunk, Beaver and Otter Rivers, in Carlton and St. Louis Counties, Minnesota. Copies of correspondence regarding the application should be sent to: Mr. James R. Habicht, Minnesota Power and Light Company, 30 West Superior Street, Duluth, Minnesota 55802.

The Exhibit R includes existing recreational developments of Wild Rice, Fish, Island and Boulder Lakes which include boat ramps, parking and sanitation facilities, and a licensee maintained picnic and swimming area at Island Lake. The U.S. Forest Service operates and maintains a campground and picnic area with boat launching facilities and swimming beach at Whiteface Lake. The licensee proposes to upgrade certain existing facilities and to provide additional camping sites, hiking trails, boat launching facilities and day use areas.

Anyone desiring to be heard or to make any protest about this application should file a petition to intervene or a protest with the Federal Energy Regulatory Commission, in accordance with the requirements of the Commission's Rules of Practice and Procedure, 18 CFR § 1.8 or § 1.10 (1979). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in § 1.10 for protests. In determining the appropriate acton to take, the Commission will consider all protests or other comments filed, but a person who merely files a protest or comments does not become a party to the proceeding. To become a party, or to participate in any hearing, a person must file a petition to intervene in accordance with the Commission's Rules. Any comments, protest, or petition to intervene must be filed on or before January 14, 1980. The Commission's address is: 825 North Capitol Street, N.E., Washington, D.C. 20426. The application is on file with the Commission and is available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79–37241 Filed 12–3–79; 8:45 am]

BILLING CODE 6450–01–M

[Docket No. CP80–76]

Montana-Dakota Utilities Co.; Application

November 28, 1979.

Take notice that on November 9, 1979, Montana-Dakota Utilities Co. (Applicant), 400 North Fourth Street, Bismarck, North Dakota 58501, filed in Docket No. CP80–76 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain facilities on its interstate natural gas transmission system, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that the addition of new reserves from the Wind River Basin area of Wyoming and the Williston Basin area of Montana and North Dakota along with the attendant increase in daily input to its system has resulted in capacity problems on certain segments of its transmission system, which problems are not peak day winter problems but rather summer day problems in transporting gas purchased to storage reservoirs. Applicant proposes to alleviate these problems by the construction and operation of the following facilities:

(1) Approximately 21.4 miles of 12¾-inch O.D. natural gas transmission loop line beginning at a point in Lot 17, Section 30, T49N, R92W, and terminating at a point in the SW¼ of Section 23, T52N, R94W, all in Big Horn County, Wyoming.

(2) Approximately 16.1 miles of 6⅝-inch O.D. natual gas transmission loop line beginning at a point in the NE¼ of Section 31, T151N, R101W, and terminating at a point in the SW¼ of Section 14, T150N, R99W, all in McKenzie County, North Dakota.

(3) A new compressor station consisting of two 600 horsepower reciprocating compressor sets and

related facilities to be located in or near Section 31, T18N, R56E, Dawson County, Montana.

(4) A new compressor station consisting of one 600 horsepower reciprocating compressor set and related facilities to be located in or near Section 22, T154N, R101W, near Willston, Williams County, North Dakota.

Applicant states that: (1) the proposed looping with 21.4 miles of 12¾-inch O.D. line would allow for transfer of an additional 11,300 Mcf of gas per day to its Elk Basin storage reservoir in Wyoming; (2) the proposed looping with 16.1 miles of 6⅝-inch O.D. pipeline would allow it to purchase and receive up to 13,000 Mcf of gas per day from a new field owned by Alpar Resources approximately 5 miles southwest of Watford City, North Dakota; (3) the installation and operation of the proposed compressor facilities would increase the gas storage capacity of Applicant's North Dakota loop from 71,800 Mcf per day day to 98,200 Mcf per day, said installations providing the most economical means for transporting additional volumes to storage at Cabin Creek, Montana. These additions total, it is stated, 70,000,000 Mcf of new reserves.

The total cost is estimated to be $4,693,600, which cost is to be financed through internally generated funds and/or short-term bank loans.

Applicant proposes to begin construction around March 1, 1980, and complete construction within one year from that date.

Applicant states that it is in curtailment and has need for all the gas it can add to its system.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 petition 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 is required by the public convenience and necessity. If a petition 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37242 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-66]

Mountain Fuel Supply Co.; Application

November 28, 1979.

Take notice that on November 8, 1979, Mountain Fule Supply Company (Applicant), 180 East First South Street, Salt Lake City, Utah 84139, filed in Docket No. CP80-66 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing it to place in service two mainline taps to be used for delivery to and receipt of natural gas from a gas treatment plant, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states its Main Line No. 36 transports gas produced in the Yellow Creek Field and other overthrust Belt producing areas of Uinta County, Wyoming, to Applicant's primary transmission lines.

According to Applicant, by letter agreement dated August 29, 1979, Champlin Petroleum Company (Champlin) has agreed to build a gas processing facility at the southern terminus of Applicant's Main Line No. 36 in the vicinity of existing liquid handling and storage facilities. Applicant maintains it has agreed to deliver all of the gas which it owns, purchases, or transports for others from the Yellow Creek Field area to Champlin for further processing in Champlin's plant. It is stated that the agreement also permits Applicant to Transport and deliver to Champlin gas owned or acquired by purchase or through transportation agreements and transported through Main Line No. 36 from sources other than the Yellow Creek Field Area.

According to Applicant, in order to make gas deliveries from Main Line No. 36 to Champlin's plant. Applicant would use existing valve assemblies associated with its liquid handling and storage facilities to deliver raw gas to and receive process gas back from Champlin's plant. Applicant states the cost of these existing facilities was $14,755 which cost was financed from funds on hand. Applicant request authorization to place in service these existing valve assemblies to deliver gas to Champlin.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 of no petition 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 is requred by the public convenience and necessity. If a petition 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.

Kenneth F. Plum,

Secretary.

[FR Doc. 79-37243 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP78-171]

Southern Natural Gas Co. et al.; Petition To Amend

November 28, 1979.

Take notice that on September 26, 1979, Southern Natural Gas Company (Southern), P.O. Box 2563, Birmingham, Alabama 35202, Texas Gas Transmission Corporation (Texas Gas), 3800 Frederica Street, Owensboro, Kentucky 42301, and United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77001, filed in Docket No. CP78-171 a joint petition to amend the order issued July 19, 1978, in the instant docket pursuant to Section 7(c) of the Natural Gas Act, so as to authorize an additional delivery point for the transportation of natural gas, all as more fully set forth in the petition to amend which is on file with the Commission and open to the public inspection.

Petitioners state that by order issued July 19, 1978, they were authorized to transport and exchange natural gas purchased from Southern by Mississippi Valley Gas Company (Mississippi), a local distribution company. It is stated that the volumes of gas purchased by Mississippi are displaced by equivalent volumes of gas from points in the State where Mississippi receives its gas supply from United and/or Texas Gas.

Petitions state the operations at the delivery point where Southern displaced gas to Texas Gas for Mississippi's account in Iberia Parish, Louisiana, have not been satisfactory. Therefore, Petitioners propose to establish a new deliver point so that the subject gas can be efficiently delivered to Texas Gas for Mississippi's account. It is asserted that Mississippi has entered into separate amended agreements with each of the three companies for the establishment of an additional delivery point at an existing point of interconnection of the facilities of the Texas Gas and United near Lonewa and Monroe in Ouachita Parish, Louisiana. It is stated that the agreement with United provides for United to redeliver at the additional point those volumes that it presently receives at an interconnection with Southern's facilities near Perryville, Ouachita Parish, Louisiana.

Petitioners assert that Mississippi's agreement with Texas Gas would increase the maximum volumes that Texas Gas receives on behalf of Mississippi from 10,000 Mcf to 20,000 Mcf per day during the winter season, and from 10,000 Mcf to 20,000 Mcf per day during the winter season, and from 6,000 to 10,000 Mcf during the summer season.

Petitioners further state that the agreement with Southern would increase from seven to fourteen days the period in which Mississippi would purchase intrastate gas to balance with gas transported by Southern.

Petitioners state that the additional exchange point would require no new facilities.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37244 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. GP80-2]

Spradling Drilling Co.; Petition for Declaratory Order

November 29, 1979.

Take notice that on October 4, 1979, Spradling Drilling Company (Spradling), P.O. Box 5210, Borger, Texas 79007 filed a petition for a declaratory order under 18 CFR 1.7(c) of the Commission's Rules of Practice and Procedure. Spradling requests that the Commission issues a declaratory order stating which maximum lawful price established under the Natural Gas Policy Act of 1978 (NGPA) applies to its "first sales" of natural gas.

Spradling states that it is currently negotiating a gas purchase contract with Natural Gas Pipeline Company of America (Natural) to sell gas produced from Spradling's Brown Nos. 2 and 3 wells.[1] Under the terms of the proposed contract, Natural will agree to pay the highest price available under the NGPA for this gas. Spradling also states that the acreage on which these wells are drilled was originally leased to Natural under a 50-year term lease that expired January 6, 1976. Spradling's own lease of this acreage began on May 1, 1979. The details of this gas purchase contract and the leases are provided in Spradling's application.

Copies of this application are on file with the Commission and are available for public inspection in the Office of Public Information, Room 1000.

Any person desiring to be heard or to make any protest to this petition should honor before December 14, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C., 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). 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 party wishing to become a party to a proceeding, or to participate as a party in any hearing therein, must file a petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37245 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[1] These wells are located in Sections 3 and 4, Block M-1, W. E. Bennett Survey, Moore County, Texas.

[Dockets Nos. CP76-322, CP77-127, CP78-53, and CP78-87]

Tennessee Gas Pipeline Co., a Division of Tenneco, Inc., and East Tennessee Natural Gas Co.; Petition To Amend

November 30, 1979.

Take notice that on November 16, 1979, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), P.O. Box 2511, Houston, Texas 77001, and East Tennessee Natural Gas Company (East Tennessee), 8200 Kingston Pike, Knoxville, Tennessee 37919, filed in Docket Nos. CP76-322, CP77-127, CP78-53 and CP78-87 a petition to amend orders issued June 30, 1976,[1] February 12, 1977,[1] December 27, 1978, and January 23, 1978, respectively, in the instant dockets pursuant to Section 7(c) of the Natural Gas Act and Section 2.79 of the General Policy and Interpretations (18 CFR 2.79) so as to authorize the modification of such certificates issued in said dockets, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Petitioners state that by Order No. 52, issued October 5, 1979, in Docket No.

[1] This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Commission.

RM80–1, the Commission issued an interim rule whereby end use limitations in existing certificates may be modified to remove some of the end use restrictions. Petitioners seek to modify the following certificates to comply with Order No. 52.

(1) CP76–322, transportation for Stauffer Chemical Company. The order was issued June 30, 1976, and Petitioners seek to amend ordering paragraph (c)(2) to comply with Section 2.79(m) of the Commission's General Policy and Interpretations.

(2) CP77–127, transportation for William J. Bonnell Company. The order was issed February 12, 1977, and Petitioners seek to amend ordering paragraphs (c)(2) and (c)(3) to comply with Section 2.79(m) of the Commission's General Policy and Interpretations.

(3) CP78–53, transportation for W. G. Bush & Company. The order was issued December 27, 1978, and Tennessee seeks to add 2.79(m) to the requirements of compliance with Section 2.79 of the Commission's General Policy and Interpretations.

(4) CP78–87, transportation for Consolidated Aluminum Corporation. The order was issued January 23, 1978, and Tennessee seeks to amend the conditions thereof to include Section 2.79(m) of the Commission's General Policy and Interpretations.

The terms which Petitioners would seek to have included are as follows: 2.79(m) Volumes and End-Use Restrictions.

(1) *Inapplicability of certain use and volumetric restrictions.*

Except as provided in paragraph (m)(2), a certificate issued under this section to which this paragraph applies: (i) does not limit the customer from purchasing any volumes of natural gas from its supplies which does not exceed its normal entitlement, and (ii) does not impose any end-use restriction upon the natural gas transported under the certificate.

(2) *Volumetric limitations.*

The customer's aggregate supply volumes may not exceed the greater of: (i) the customer's high priority requirements, or (ii) the sum of: (a) the customer's normal entitlement, plus (b) the fuel oil displacement volume authorized to be delivered under Subpart F of Part 284, plus (c) the direct sale volumes authorized to be delivered under certificates issued pursuant to Subpart E of Part 157.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79–37246 Filed 12–3–79; 8:45 am]

BILLING CODE 6450–01–M

[Docket No. CP80–83]

Tennessee Gas Pipeline Co., a Division of Tenneco, Inc.; Application

November 28, 1979.

Take notice that on November 14, 1979, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Applicant), P. O. Box 2511, Houston, Texas 77001, filed in Docket No. CP80–83 an application pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of the Regulations thereunder (18 CFR 157.7(b)) for a certificate of public convenience and necessity authorizing the construction and/or acquisition, during calendar year 1980, and operation of facilities to enable Applicant to take into its certificated main pipeline system natural gas which would be purchased from producers and other similar sellers thereof, all as more fully set forth in the application on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in connecting to its pipeline system supplies of natural gas which may become available from various producing areas generally coextensive with its pipeline system or the systems of other pipeline companies which may be authorized to transport gas for the account of or exchange gas with Applicant.

Applicant states that the total cost of the proposed facilities would not exceed $20,000,000, with no single onshore project to exceed $2,500,000 and no single offshore project to exceed $3,500,000. Applicant proposes to finance these costs from general funds and/or borrowings under revolving credit agreements.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 petition 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 is required by the public convenience and necessity. If a petition 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79–37248 Filed 12–3–79; 8:45 am]

BILLING CODE 6450–01–M

[Docket No. CP63–177]

Texas Eastern Transmission Corp., and Tennessee Gas Pipeline Co., a Division of Tenneco, Inc.; Petition To Amend

November 29, 1979.

Take notice that on November 5, 1979, Texas Eastern Transmission Corporation (Texas Eastern), P.O. Box 2521, Houston, Texas 77001, and Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), P.O. Box 2511, Houston, Texas 77001,

filed in Docket No. CP63–177 a petition to amend the Commission's order issued pursuant to Section 7(c) of the Natural Gas Act on March 18, 1963,[1] as amended February 7, 1974, July 18, 1975, and August 30, 1977, in the instant docket so as to authorize an additional exchange point and the exchange of natural gas, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Petitioners state that they are parties to a currently effective exchange agreement dated July 30, 1974, as amended October 17, 1974, which agreement provides for the exchange of natural gas on a gas-for-gas basis at various onshore points.

Petitioners propose herein to add a point of exchange pursuant to an amendment to the exchange agreement, dated October 2, 1979, at a mutually agreeable point on Texas Eastern's Wilcox Trend 14-inch pipeline in Live Oak County, Texas.

According to petitioners, the facilities required for the additional delivery point would be constructed under Tennessee's budget-type authorization.

Petitioners assert that the proposed exchange point would enable Tennessee to receive additional gas supplies into its system from a dedicated supply source in proximity to Texas Eastern's system which would not otherwise be feasibly connected directly to its system. According to Petitioners, Texas Eastern has ample capacity on its system to render the service contemplated herein, and its obligations under the exchange agreement would have no significant effect on the operation of its system.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37249 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[1] This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Commission.

[Docket No. CP80–77]

United Gas Pipe Line Co.; Application

November 28, 1979.

Take notice that on November 13, 1979, United Gas Pipe Line Company (Applicant), P.O. Box 1478, Houston, Texas 77001, filed in Docket No. CP80–77 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the transportation of natural gas for Mid-Louisiana Gas Company (Mid-Louisiana), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Pursuant to an agreement dated November 7, 1979, Applicant proposes to transport up to 1,000 Mcf of natural gas per day for Mid-Louisiana. It is stated that Mid-Louisiana has acquired such gas from production in the Jennings Field located in Acadia Parish, Louisiana, attributable to the interest of Goldking Production Company.

Applicant states that under the transportation agreement, Mid-Louisiana would deliver or cause to be delivered up to 1,000 Mcf per day to Applicant, at a point of receipt located on Applicant's existing 10-inch pipeline, near the Jennings Field, Acadia Parish, Louisiana. Applicant proposes to transport and redeliver equivalent quantities less fuel and company use gas at the existing point of interconnection between Applicant's and Mid-Louisiana's pipelines located at the Scotland Compressor Station site, East Baton Rouge Parish, Louisiana and/or at other mutually agreeable existing points of interconnection.

Applicant states Mid-Louisiana would pay an amount per MCF equal to Applicant's jurisdictional transportation rate in effect from time to time in applicant's Southern Rate Zone, based on rate filings made from time to time with the Commission, less any amount included in such jurisdictional transportation rate which is attributable to fuel and unaccounted for gas for the transportation service. Applicant asserts that such rate is presently 19.40 cents per Mcf.

It is asserted that the proposed transporation would allow Mid-Louisiana to receive additional quantities of natural gas into its system without the costly construction of transmission facilities.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Enery 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 petition 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 is required by the public convenience and necessity. If a petition 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.

Kenneth F. Plumb,

Secretray.

[FR Doc. 79-37250 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. RP75–62]

Cities Service Gas Co.; Notice of Extension of Time

November 27, 1979.

On November 20, 1979, Cities Service Gas Company filed a request for an extension of time to file Briefs on Exceptions to the Initial Decision issued October 29, 1979, in the above-docketed proceeding. In support of this request the motion states that the parties to this proceeding have agreed to hold a settlement conference to resolve issues raised by the Initial Decision and other

curtailment matters affecting Cities Service. The Company requests that additional time be granted pending the convening of the initial settlement conference in this proceeding.

Upon consideration, notice is hereby given that an extension of time for filing Briefs on Exceptions is granted to and including December 28, 1979. Briefs Opposing Exceptions shall be filed on or before January 17, 1980.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37197 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket Nos. G-4579, et al.]

Cities Service Co. (Operator), et al.; Notice of Applications for "Small Producer" Certificates [1]

November 27, 1979.

Take notice that each of the Applicants listed herein has filed an application pursuant to section 7(c) of the Natural Gas Act and § 157.40 of the Regulations thereunder for a "small producer" certificate of public convenience and necessity authorizing the sale for resale and delivery of natural gas in interstate commerce, all as more fully set forth in the applications which are on file with the Commission and open to public inspection.

It appears reasonable and consistent with the public interest in this case to prescribe a period shorter than 10 days for the filing of protests and petitions to intervene. Therefore, any person desiring to be heard or to make any protest with reference to said application should on or before December 6, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). 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 petition 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 on all applications in which no petition to intervene is filed within the time required herein if the Commission on its own review of the matter believes that a grant of the certificates is required by the public convenience and necessity. Where a petition for leave to intervene is timely filed, or where the Commission in 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 Applicants to appear or be represented at the hearing.

Secretary.

Kenneth F. Plumb,

[1] This notice does not provide for consolidation for hearing of the several matters covered herein.

Docket No. and date filed	Applicant	Purchaser and location	Price per 1,000 ft.[3]	Pressure base
G-4579, F, Mar. 12, 1979	Cities Service Company (Operator), et al., P.O. Box 300, Tulsa, Okla. 74102.	El Paso Natural Gas Company, Cities' Owens "C" No. 2 Well, Crockett County, Texas.	(2)	14.65
CI73-60, C, Apr. 3 1978	Kerr-McGee Corporation, P.O. Box 25861, Oklahoma City, Okla. 73125.	Transcontinental Gas Pipe Line Corporation, Brazos Area, Block A-1 Field, Offshore Texas.	(2)	14.65
CI73-938, C, Aug. 11, 1975, Oct. 14, 1975.	Continental Oil Company, P.O. Box 2197, Houston, Tex. 77001.	El Paso Natural Gas Company, Blanco Field, San Juan County, New Mexico.	(2)	15.025
CI75-605, C, Aug. 9, 1979	Cities Service Company	El Paso Natural Gas Company, Burton Flats Plant, Eddy County, New Mexico.	(2)	14.65

[1] The effective date of transfer of property is 4-6-75 and Cities' requests to continue the sale of gas previously sold by Fluor Oil and Gas Corporation under small producer certificate Docket No. CS73-658.

[2] Applicant is willing to accept a certificate conditioned to the Applicable National Rate.

Filing Code: A—Initial Service. B—Abandonment. C—Amendment to add acreage. D—Amendment to delete acreage. E—Total Succession. F—Partial Succession.

[FR Doc. 79-37198 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-33]

Columbia LNG Corp. and Consolidated System LNG Co.; Notice of Application

November 27, 1979.

Take notice that on November 6, 1979, Columbia LNG Corporation (Columbia), 20 Montchanin Road, Wilmington, Delaware 19807, and Consolidated System LNG Company (Consolidated), 445 W. Main Street, Clarksburg, West Virginia 26301, filed in Docket No. CP80-33 a joint application pursuant to Section 7(c) of the Natural Gas Act, for a certificate of public convenience and necessity and Section 16 of the National Gas Act so as to authorize replacement of certain facilities at their liquefied natural gas plant located at Cove Point, Maryland, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicants state that on October 6, 1979, deliveries of natural gas from Cove Point were interrupted due to the destruction of certain facilites caused by an explosion and fire in an electrical substation. Applicants propose herein to construct and operate interim facilities to restore Cove Point to service at levels up to approximately 500,000 Mcf per day in accordance with a three-step program. Applicants propose to construct and operate electrical switchgear, wiring, and appurtenant facilities for five sendout pumps, two exhaust heat vaporizers and three gas fired vaporizers.

Applicants state that the design and construction for the replacement substation is basically the same as originally planned. It is stated that there would be certain modifications including the installation of air gaps in the conduit and cable runs from the pumps to the substation, and the pump seal would be modified to place it outside the junction box on the pump. It is asserted that solid-state programers would be substituted for the large relay rack orignally installed to control the gas fired vaporizer.

Applicants state the total estimated costs associated with the proposed

construction is approximately $3,133,500 which would be financed by internally generated funds and insurance proceeds.

Applicants request that the authorization herein should be issued pursuant to section 16 of the Natural Gas Act rather than pursuant to section 7(c) of the Natural Gas Act. Applicants do not concede that the Commission has jurisdiction in this instance to require Applicants to obtain a certificate under section 7(c), but indicate that they would accept a certificate and would not contest Commission jurisdiction under section 7(c).

Any person desiring to be heard or to make any protest with reference to said application should on or before December 19, 1979, filed with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 petition 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 is required by the public convenience and necessity. If a petition 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.

Kenneth F. Plumb,

Secretray.

[FR Doc. 79-37199 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. SA80-29]

Cordova Chemical Co. of Michigan; Application for Adjustment

November 28, 1979.

On November 6, 1979, Cordova Chemical Company of Michigan, filed with the Federal Energy Regulatory Commission an application for an adjustment under Section 502(c) of the Natural Gas Policy Act (exempting from incremental pricing surcharges natural gas used as boiler fuel, based on special circumstances). Cordova Chemical Company of Michigan requests this exemption as a hardship case.

The procedures applicable to the conduct of this adjustment proceeding are found in Section 1.41 of the Commission's Rules of Practice and Procedure, Order No. 24 issued March 22, 1979.

Any person desiring to participate in this adjustment proceeding shall file a petition to intervene in accordance with the provisions of § 1.41. All petitions to intervene must be filed within 15 days after publication of this notice in the **Federal Register.**

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37200 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. ER80-98]

Consumers Power Co.; Proposed Tariff Change

November 28, 1979.

The filing company submits the following:

Take notice that Consumers Power Company ("Consumers Power") on November 19, 1979 tendered for filing a standard Schedule of Rates Governing the Sale of Transmission Service, which are proposed to supersede the rates for transmission service contained in Supplement G and Supplement F to the Interconnection Agreement between Consumers Power and the Michigan Municipal Cooperative Power Pool (MMCPP), FERC Rate Schedule No. 34. Consumers Power states that this Schedule of Rates Governing Transmission Service is available to any neighboring utility located in its service area as well as specifically superseding the transmission service rates contained in the above referenced Interconnection Agreement between the Company and the MCPP.

Consumers Power states that the standard rates for Transmission Service should be placed into effect on January 18, 1980. Consumers Power states that the proposed rates represent a rate decrease approximating 9.4 percent for the 12-month periods ending December 31, 1979 and 1980 for the only customer, the MCPP, presently utilizing the Company's bulk power transmission system for wheeling power on a regular, scheduled basis.

Consumers Power states that the standard Schedule of Rates provide for transmission service either on a firm or interruptible basis. Further, the proposed demand charges distinguish between transmission service at 138,000 volts and higher, and 46,000 volts, and are predicated on a weekly billing demand determination. For interruptible service, the Rate Schedule also provides for service on an hourly basis. The Schedule of Rates allows for a reduction in the capacity and energy delivered to the customer to reflect electrical line losses on the transmission system of Consumers Power.

Consumers Power states that the Schedule of Rates Governing Transmission Service was a product of negotiations between the Company and nearly all other electric utilities located in its service area. Consumers Power states that it is filing these Transmission Service Rates pursuant to the provisions of an agreement reached during said negotiations and pursuant to provisions in FERC Rate Schedule No. 34, an Interconnection Agreement between Consumers Power and the MMCPP, which provide for the unilateral filing of rate schedule changes.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 18, 1979. 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 petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37201 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. ER-80-100]

Detroit Edison Co.; Proposed Tariff Changes

November 27, 1979.

Take notice that The Detroit Edison Company (DEC) on November 21, 1979 tendered for filing the following revised and original tariff sheets:

FERC Electric Tariff Original Volume No. 1

Second Revised Sheet No. 1.
Third Revised Sheet No. 4.
Third Revised Sheet No. 5.
Third Revised Sheet No. 6.
Third Revised Sheet No. 7.
Third Revised Sheet No. 8.
Third Revised Sheet No. 9.
Third Revised Sheet No. 10.
Second Revised Sheet No. 15.
Original Sheet No. 16A.
First Revised Sheet No. 18.

DEC states that these tariff sheets implement a general rate increase for the Company's jurisdictional sales of electric energy, and the proposed availability of an Experimental Interruptible Option which will terminate not later than May 31, 1981. The proposed changes would increase revenues from jurisdictional sales and service by $6,240,000 based on the twelve month period ending December 31, 1980. DEC requests that the proposed rates and tariffs be made effective on January 22, 1980.

DEC further states that it is essential that these increased revenues be made available to the Company on the proposed effective date or as close thereto as possible, in order to offset rapidly increasing costs which are resulting in deteriorating earnings to the Company from this class of service. DEC has not filed any rate increase applicable to its jurisdictional sales since November 20, 1978. Since that time, all costs including capital costs incurred by the Company have been subjected to the continuous impact of inflation and other factors making it essential to adjust the rates to meet these increased costs.

DEC also states that copies of the filing were served upon the public utility's jurisdictional customers and the Michigan Public Service Commission.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 18, 1979. 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 petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37202 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. ER79-526]

El Paso Electric Co.; Compliance Filing

November 28, 1979

The filing company submits the following:

Take notice that on October 29, 1979, El Paso Electric Company (EPEC) tendered for filing revisions to its application filed July 27, 1979 pursuant to the Commission's order issued September 24, 1979.

The proposed filing reflects, as per the Commission's order, the 46% federal income tax rate, the elimination of the New Mexico electrical energy tax, and a correction for a computational error. The net effect of these changes is an increase in the wholesale cost of service of $46,849.

EPEC respectfully requests the waiver of any of the Commission's regulations as may be necessary to effectuate this filing. Should the Commission reject this filing, EPEC requests that the Commission accept Revision B, tendered herewith.

A copy of this filing has been served upon Community Public Service Company, Rio Grande Electric Cooperative, Inc., New Mexico Public Service Commission, an the Public Utilite Commission of Texas.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.9 or 1.10). All such petitions or protests should be filed on or before December 18, 1979. 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 petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37203 Filed 12-3-79 8:45 am]

BILLING CODE 6450-01-M

[Docket No. ER80-101]

Florida Power & Light Co.; Proposed New Delivery Points

November 27, 1979.

The following Company submits:

Take notice that on November 21, 1979, Florida Power & Light Company (FPL) tendered for filing an "Agreement for Alterations to Delivery Points and Service Voltage for Delivery of Electric Power and Energy," which provides for new delivery points and service voltages to Lee County Electric Cooperative, Inc. In accordance with the terms of that Agreement, FPL will sell and deliver electric power and energy to Seminole Electric Cooperative, Inc. on behalf of Lee County Electric Cooperative, Inc. Therefore, FPL has also tendered for filing an "Agreement to Provide Firm Power Electric Service," which provides for such sales.

FPL proposes an effective date of December 15, 1979 for both Agreements, and therefore requests waiver of the Commission's notice requirements.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C., 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 18, 1979. 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 petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37204 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. SA80-31]

Howell (Division of Burd, Inc.); Application for Adjustment

November 28, 1979.

On November 5, 1979, Howell (Division of Burd, Inc.), filed with the Federal Energy Regulatory Commission

an application for an adjustment under the provisions of subsection 206(d) of the Natural Gas Policy Act. Howell (Division of Burd, Inc.) hereby petitions the Commission for a change of exemption status under the Incremental Pricing Program for Certain Categories of Industrial Boiler Fuel Use of Natural Gas.

The procedures applicable to the conduct of this adjustment proceeding are found in Section 1.41 of the Commission's Rules of Practice and Procedure, Order No. 24 issued March 22, 1979.

Any person desiring to participate in this adjustment proceeding shall file a petition to intervene in accordance with the provisions of Section 1.41. All petitions to intervene must be filed on or before December 19, 1979.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37205 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. SA80-27]

Illinois Brick Co.; Application for Adjustment

November 28, 1979.

On November 6, 1979, Illinois Brick Company, filed with the Federal Energy Regulatory Commission an application for an adjustment for relief from the incremental pricing provisions of the Natural Gas Policy Act of 1978 (Pub. L. 95-621), as provided by Section 206(d) and Section 502(c).

The procedures applicable to the conduct of this adjustment proceeding are found in § 1.41 of the Commission's Rules of Practice and Procedure, Order No. 24 issued March 22, 1979.

Any person desiring to participate in this adjustment proceeding shall file a petition to intervene in accordance with the provisions of § 1.41. All petitions to intervene must be filed on or before December 19, 1979.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37206 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. SA80-32]

Lake Superior District Power Co.; Application for Adjustment

November 28, 1979.

On November 8, 1979, Lake Superior District Power Company, filed with the Federal Energy Regulatory Commission an application for an adjustment under Section 502(c) of the Natural Gas Policy Act of 1978. Lake Superior District Power Company requests an exemption for that natural gas delivered by Lake Superior District Power Company to the Flambeau Paper Corporation in lieu of contracted co-generation steam deliveries.

The procedures applicable to the conduct of this adjustment proceeding are found in Section 1.41 of the Commission's Rules of Practice and Procedure, Order No. 24 issued March 22, 1979.

Any person desiring to participate in this adjustment proceeding shall file a petition to intervene in accordance with the provisions of Section 1.41. All petitions to intervene must be filed within 15 days after publication of this notice in the Federal Register.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37207 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CI78-704]

Mitchell Energy Corp.; Extension of Time

November 27, 1979.

On November 9, 1979, Mitchell Energy Corporation filed a request for an extension of time to file an abandonment application pursuant to a Commission Order issued October 23, 1979, in the above-referenced proceeding. In support of this request, the motion states that Mitchell is presently preparing an application for rehearing of the Commission's October 23, 1979, order and is involved in an extensive examination of its files to provide data for the abandonment application.

Upon consideration, notice is hereby given that an extension is granted to and including December 31, 1979, for the filing of an abandonment application in this proceeding.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37196 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-54]

Mountain Fuel Resources, Inc.; Application

November 27, 1979.

Take notice that on October 26, 1979, Mountain Fuel Resources, Inc. (Applicant), 180 East First South Street, Salt Lake City, Utah 84139, filed in Docket No. CP80-54 an application pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of the Regulations thereunder (18 CFR 157.7(b)) for a certificate of public convenience and necessity authorizing the construction, during the calendar year 1980, and operation of facilities to enable Applicant to take into its certificated main pipeline system natural gas which would be purchased from producers and other similar sellers thereof, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in connecting to its pipeline system supplies of natural gas which may become available from various producing areas generally coextensive with its pipeline system or with the systems of other pipeline companies which may be authorized to transport gas for the account of or exchange gas with Applicant.

Applicant states that the total cost for the proposed facilities would not exceed $894,524, with no single project to exceed $223,631.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) and the Regulations under the Natural Gas Act (18 CFR 157.70). 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 petition 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 Section 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 petition 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 permission and approval for the proposed abandonment are required by the public convenience and necessity. If a petition 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37208 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-61]

National Fuel Gas Supply Corp.; Application

November 27, 1979.

Take notice that on November 2, 1979, National Fuel Gas Supply Corporation (Applicant), 10 Lafayette Square, Buffalo, New York 14240, filed in Docket No. CP80-61 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of a 2,834-foot pipeline and related facilities to be located in Erie County, New York, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Applicant proposes to construct and operate 2,834 feet of 4-inch steel pipeline, a 24-inch block valve, 6-inch blow-off assembly, and a pressure reducing station, all to be located in Erie County, New York. Applicant states that such facilities would be utilized for the purpose of delivering natual gas to National Fuel Gas Distribution Corporation (Distribution), an existing customer, for sale and delivery to Gold Band Building Products' (Gold Band) plant, located in Clarence Center, New York.

Applicant further states that the cost of the subject line and facilities, and the serving of necessary rights-of-way, would be $68,875, to be financed with internally generated funds.

Applicant states that Gold Band has requested Distribution to supply natural gas for its wallboard manufacturing facility in Clarence Center, New York, to avert the process and cost efficiency problems of its current fuel oil operation. It is further stated that Distribution would supply Gold Band with up to 3,600 Mcf of gas per day in order to meet Gold Band's energy requirements.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 20, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 petition 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 is required by the public convenience and necessity. If a petition 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37209 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP80-58]

Panhandle Eastern Pipe Line Co.; Application

November 27, 1979.

Take notice that on October 30, 1979, Panhandle Eastern Pipe Line Company (Applicant), P.O. Box 1642, Houston, Texas 77001, and P.O. Box 1348, Kansas City, Missouri 64141, filed in Docket No. CP80-58 an application for a certificate of public convenience and necessity pursuant to Section 7(c) of the Natural Gas Act authorizing the construction and operation of certain compressor, pipeline and related facilities on its gas supply system, and authorizing the construction and operation of compressor units appurtenant to its existing gathering lines, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant requests authorization to construct and operate additional compressor horsepower and pipelines to be located in its gas supply areas in Oklahoma, Kansas and Texas.

Applicant proposes to construct and operate the following facilities:

(1) Meade County, Kansas:

Plains Compressor Station.—To replace the existing 660 horsepower compressor facilities with two new 300 horsepower units, facilitating the conversion of the station from a three-stage compression to four-stage compression.

(2) Seward County, Kansas:

Davies Compressor Station.—The existing 440 horspower two-stage compressor would be replaced by 700 horsepower of new four-stage compression facilities and install 2.3 miles of 8-inch pipeline.

(3) Morton County, Kansas:

2.9 miles of 8-inch pipeline would be constructed.

(4) Steven County, Kansas:

(a) Moscow Compressor Station.—A new compressor station to be equipped with 3,000 horsepower of two-stage compression facilities, convertible to three stages of compression.

(b) Panoma Low Compressor Station.—To be equipped with 3,000 horsepower of two-stage compression facilities, convertible to three stages of compression.

(c) Dunne Compressor Station.—A new compressor station to be equipped with 1,200 horsepower of two-stage compression facilities, convertible to three-stage compression.

(d) Breech Low Compressor Station.—To add 3,000 horsepower of two-stage compression facilities, convertible to three-stage compression.

(e) To construct 3.7 miles of 8-inch pipeline and 14.9 miles of 16-inch pipeline.

(5) Haskell County, Kansas:

Satana Field Compression Station.—To expand present facilities through the addition of 600 horsepower of new two-stage compression facilities.

(6) Grant County, Kansas:

(a) Cognac Compressor Station.—To expand present facilities by the addition of 1,500 horsepower of new compression facilities.

(b) Ulysses Field Compressor Station.—To expand present capability by the addition of 600 horsepower of new compression facilities.

(c) To construct 2.4 miles of 8-inch pipeline and 2.7 miles of 12-inch pipeline.

(7) Ellis County, Oklahoma:

(a) Arnett Compressor Station.—A new compressor station to be equipped with 150 horsepower of two-stage compression facilities, convertible to three-stage compression.

(b) Peek Compressor Station.—A new compressor station to be equipped with 700 horsepower of two-stage compression facilities, capable of conversion to three-stage compression.

(c) Higgins Compressor Station.—A new compressor station to be equipped with 700 horsepower of two-stage compression facilities, capable of conversion to three-stage compression.

(d) To construct 1.5 miles of 6-inch pipeline.
(8) Texas County, Oklahoma:
To construct 1.5 miles of new 8-inch pipeline.
(9) Woods County, Oklahoma:
To construct 10 miles of 12-inch pipeline.
(10) Hansford County, Texas:
To construct 11.7 miles of 8-inch pipeline.
(11) Carson County, Texas:
To construct 1.2 miles of 10-inch pipeline.
(12) Moore County, Texas:
To construct 1.8 miles of 8-inch pipeline.

Applicant states that the requested facilities would compensate for the natural decline in gas reservoir pressures, and would assist Applicant to deliver contractually committed volumes of natural gas to its mainline systems.

It is stated that the total estimated cost of the facilities above would be $25,710,000 which be financed from funds available to the Company.

Applicant states that the estimated increases in deliverability during the first three years of operation would be as follows:

Increased Deliverability (MMcf/Day)

Year 1—45.5
Year 2—45.4
Year 3—51.8.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 petition 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 is required by the public convenience and necessity. If a petition 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.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-37210 Filed 12-3-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. SA80-28]

Rogers Dye-Finishing; Application for Adjustment

November 28, 1979.

On November 6, 1979, Rogers Dye-Finishing, filed with the Federal Energy Regulatory Commission an application for an adjustment Section 502(c) of the Natural Gas Policy Act (exempting from incremental pricing surcharges natural gas used as boiler fuel, based on special circumstances). Rogers Dye-Finishing requests an exemption for their Constellation Plant, located at Riverbend Drive, Dalton, Georgia (carpet printing operation.)

The procedures applicable to the conduct of this adjustment proceeding are found in § 1.41 of the Commission's Rules of Practice and Procedure, Order No. 24 issued March 22, 1979.

Any person desiring to participate in this adjustment proceeding shall file a petition to intervene in accordance with the provisions of § 1.41. All petitions to intervene must be filed on or before December 19, 1979.

Kenneth F. Plumb,
Secretary.

[FR Doc. 79-37211 Filed 12-3-79; 8:45 am]
BILLING CODE 6450-01-M

[Docket No. CP80-56]

South Texas Natural Gas Gathering Co.; Application

November 27, 1979.

Take notice that on October 29, 1979, South Texas Natural Gas Gathering Company (Applicant), P.O. Box 1569, San Antonio, Texas 78296, filed in Docket No. CP80-56 an application pursuant to Section 7(c) of the Natural Gas Act and Section 157.7(b) of the Regulations thereunder (18 CFR 157.7(b)) for a certificate of public convenience and necessity authorizing the construction, during the 12-month period commencing with the date of this order, and operation of facilities to enable Applicant to take into its certificated main pipeline system natural gas which would be purchased from producers and other similar sellers thereof, all as more fully set forth in the application on file with the Commission and open to public inspection.

The stated purpose of this budget-type application is to augment Applicant's ability to act with reasonable dispatch in connecting to its pipeline system supplies of natural gas which may become available from various producing areas generally coextensive with its pipeline system or the systems of other pipeline companies which may be authorized to transport gas for the account of or exchange gas with Applicant.

Applicant states that the total cost of the proposed facilities would not exceed $375,000, with no single project to exceed $93,750 which would be financed from cash on hand and from cash generated internally.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to 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 petition 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 is required by the public convenience and necessity. If a petition 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

unecessary for Applicant to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37212 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. ER80-99]

Southern California Edison Co.; Cancellation

November 27, 1979.

The filing Company submits the following:

Take notice that on November 14, 1979, Southern California Edison Company tendered for filing a notice of cancellation of Rate Schedule FERC No. 103 and Rate Schedule FERC No. 105.

Both schedules will expire as of their own terms on January 22, 1980.

Copies of this filing have been served upon Pacific Gas and Electric Company and the Public Utilities Commission of California.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with Sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All such petitions or protests should be filed on or before December 18, 1979. 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 petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37213 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket Nos. CP75-23 and CP75-119]

Tennessee Gas Pipeline Co., a Division of Tenneco, Inc.; Petition for Declaratory Order and Motion for Certificate Amendment

November 28, 1979.

Take notice that on October 24, 1979, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Applicant), P.O. Box 2511, Houston, Texas 77001, filed in Docket Nos. CP75-23 and CP75-119 a petition pursuant to Section 1.7(c) of the Commission's Rules of Practice and Procedure (18 CFR 1.7(c)) for a declaratory order to remove the uncertainty of whether the certificates of public convenience and necessity issued to it in the instant dockets permit Air Products and Chemicals, Inc. (Air Products), to use natural gas transported by Applicant as a heat source for its ammonia reformers, and that the Commission require Air Products to furnish to Applicant all monthly gas usage reports, all as more fully set forth in the petition which is on file with the Commission and open to public inspection.

Applicant states that by order issued by FPC on July 21, 1978, in Docket Nos. CI75-45, *et al.*, Opinion No. 789, it was authorized within certain limitations to transport gas supplied by Shell Oil Company (Shell) and Tenneco Oil Company (Tenneco Oil) from certain sources for ultimate use by Air Products in its ammonia and hydrogen plants at its complex in Orleans Parish, Louisiana. Such authorization, Applicant states, limited the use of gas by Air Products for process and feedstock requirements, plus a small volume for flame stabilization purposes.

Applicant states that in FERC Opinion No. 10, which amended Opinion No. 789, the Commission defined process gas as "gas use for which alternate fuels are not technically feasible such as in applications requiring precise temperature controls and precise flame characteristics. For the purposes of this definition propane and other gaseous fuels shall not be considered alternate fuels."

Applicant also states that the Commission, in FERC Opinion No. 10-A, stated that Air Products shall file a report with the Commission containing information required under Section 2.79(b)(2) of the Regulations so as to enable Applicant to comply with Commission orders. The report would insure that gas transported by Applicant for Air Products is used only for process and feedstock purposes as required by the Commission's order, it is asserted.

Applicant states that Air Products has refused to provide it with such gas usage reports; however, Air Products has provided Applicant with a copy of a letter to the Commission with regard to gas usage for a "typical month" at its New Orleans facility. The letter, Applicant continues, indicates that in addition to gas, transported by Applicant, used as feedstock in its ammonia and hydrogen plants, Air Products is using over 200,000 Mcf of gas per month as a heat source for its ammonia reformers. Air Products is treating this use of gas as "process gas" within the meaning of the Commission's certificate of July 21, 1978, it is stated.

Take further notice that on October 29, 1979, Air Products filed in these dockets a motion for an order modifying the end-use restrictions contained in certificate conditions, in the July 21, 1978, order. Air Products asserts that developments since the issuance of such authorization, particularly the disruption of and increase in the price of imported oil, and the enactment of the Natural Gas Policy Act of 1978 which caused an increase in natural gas supplies available in the interstate market and an attendant decrease in curtailment levels, have undermined the basis of the Commission's end-use restrictions. Air Products states the end-use restrictions in the certificateds issued in the instant dockets are directly at odds with the result and principles announced in the Commission's Order No. 52, and should be eliminated.

Applicant states that Air Products seeks to distinguish between its authority to use gas being transported by Applicant as a heat source for the hydrogen reformers on the ground that the ammonia plant lacks installed facilities which would enable it to use fuel oil as an alternate fuel, whereas the hydrogen plants have such facilities. Applicant states that the fact that Air Products has not installed all the necessary facilities in its ammonia plant to use fuel oil does not demonstrate that it is not technically feasible to do so. Applicant states that the Commission found, in Docket No. RP74-39-8, order issued February 26, 1975, that it was technically feasible to install alternate facilities for such purposes for ammonia plants owned by others. These circumstances, Applicant states, raise doubts as to whether Air Products' use of gas transported by Applicant as a heat source for the ammonia reformer is in compliance with the authorizations issued.

Any person desiring to be heard or to make any protest with reference to said petition or motion should on or before January 3, 1980, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). 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 petition

to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37214 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP75-127]

Texas Eastern Transmission Corp., and Tennessee Gas Pipeline Co., a Division of Tenneco, Inc.; Petition To Amend

November 27, 1979.

Take notice that on October 30, 1979, Texas Eastern Transmission Corporation (Tetco), P.O. Box 2511, Houston, Texas 77001, and Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee), P.O. Box 2521, Houston, Texas 77001, filed in Docket No. CP75-127 a petition to amend the order of July 18, 1975, as amended September 22, 1977,[1] so as to authorize the inclusion of an additional gas supply source, located in East Cameron Block 353, offshore Louisiana, to Tetco's present pipeline system, all as more fully set forth in the petition to amend which is on file with the Commission and open for public inspection.

Petitioners state that they are parties to a currently effective transportation and exchange agreement dated October 17, 1974, as amended June 27, 1977, which provides for the transportation and exchange of gas volumes up to 230,000 Mcf per day at various points in offshore Louisiana. It is stated that said exchange agreement was authorized by Commission order dated July 18, 1975, as amended on September 22, 1977.

Petitioners propose herein to include natural gas volumes produced from the East Cameron Block 353 field, offshore Louisiana, in the transportation and exchange agreement, pursuant to amendment to the agreement between the parties dated September 5, 1979.

Petitioners state that implementation of the proposed additional supply source, the rights to which have recently been purchased by Tetco, would allow Tetco to receive additional gas supplies from a dedicated supply source in proximity to Tennessee's system which could not otherwise be feasibly connected directly to Tetco's system. Petitioners further state that Tennessee's obligations under the exchange agreement would have no significant effect on the operation of its system.

[1] This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Commission.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervent or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37215 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

[Docket No. CP78-379]

Trunkline Gas Co.; Petition To Amend

November 27, 1979.

Take notice that on October 29, 1979, Trunkline Gas Company (Petitioner), P.O. Box 1642, Houston, Texas 77001, filed in Docket No. CP78-379 a petition to amend the order issued December 21, 1978, in the instant docket pursuant to Section 7(c) of the Natural Gas Act so as to authorize the exchange of natural gas from a new delivery point in West Cameron Block 601 offshore Louisiana, and a new balancing point in West Cameron Block 630 offshore Lousisiana, with Columbia Gulf Transmission Company (Columbia Gulf) and Columbia Gas Transmission Corporation (Columbia Gas), all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Petitioner states that pursuant to an exchange agreement between it, Columbia Gulf and Columbia Gas dated March 28, 1978, authorized by Commission order issued December 21, 1978, the parties agreed to exchange up to 35,000 Mcf of natural gas per day. It is stated that, pursuant to the exchange agreement, Columbia Gas would deliver volumes of gas to Stingray Pipeline Company (Stringray) for the account of Petitioner at an existing side tap on Stingray's 30-inch pipeline in West Cameron Block 565. Petitioner asserts that it would redeliver to Columbia Gulf thermally equivalent volumes of gas at (1) a point on Exxon Company USA's (Exxon) existing "A" platform in Eugene Island Block 314, (2) an existing side tap on a 20-inch pipeline in the Eugene Island Area which is part of a system jointly owned by Columbia Gulf, Tennessee Gas Pipeline Company, a Division of Tenneco Inc. (Tennessee) and Natural Gas Pipe Line Company of America (Natural), (3) a point on Texaco, Inc., *et al.*, existing "A" platform in Eugene Island Block 313, and (4) a point on Shell Oil Company's (Shell) existing "A" platform located in Eugene Island Block 331. Petitioner asserts that balancing would be achieved at a point on Exxon's existing platform located in West Cameron Block 616.

Petitioner proposes herein to add (1) an additional delivery point at West Cameron Block 601 and (2) an additional balancing point located in West Cameron Block 630.

Petitioner states that it has purchased 88 percent of the east Cameron Block 353 natural gas reserves from Sun Oil Company, Texas Pacific Oil Company, Diamond Shamrock Corporation, and Anadarko Production Company. It is stated that the remaining 12 percent interest is held by Panhandle Eastern Pipe Line Company (Panhandle), and that Petitioner would seek authorization to transport Panhandle's gas from East Cameron Block 353. It is further stated that a joint application has been filed in Docket No. CP80-30 by Petitioner, Tennessee, Texas Eastern Transmission Company and Natural to Construct and operate lateral line facilities from East Cameron Block 353 to West Cameron Block 601.

Petitioner states that pursuant to an amendment to the exchange agreement with Columbia Gulf and Columbia Gas dated May 16, 1979, Petitioner would use its capacity in the proposed jointly owned East Cameron Block 353 lateral to deliver natural gas produced from East Cameron Block 353 to a pipeline jointly owned by Columbia Gulf and Tennessee in West Cameron Block 601.

It is stated that the currently authorized exchange volume of 35,000 Mcf per day is sufficient to accomodate the natural gas to be purchased by Petitioner and Panhandle from East Cameron Block 353.

It is stated that Columbia Gulf would utilize a portion of its capacity in the Columbia Gulf-Tennessee pipeline to effect the exchange of East Cameron Block 353 gas.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before December 19, 1979, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance

with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

Secretary.

[FR Doc. 79-37216 Filed 12-3-79; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

OPP-50415A; [FRL 1364-5]

Pennwalt Corp.; Amendment to Experimental Use Permit

On Friday, April 13, 1979 (44 FR 22174), information appeared pertaining to the issuance of an experimental use permit, No. 4581-EUP-31, to Pennwalt Corporation. At the request of the company, that permit has been amended. The experimental use permit now allows the use of an additional 90 pounds (188 pounds originally authorized) of the fungicide 1-[2-(2-propenyloxy)ethyl]-1*H*-imidazole on citrus to evaluate control of *Penicillium* green mold, *Penicillium* blue mold, phomopais stem-end rot, and diplodia rot. A total of 270 tons of citrus are involved; the program is authorized only in the States of Arizona, California, Florida, and Texas. The experimental use permit is effective from March 12, 1979 to March 12, 1980. A temporary tolerance for residues of the active ingredient in or on citrus has been established. (PM-21, Henry Jacoby, Room: E-305, Telephone: 202/755-2562).

(Section 5 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended in 1972, 1975, and 1978 (92 Stat. 819; 7 U.S.C. 136))

Dated: November 27, 1979.

Douglas D. Campt,

Director, Registration Division.

[FR Doc. 79-37183 Filed 12-3-79 8:45 am]

BILLING CODE 6560-01-M

[PF-159; FRL 1370-1]

Pesticide Programs; Filing of Pesticide Petitions

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA or the Agency).

ACTION: Notice of filing.

SUPPLEMENTARY INFORMATION: EPA gives notice that the following petitions have been submitted to the Agency for consideration.

PP 9F2270. Dow Chemical Co., PO Box 1706, Midland, MI 48640. Proposes that 40 CFR 180.342 be amended by establishing tolerance for residues of the insecticide chlorpyrifos [*0,0*-diethyl *0*-(3,5,6-trichloro-2-pyridyl)phosphorothioate] in or on the following raw agricultural commodities:

Commodity:	Part(s) per million (ppm)
Fat, meat, and meat byproducts of goats and sheep	1.0
Soybeans	1.0
Soybeans, forage	8.0
Soybeans, straw	10.0

The proposed analytical method for determining residues is gas chromatography using a flame photometric detector which responds with high specificity to phosphorus. Product Manager (PM) 12, Mr. Frank Sanders, Room E-335, 202/426-2645.

PP 0F2277. Union Carbide Co., Inc., 300 Brookside Ave., Ambler, PA 19002. Proposes that 40 CFR 180.155 be amended by establishing tolerances for residues of the plant regulator 1-naphthaleneacetic acid in or on the raw agricultural commodities apples and pears at 1.0 ppm and olives at 0.1 ppm (negligible residue) resulting from the application of 1-naphthaleneacetic acid or the ethyl ester of 1-naphthaleneacetic acid. The proposed analytical methods for determining residues are liquid chromatography and ultraviolet absorption. PM-25, Mr. Robert Taylor, Room E-359, 202/755-2196.

COMMENTS/INQUIRIES: Comments may be submitted, and inquiries directed, to the designated Product Manager (PM) Registration Division (TS-767), Office of Pesticide Programs, EPA, 401 M St., SW, Washington, D.C. 20460 at the telephone numbers cited. Writen comments should bear a notation indicating the petition number to which the comments pertain. Comments may be made at any time while the petition is pending before the Agency. All written comments filed pursuant to this notice will be available for public inspection in the Product Manager's office from 8:30 a.m. to 4:00 p.m., Monday through Friday, excluding holidays.

(Sec. 408(d)(1), Federal Food, Drug, and Cosmetic Act, [21 U.S.C. 346a])

Dated: November 27, 1979.

Douglas D. Campt,

Director, Registration Division.

[FR Doc. 79-37184 Filed 12-3-79; 8:45 am]

BILLING CODE 6560-01-M

[PP 9G2271/T222; FRL 1370-2]

Tetrahydro-5,5-dimethyl-2(1H)-pyrimidinone(3-[4-trifluoromethyl)phenyl]-1-(2-[4-trifluoromethyl)phenyl]ethenyl)-2-propenylidene)hydrazone; Establishment of a Temporary Tolerance

American Cyanamid Co., P.O. Box 400, Princeton, New Jersey 08540, submitted a pesticide petition (PP 9G2271) to the Environmental Protection Agency (EPA). This petition requested that a temporary tolerance be established for residues of the insecticide tetrahydro-5,5-dimethyl-2(1*H*)-pyrimidinone[3-[4-(trifluoromethyl)phenyl]-1-[2-[4-trifluoromethyl)phenyl]ethenyl)-2-propenylidene]hydrazone in or on the raw agricultural commodity forage grass at 0.05 part per million (ppm). This temporary tolerance will permit the grazing of the agricultural commodity when treated in accordance with the amended experimental use permit, 241-EUP-93, that has been issued under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended in 1972, 1975, and 1978 (92 Stat. 819; 7 U.S.C. 136).

An evaluation of the scientific data reported and other relevant material showed that the requested tolerance was adequate to cover residues resulting from the proposed experimental use, and it was determined that the temporary tolerance would protect the public health. The temporary tolerance has been established for the pesticide, therefore, with the following provisions:

1. The total amount of the pesticide to be used must not exceed the quantity authorized by the experimental use permit.

2. American Cyanamid Company will immediately notify the Environmental Protection Agency of any findings from the experimental use that have a bearing on safety. The firm must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This temporary tolerance expires October 16, 1980. Residues not in excess of 0.05 ppm in or on forage grass after this expiration date will not be considered actionable if the pesticide is legally applied during the term of and in accordance with the provisions of the experimental use permit and temporary tolerance. This temporary tolerance may be revoked if the experimental use permit is revoked or if scientific data or experience with this pesticide indicates

such revocation is necessary to protect the public health. Inquiries concerning this notice may be directed to George Larocca, Product Manager 15, Registration Division (TS–767), Office of Pesticide Programs, 401 M St., SW, Washington, DC 20460 (202/426–9490).

Dated: November 27, 1979.

(Sec. 408(j) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 34a(j)].)

Douglas D. Campt,

Director, Registration Division.

[FR Doc. 79–37182 Filed 12–3–79; 8:45 am]

BILLING CODE 6560–01–M

[FRL 1369–8]

Quiet Communities Act of 1978; Intent To Award Financial Assistance

The U.S. Environmental Protection Agency (EPA) intends to award two types of financial assistance to units of State and local government and other eligible organizations and agencies. First, is State and local Assistance; second is Demonstration Assistance governed by CFR 40. Both are governed by 40 CFR Part 30. In almost all cases, financial assistance will take the form of Cooperative Agreement, which indicates substantial involvement on the part of the awarding office throughout the conduct of the respective programs and projects funded under the Quiet Communities Act of 1978.

Under authority of the Quiet Communities Act of 1978, and conforming to the regulations in effect under the Code of Federal Regulations (CFR) chapters cited above, EPA is hereby issuing the following guidance relative to programs and projects to be funded. Applications for assistance for projects must be submitted by February 29, 1980. Section 14 of the Quiet Communities Act of 1978 expanded the role of the U.S. Environmental Protection Agency to provide increased assistance to States and local governments. The Act includes financial assistance to emerging or expanding noise control programs, demonstration grants for evaluating techniques to control noise, assistance in identifying the nature and extent of a particular community's noise problem, and, transportation noise planning. Continuing support for a noise program is not envisioned, but, rather short-term, capacity building financial assistance.

Units of State and local governments and other organizations, agencies and institutions desiring to apply for assistance under Section 14 of the Quiet Communities Act of 1978, are advised that funding is extremely limited. Additional information may be obtained from EPA/ONAC; State and Local Programs Division, Washington, D.C. 20460, or the EPA Regional Offices: Region I: Mr. Al Hicks, JFK Bldg., Boston, MA 02203 (617–223–5708); Region II: Mr. Tom O'Hare, 26 Federal Plaza, New York, NY 10007 (212–264–2110); Region III: Mr. Pat Anderson, Curtis Building, 6th & Walnut Sts., Philadelphia, PA 19106 (215–597–9118); Region IV: Dr. Kent Williams, 345 Courtland St., N.E., Atlanta, GA 30308 (404–881–4861); Region V: Mr. Horst Witschonke, 230 S. Dearborn St., Chicago, IL 60604 (312–353–2202); Region VI: Mr. Mike Mendias, 1201 Elm St., Dallas, TX 75270 (214–767–7242); Region VII: Mr. Vincent Smith, 324 E. 11th St. Kansas City, MO 64106 (816–374–3307); Region VIII: Mr. Larry Svoboda, 1860 Lincoln St., Denver, CO 80295 (303–837–2221); Region IX: Dr. Richard Procunier, 215 Fremont St., San Francisco, CA 94105 (415–556–4606); Region X: Ms. Helen Baer, 1200 Sixth Ave., Seattle, WA 98101 (206–442–1253).

Dated: November 27, 1979.

Edward F. Tueek,

Acting Assistant Administrator for Air, Noise and Radiation.

[FR Doc. 79–37185 Filed 12–3–79; 8:45 am]

BILLING CODE 6560–01–M

FEDERAL COMMUNICATIONS COMMISSION

[Report No. A–5]

AM Broadcast Applications Accepted for Filing and Notification of Cut-Off Date

Released: November 30, 1979.

Cutoff Date: January 16, 1980.

Notice is hereby given that the applications listed in the attached appendix are hereby accepted for filing. They will be considered to be ready and available for processing after January 16, 1980. An application, in order to be considered with any application appearing on the attached list or with any other application on file by the close of business on January 16, 1980, which involves a conflict necessitating a hearing with any application on this list, must be substantially complete and tendered for filing at the offices of the Commission in Washington, D.C., not later than the close of business on January 16, 1980.

Petitions to deny any application on this list must be on file with the Commission not later than the close of business on January 16, 1980.

Federal Communications Commission

William J. Tricarico,

Secretary.

Appendix

BP–20,480 (new), Cornell, Wisconsin, Stewards of Sound Radio Company, Req: 680 kHz, 2.5 kW, DA-Day.

BP–790314AA (new), Mt. Pocono, Pennsylvania, Mount Pocono Broadcasting, Inc., Req: 960 kHz, 1 kW, DA-Day.

BP–790330AB (WHIN), Gallatin, Tennessee, Sumner County Broadcasting Co., Has: 1010 kHz, 1 kW, Day, Req: 1010 kHz, 5 kW, Day.

BP–790419AB (new), Wicklife, Kentucky, Ballard-Carlisle Broadcasting Co., Req: 1010 kHz, 250 W, DA-Day.

BP–790420AA (WPGR), Crystal Springs, Mississippi, Joseph K. Hollingsworth, Has: 1520 kHz, 250 W, Day (Port Gibson, Mississippi), Req: 1520 kHz, 250 W, Day (Crystal Springs, Mississippi).

BP–790423AB (WHIM), East Providence, Rhode Island, Franks Broadcasting Company, Inc., Has: 1110 kHz, 1 kW, Day (Providence), Req: 1110 kHz, 5 kW, DA-Day (East Providence).

BP–790507AF (new), Harrogate, Tennessee, Harrogate Radio Company, Req: 740 kHz, 250 W, Day.

BP–790515AD (WTCM), Traverse City, Michigan, Midwestern Broadcasting Company, Has: 1400 kHz, 250 W, 1 kW–LS, U, Req: 580 kHz, 500 W, 2.5 kW–LS, DA–N, U.

[FR Doc. 79–37180 File 12–3–79; 8:45 am]

BILLING CODE 6712–01–M

FEDERAL RESERVE SYSTEM

Bank Holding Companies; Proposed De Novo Nonbank Activities

The bank holding companies listed in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to each application, interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsound banking practices." Any comment on an application that requests a hearing must include a statement of the reasons a written presentation would not suffice in lieu of a hearing,

identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of that proposal.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearings should identify clearly the specific application to which they relate, and should be submitted in writing and received by the appropriate Federal Reserve Bank not later than December 27, 1979.

A. *Federal Reserve Bank of New York*, 33 Liberty Street, New York, New York 10045:

1. LINCOLN FIRST BANKS INC., Rochester, New York (trust company activities; Florida): to engage de novo through its subidiary, First Trust Company of Florida, N.A., in activities that may be carried on by a trust company, including acting as a fiduciary, investment advisor, agent or custodian. These activities would be conducted from an office in Boca Raton, Florida, serving Palm Beach, Dade and Broward Counties, Florida.

2. BARCLAYS BANK LIMITED and its subsidiary, BARCLAYS BANK INTERNATIONAL LIMITED, each a bank holding company whose prinicpal office is in London, England (financing and insurance activities; Kentucky, North Carolina, South Carolina, and Utah): to engage, through their subsidiary, BarcalsAmerican Corporation ("BAC"), in (i) making direct consumer loans and purchasing of sales finance contracts representing extensions of credit such as would be made or acquired by a consumer finance company, and wholesale financing (floor planning), and (ii) acting as agent for the sale of related credit life, credit accident and health and credit property insurance. These activities would be conducted from offices in Ownesboro, Kentucky; Charlotte, North Carolina; Rock Hill, South Carolina; and Roy, Utah, each such office serving portions of the county in which such office is located and in certain cases portions of contiguous counties. The proposals relating to the Kentucky, North Carolina and South Carolina offices involve relocations of existing offices.

3. CHEMICAL NEW YORK CORPORATION, New York, New York (financing activities; Arizona) to expand the activities of its subsidiary, Sunamerica Financial Corporation, to include revolving (open-end) credit. This activity would be conducted from offices in Mesa, Scottsdale, and Phoenix, Arizona, serving all sections of Mesa plus its southeast suburbs, all sections of Scottsdale, and the northwest section of Phoenix plus its suburb, Glendale.

B. *Federal Bank of San Francisco*, 400 Sansome Street, San Francisco, California 94120:

SECURITY PACIFIC CORPORATION, Los Angeles, California (securities clearing and custodian services; United States): to engage, through its subsidiary, Security Pacific Clearing & Services Corporation in certain clearing and custodian activities with respect to securities, as well as activities incident thereto, such as the making of call loans to securities dealers. These activities would be conducted from offices located in New York, New York; Los Angeles, California; Chicago, Illinois; Pittsburgh, Pennsylvania and Memphis, Tennessee and would serve the United States.

C. *Other Federal Reserve Banks:* None.

Board of Governors of the Federal Reserve Systems, November 27, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37146 Filed 11-30-79; 8:45 am]

BILLING CODE 6210-01-M

Empire Holdings LTD. and Empire Holdings Inc.; Bank Holding Companies

Empire Holdings Limited, Road Town, Tortola, British West Indies, and its subsidiary, Empire Holdings Inc., San Francisco, California, have applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become bank holding companies through the acquisition by Empire Holdings Inc. of 100 percent of the voting shares of the successor by merger to Redwood Bancorp, San Francisco, California, a bank holding company that controls 100 percent of the voting shares of Redwood Bank, San Francisco. California. 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)).

Empire Holdings Limited and Empire Holdings Inc. have also applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to acquire indirectly voting shares of Redwood National Mortgage Company and Eucalyptus Financial Corporation, San Francisco, California, existing nonbank subsidiaries of Redwood Bancorp.

Applicants state that Redwood National Mortgage Company engages in the origination and sale of mortgage loans secured by commercial real estate, and Eucalyptus Financial Corporation acts as named trustee in deeds of trust supporting real estate loans, principally in connection with extensions of credit made by Redwood Bank and Redwood National Mortgage Company. These activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b). They would continue to be performed from offices of Redwood National Mortgage Company in Los Angeles and San Francisco, California, and from an office of Eucalyptus Financial Corporation in San Francisco, California. The geographic areas to be served are the Los Angeles SMSA and the San Francisco SMSA.

With respect to the proposal to acquire Redwood National Mortgage Company and Eucalyptus Financial Corporation, interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices". Any request for a hearing must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The applications may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of San Francisco.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than December 27, 1979.

Board of Governors of the Federal Reserve System, November 27, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37147 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

Federal Open Market Committee; Domestic Policy Directive of October 6, 1979

In accordance with § 271.5 of its rules regarding availability of information,

there is set forth below the committee's Domestic Policy Directive issued at its meeting held on October 6, 1979.[1]

Taking account of past and prospective developments in employment, unemployment, production, investment, real income, productivity, international trade and payments, and prices, the Federal Open Market Committee seeks to foster monetary and financial conditions that will resist inflationary pressures while encouraging moderate economic expansion and contributing to a sustainable pattern of international transactions. At it meeting on July 11, 1979, the Committee agreed that these objectives would be furthered by growth of M–1, M–2, and M–3 from the fourth quarter of 1978 to the fourth quarter of 1979 within ranges of 1½ to 4½ percent, 5 to 8 percent, and 6 to 9 percent respectively, the same ranges that had been established in February. The range for M–1 had been established on the basis of an assumption that expansion of ATS and NOW accounts would dampen growth by about 3 percentage points over the year. It now appears that expansion of such accounts will dampen growth by about 1½ percentage points over the year; thus, the equivalent range for M–1 is now 3 to 6 percent. The associated range for bank credit is 7½ to 10½ percent. The Committee anticipates that for the period from the fourth quarter of 1979 to the fourth quarter of 1980, growth may be within the same ranges, depending upon emerging economic conditions and appropriate adjustments that may be required by legislation or judicial developments affecting interest-bearing transactions accounts. These ranges will be reconsidered at any time as conditions warrant.

In the short run, the Committee seeks to restrain expansion of reserve aggregates to a pace consistent with deceleration in growth of M–1, M–2, and M–3 in the fourth quarter of 1979 to rates that would hold growth of these monetary aggregates over the whole period from the fourth quarter of 1978 to the fourth quarter of 1979 within the Committee's longer-run ranges, provided that in the period before the next regular meeting the weekly average federal funds rate remains within a range of 11½ to 15½ percent. The Committee will consider the need for supplementary instructions if it appears that operations to restrain expansion of reserve aggregates would maintain the federal funds rate near the upper limit of its range.

By order of the Federal Open Market Committee, November 23, 1979.

Murray Altmann

Secretary.

[FR Doc. 79-37150 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

[1] The Record of Policy Actions of the Committee for the meeting of October 6, 1979, is filed as part of the original document. Copies are available on request to the Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

First McHenry Corp.; Formation of Bank Holding Company

First McHenry Corporation, McHenry, Illinois, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of First National Bank of McHenry, McHenry, Illinois. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than December 26, 1979. 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.

Board of Governors of the Federal Reserve System, November 26, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37152 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

Ida Holding Company, Inc.; Formation of Bank Holding Company

November 28, 1979.

Ida Holding Company, Inc., Ida Grove, Iowa, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 83.9 percent of the voting shares of First State Bank, Ida Grove, Iowa. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than December 27, 1979. 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.

Board of Governors of the Federal Reserve System, November 27, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37145 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

Lake Jackson Bancshares, Inc.; Formation of Bank Holding Company

Lake Jackson Bancshares, Inc., Lake Jackson, Texas, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares (less directors' qualifying shares) of The Lake Jackson Bank of Lake Jackson, Texas, Lake Jackson, Texas. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Dallas. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than December 24, 1979. 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.

Board of Governors of the Federal Reserve System, November 23, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37153 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

Lakota Bank Holding Company, Inc.; Formation of Bank Holding Company

Lakota Bank Holding Company, Inc., Lakota, North Dakota, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 percent of the voting shares of State Bank of Lakota, Lakota, North Dakota. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of

Minneapolis. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than December 27, 1979. 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.

Board of Governors of the Federal Reserve System, November 27, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37144 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

Leigh Corp.; Formation of Bank Holding Company

Leigh Corporation, Leigh, Nebraska, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of Bank of Leigh, Leigh, Nebraska. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, be received no later than December 26, 1979. 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.

Board of Governors of the Federal Reserve System, November 27, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37143 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

Multi-Line, Inc.; Formation of Bank Holding Company

Multi-Line, Inc., Tampa, Florida, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 86.1 percent or more of the voting shares of Bank of Clearwater, Clearwater, Florida. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received no later than December 26, 1979. 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.

Board of Governors of the Federal Reserve System, November 26, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37151 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

Nekoosa Port Edwards Bancorporation Inc.; Formation of Bank Holding Company

Nekoosa Port Edwards Bancorporation Inc., Nekoosa, Wisconsin, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80 percent or more of the voting shares of Nekoosa Port Edwards State Bank, Nekoosa, Wisconsin. The factors that are considered in acting on the application are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than December 27, 1979. 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.

Board of Governors of the Federal Reserve System, November 27, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37148 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

Northwestern Financial Corp.; Proposed Retention of M & J Financial Corp.

Northwestern Financial Corporation, Wilkesboro, North Carolina has applied, pursuant to section 4 (c)(8) of the Bank Holding Company Act (12 U.S.C. 1843 (c)(8)) and section 225.4 (b)(2) of the Board's Regulation Y (12 CFR 225.4 (b)(2)), for permission to retain voting shares of M & J Financial Corporation, Shelby, North Carolina.

Applicant states that the proposed subsidiary would perform the activities of direct installment loans to individuals, discount or purchase of retail installment notes, lease financing, commercial loans, wholesale loans to dealers, acting as agent for credit life, accident, health and property damage insurance on borrowers and property in connection with extension of credit by the company and providing computer data processing services. These activities would be performed from offices of Applicant's subsidiary in Forest City, Asheville, Statesville, Winston-Salem, Kernersville, Hickory, Newton, North Wilkesboro, Madison, Eden, Reidsville, Waynesville, Greensboro, High Point, Taylorsville, Graham, Mt. Airy, West Jefferson, Lincolnton, Shelby, Durham, Murphy, Gastonia, Monroe, Wilmington and Asheboro, North Carolina, and Lancaster, Rock Hill, Anderson, Spartanburg, Greenville, Chester and Seneca, South Carolina, and the geographic areas to be served are Rutherford, Buncombe, Iredell, Forsyta, Catauba, Wilkes, Rockinghan, Haywood, Guilford, Alexander, Alamance, Lurry, Ashe, Lincoln, Cleveland, Durham, Cherokee, Gaston, Union, New Hanover and Randolph Counties North Carolina and York, Lancaster, Anderson, Spartanburg, Greenville, Chester and Oconee Counties, South Carolina. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of

the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Richmond.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than December 24, 1979.

Board of Governors of the Federal Reserve System, November 23, 1979.

Theodore E. Allison,

Secretary of the Board.

[FR Doc. 79-37154 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

Subpal Bancorp., Inc.; Formation of Bank Holding Company

Subpal Bancorp., Inc., Palatine, Illinois, has applied for the Board's approval under Section 3 (a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 51 percent or more of the voting shares (less directors' qualifying shares) of Suburban National Bank of Palatine, Palatine, Illinois. The factors that are considered in acting on the application are set forth in Section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than December 27, 1979. 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.

Board of Governors of the Federal Reserve System, November 27, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 79-37149 Filed 12-3-79; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

[F-79-5]

Delegation of Authority to the Secretary of Defense

1. *Purpose.* This delegation authorizes the Secretary of Defense to represent, in conjunction with the Administrator of General Services, the consumer interests of the executive agencies of the Federal Government in proceedings before the South Carolina Public Service Commission involving tariff rates for intrastate telecommunications service.

2. *Effective date.* This delegation is effective immediately.

3. *Delegation.*

a. Pursuant to the authority vested in me by the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the Federal executive agencies before the South Carolina Public Service Commission involving the application of the Southern Bell Telephone Company for rate increases for intrastate telecommunication services. The authority delegated to the Secretary of Defense shall be exercised concurrently with the Administrator of General Services.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

Dated: November 21, 1979.

R. G. Freeman III,

Administrator of General Services.

[FR Doc. 79-37221 Filed 12-3-79; 8:45 am]

BILLING CODE 6820-25-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[Docket No. 77N-0238]

Vending of Food and Beverages Including a Model Sanitation Ordinance; Availability

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration announces availability of "The Vending of Food and Beverages (1978) Including a Model Sanitation Ordinance."

ADDRESS: Copies of the manual are available from the Superintendent of Documents, U.S. Government Printing Office, Washington D.C. 20402, at $1.75 per copy, properly identified as "The Vending of Food and Beverages, DHEW Publication No. (FDA) 78-2091."

FOR FURTHER INFORMATION CONTACT: William F. Bower, Bureau of Foods (HFF-340), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-245-1511.

SUPPLEMENTAL INFORMATION: In the Federal Register of October 6, 1978 (43 FR 46377), FDA announced revision of "The Vending of Food and Beverages Including a Model Sanitation Ordinance" recommended for State and local government adoption. Draft copies of the model ordinance were then sent to Federal and State offices so they could familiarize themselves with it.

Printed copies of the manual are now available. Copies have been mailed to appropriate Federal and State offices, and a copy has been placed on display in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

Dated: November 27, 1979.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 79-37118 Filed 12-3-79; 8:45 am]

BILLING CODE 4110-03-M

[Docket No. 79C-0400]

Welch Foods, Inc.; Filing of Color Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: Welch Foods, Inc., has filed a petition proposing that the color additive regulations be amended to provide for the safe use of grape color extract in food and drugs.

FOR FURTHER INFORMATION CONTACT: Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 706(d), 74 Stat. 402-403 (21 U.S.C. 376(d))), notice is given that a petition (CAP 6C0124) has been filed by Welch Foods, Inc., Westfield, NY 14787,

proposing that the color additive regulations be amended to provide for the safe use of grape color extract in food and drugs exempt from certification.

The environmental impact analysis report and other relevant material have been reviewed, and it has been determined that the proposed use of the additive will not have a significant environmental impact. Copies of the environmental impact analysis report may be seen in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Dated: November 26, 1979.

Sanford A. Miller,

Director, Bureau of Foods.

[FR Doc. 79-38989 Filed 12-3-79; 8:45 am]

BILLING CODE 4110-03-M

Public Health Service

Home Health Services; Delegations of Authority

Notice is hereby given that there have been made the following delegation and redelegations of authority regarding home health services under section 339 of the Public Health Service Act (42 U.S.C. 255), as amended:

1. Delegation by the Secretary of Health, Education, and Welfare to the Assistant Secretary for Health, with authority to redelegate, of all the authorities, excluding the authority to issue regulations, vested in the Secretary under section 339 of the Public Health Service Act, as amended.

2. Redelegation by the Assistant Secretary for Health to the Administrator, Health Services Administration, with authority to redelegate, of all the authorities delegated by the Secretary to the Assistant Secretary for Health under section 339 of the Public Health Service Act, as amended.

3. Redelegation by the Administrator, Health Services Administration, to the Regional Health Administrators, Public Health Service Regional Offices, with authority to redelegate, of authority to make grants, other than grants that are national or multiregional in scope, to public and nonprofit private entities within their respective regions (a) to meet the initial costs of establishing and operating home health agencies and to expand the services available through existing agencies; (b) to meet the cost of compensating professional and paraprofessional personnel during the initial operation of such agencies or the expansion of service of existing agencies; and (c) to demonstrate the training of professional and paraprofessional personnel to provide home health services, as defined in section 1861(m) of the Social Security Act.

4. Redelegation by the Administrator, Health Services Administration, to the Director, Bureau of Community Health Services, Health Services Administration, with authority to redelegate, of all the authorities delegated by the Assistant Secretary for Health to the Administrator, Health Services Administration, under section 339 of the Public Health Service Act, as amended, excluding the authorities specifically delegated to the Regional Health Administrators.

The above delegation and redelegations were effective on November 13, 1979.

Dated: November 26, 1979.

Frederick M. Bohen,

Assistant Secretary for Management and Budget.

[FR Doc. 79-37251 Filed 12-3-79; 8:45 am]

BILLING CODE 4110-84-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Indian Child Welfare Act; Grant Fund Distribution Formula

This notice is published in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary, Indian Affairs by 209 DM 8.

Title II of the Indian Child Welfare Act of 1978 authorizes the Secretary of the Interior to make grants to Indian tribes and Indian organizations for establishment and operation of Indian child and family service programs.

In order to ensure insofar as possible that all approved applicants receive a proportionately equitable share of available grant funds the distribution of these funds will be accomplished in accordance with the following formula: Each grant applicant approved under the provisions of 25 CFR 23 ranking and related criteria established by the Bureau of Indian Affairs will receive (a) a base amount equal to .2% of total grant funds available, or $15,000 whichever is greater. (b) The maximum amount of grant award cannot exceed an additional amount equal to the product resulting when the estimated clientele percentage of the total national Indian client population to be served by the grant applicant is multiplied by the total amount of grant funds remaining after (a) above is accomplished for all approved grant applicants. In this computation, the total national Indian client population figure will be based upon the best information available from the U.S. Bureau of the Census and the Bureau of Indian Affairs, and other identifiable statistical resources.

If the grant applicant has requested less grant funds than would be provided under the above formula the approved applicant will be funded at the level specifically requested in the application.

Forrest J. Gerard,

Assistant Secretary, Indian Affairs.

November 27, 1979.

[FR Doc. 79-37119 Filed 12-3-79; 8:45 am]

BILLING CODE 4310-02-M

Indian Child Welfare Act; Title II Grant Applications

This notice is published in excercise of authority delegated by the Secretary of the Interior to the Assistant Secretary, Indian Affairs by 209 DM 8.

Title II of the Indian Child Welfare Act of 1978 authorizes the Secretary of the Interior to make grants to Indian tribes and Indian organizations for establishment and operation of Indian child and family service programs.

The initial period for submitting grant applications is effective this date and will end January 18, 1980. Additional periods for submission of grant applications will be announced at a later date if funds remain available after the first grant application period. In this regard it is necessary that specific timeframes be established for submission of applications so that all approved applicants can receive a proportionately equitable share of available grant funds.

Application materials and related information may be obtained from Bureau of Indian Affairs offices nearest the applicant. Applications for this initial application period will be accepted in anticipation of appropriated funds for Title II purposes. All grant application approvals will be subject to availability of funds.

Forrest J. Gerard,

Assistant Secretary, Indian Affairs.

[FR Doc. 79-37120 Filed 12-3-79; 8:45 am]

BILLING CODE 4310-02-M

Cabazon Band of Mission Indians, California; Ordinance Regulating and Taxing the Introduction and Distribution of Intoxicating Beverages

This Notice is published in accordance with authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by 209 DM 8, and in accordance with the Act of August 15, 1953, Pub. L. 277, 83rd

Congress, 1st Session (67 Stat. 586). I certify that the following Ordinance relating to the application of the Federal Indian Liquor Laws on the Cabazon Indian Reservation, California, was adopted on September 8, 1979, by the Cabazon General Council which has jurisdiction over the area of Indian Country included in the Ordinance, reading as follows:

Forrest J. Gerard,

Assistant Secretary—Indian Affairs.

Cabazon Band of Mission Indians, 82–640 Miles Avenue, Indio, California 92201.

Tribal Ordinance No. 5.5: *Regulation and Taxation of Intoxicating Beverages*

Section 1: This ordinance is enacted pursuant to the Act of August 15, 1953 (Pub. L. 83–277, 67 Stat. 586, 18 U.S.C. 1161) which provides that Federal Indian Liquor laws shall be inapplicable to any act or transaction within any area of Indian Country provided such act or transaction is in conformity both with the laws of the State in which such act or transaction occurs and with an ordinance duly adopted by the tribe having jurisdiction over such area of Indian Country, certified by the Secretary of the Interior, and published in the **Federal Register.**

Section 2: The introduction, sale or possession of intoxicating beverages shall be lawful on and within the Cabazon Indian Reservation provided that such introduction, sale or possession is in conformity both with the laws of the State of California and with this Ordinance.

Section 3: All retail sales of intoxicating beverages for consumption off the premises shall be conducted through one or more retail outlets created, owned, established and operated by the Cabazon Band of Mission Indians. The Cabazon General Council may form a tribal corporation or other tribal enterprise to engage in such retail sales activities. No other person or entity may engage in the retail sale of intoxicating beverages for consumption off the premises on or within the Cabazon Indian Reservation.

Section 4: All sales of intoxicating beverages for consumption on the premises shall be conducted through one or more establishments created, owned and operated by the Cabazon Band of Mission Indians. The Cabazon General Council may form a tribal corporation or other tribal enterprise to engage in the business of selling alcoholic beverages by the drink. No other person or entity may engage in the sale of intoxicating beverages for consumption on the premises on or within the Cabazon Indian Reservation.

Section 5: The Cabazon Tax Commission is hereby empowered to establish, levy and collect an excise tax upon all intoxicating beverages distributed within the exterior boundaries of the Cabazon Indian Reservation. The amount of such excise tax shall be determined by the Cabazon Tax Commission.

Section 6: The Cabazon Tax Commission is hereby empowered to establish, levy and collect a sales or use tax upon the purchase, use, consumption handling or possession by a consumer of intoxicating beverages within the exterior boundaries of the Cabazon Indian Reservation. The amount of such tax shall be determined by the Cabazon Tax Commission.

Section 7: Any law, resolution or ordinance heretofore enacted by the Cabazon Band of Mission Indians which prohibits the introduction, sale or possession of intoxicating beverages on or within the Cabazon Indian Reservation is hereby repealed.

Section 8: This ordinance shall be effective upon its certification by the Secretary of the Interior and its publication in the **Federal Register.**

Certification

We, the undersigned certify that the above ordinance was adopted by the members of the Cabazon General Council on *September 8, 1979,* by a vote of *8* for *0* against, *0* abstaining.

Art Welmas,

Tribal Chairman.

Alfred Alvara,

Vice Chairman,

John G. James,

Secretary-Treasurer.

November 26, 1979.

[FR Doc. 79–37110 Filed 12–3–79; 8:45 am]

BILLING CODE 4310–02–M

Bureau of Land Management

Colorado and Wyoming; Reschedule the Regional Coal Team Meeting To Rank Potential Coal Tracts in the Green River-Hams Fork Coal Production Region

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice to reschedule the regional coal team ranking meeting and to further extend the ranking factor comment period for the Green River-Hams Fork Coal Production Region.

SUMMARY: In the **Federal Register** of November 9, 1979, on pages 65197–65198, a correction notice appeared to change the date and time of the regional coal team ranking meeting and to extend the ranking factor comment period for the Green River-Hams Fork Coal Production Region. This notice is to inform the public that the ranking meeting has been rescheduled and that the comment period has been extended.

DATES: The regional coal team will meet on December 13, 1979, at 9:00 a.m. The comment period on the ranking factors has been extended to noon, December 7, 1979.

ADDRESSES: The regional coal team meeting will be held at the Holiday Inn—Airport, Conference Room, 4040 Quebec Street, Denver, Colorado. Comments on the ranking factors should be sent to Gary J. Wicks, Utah State Director, Bureau of Land Management, Chairman, Regional Coal Team, University Club Building, 136 South Temple, Salt Lake City, Utah 84111.

FOR FURTHER INFORMATION CONTACT: Gary J. Wicks, Regional Coal Team Chairman, (801) 524–5311.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of November 9, 1979, on pages 65197–65198, a correction notice appeared to change the date and time of the regional coal team ranking meeting from November 28, 1979, and, if needed, November 29, 1979 to November 27, 1979, and, if needed, November 28, 1979. The notice also extended the comment period on the factors that may be considered in ranking the preliminary lease tracts to November 23, 1979.

The purpose of this notice is to inform interested parties that the regional coal team ranking meeting has been rescheduled to December 13, 1979, at 9:00 a.m., at the above address. The meeting will continue until the team completes the ranking of the potential lease tracts and makes a preliminary selection of those tracts that may be considered for possible Federal coal leasing in the region. In addition, the comment period on the factors that may be considered in ranking the potential lease tracts has been extended to noon, December 7, 1979. Comments should be received by the regional coal team chairman at the address provided above by that date.

At the last meeting of the regional coal team on November 14, 1979, some team members expressed their concern that sufficient time was not available for the review of the information and analyses of each of the potential lease tracts before the team would be required to rank the tracts. Therefore, in response to those concerns, the regional coal team chairman has decided to delay the ranking meeting to provide additional time for the team and the public to review the information developed on the potential lease tracts.

Coal tract summary matrices and abstracts are available for public review at the following locations:

1. Colordo State Office, Public Affairs Office, Bureau of Land Management, Colorado State Bank Building, 1600 Broadway, Denver, Colorado.

2. Craig District Office, Bureau of Land Management, 455 Emerson Street, Craig, Colorado.

3. Wyoming State Office, Public Affairs Office, Bureau of Land Management, 2515 Warren Avenue, Cheyenne, Wyoming.

4. Rawlins District Office, Bureau of Land Management, 1300 Third Street, Rawlins, Wyoming.

Public attendance is welcome at the regional coal team meetings.

Ed Hastey,

Associate Director.

November 29, 1979.

[FR Doc. 79-37116 Filed 12-3-79; 8:45 am]

BILLING CODE 4310-84-M

Medford District Office, Oregon; Designation of Public Lands for Off-Road Use

Correction

In FR Doc. 79-30478, appearing in the issue of Tuesday, October 2, 1979, on page 56747, in the middle column, the first line is corrected to read: "Section 31, NW¼, N½SW¼, SW¼SW¼;"

BILLING CODE 1505-01-M

[Bureau Order No. 701, Amendment No. 30]

Cadastral Survey; Redelegation of Authority

Bureau Order No. 701, dated July 23, 1964, is further amended as follows:

Part I Section 1.4 is amended to add: (a)(5) The State Director, Alaska, is authorized to perform all functions and to sign for the Director, all documents relating to approval and acceptance of original surveys only, in his area of jurisdiction.

Ed Hastey,

Acting Director.

November 23, 1979.

[FR Doc. 79-37226 Filed 12-3-79; 8:45 am]

BILLING CODE 4310-84-M

Minnesota; Commencement of Public Comment Period on Intensive Wilderness Inventory of Koochiching Bog Units 42 and 45

December 4, 1979.

This notice announces the beginning of a 45-day public comment period concerning the intensive wilderness inventory of public lands in northwest Koochiching County, Minnesota, identified as Koochiching Units 42 and 45. Beginning on the date of this announcement and running until January 17, 1980, the public is invited to review and provide comments on the intensive field inventory of the two units, one covering 10,394 acres of Federal public land north of the West Branch of the Black River, and the other a 11,012-acre parcel lying south of the river. The inventory is one part of a continuing wilderness review process conducted under the authority of Section 603 of the Federal Land Policy and Management Act of October 21, 1976.

All public lands and islands administered by the Bureau of Land Management in Minnesota have been reviewed in an initial inventory process. In addition, Koochiching Units 42 and 45 have now been intensively inventoried. The results of the inventory are published in the report, *Intensive Inventory and Wilderness Study Area Recommendations—Koochiching Bog Units 42 and 45—Minnesota.* The report consists of narrative descriptions of the features and values considered to determine the presence or absence of wilderness characteristics, summary recommendations, photographs and a map. Based on the intensive inventory results, the Director, Eastern States recommends that Koochiching Units 42 and 45 be dropped from further wilderness study because they do not qualify as wilderness study areas. The report is available for public review upon request. Written comments are encouraged, and separte worksheets for each unit are available to assist in responding about the characteristics of each area.

After the comment period closes in January, the Bureau will analyze the public response and prepare a *final* decision on whether or not the two Koochiching Units 42 and 45 will become wilderness study areas. A **Federal Register** notice, including the decision and other pertinent information, will be published. Those lands not being designated for further study will be released from wilderness-related management restrictions as set forth in Section 603(c) of the Federal Land Policy and Management Act.

For additional information, contact: Director, Eastern States, Bureau of Land Management, 350 South Pickett Street, Alexandria, Virginia 22304, telephone (703) 235-2840.

Manager, Lake States Office, Bureau of Land Management, 125 Federal Building, Duluth, Minnesota 55802, telephone (218) 727-6692, Ext. 378.

Lowell J. Udy,

Director, Eastern States.

[FR Doc. 79-37224 Filed 12-3-79; 8:45 am]

BILLING CODE 4310-84-M

Nevada; Airport Lease Application

November 23, 1979.

Notice is hereby given that pursuant to the Act of May 24, 1928 (49 U.S.C. 211-214), Clyde Summers and Bill Gates have applied for an airport lease for the following land:

Mount Diablo Meridian

T. 38 N., R. 18 E.,

Sec. 14, Tract 45, Lots A, B, C and D.

The area described comprises 160.20 acres in Washoe County, Nevada. The application was filed June 18, 1979, and on that date the land was segregated from all other forms of appropriation under the public land laws.

Interested persons may submit comments to the District Manager, Bureau of Land Management, P.O. Box 1090, Susanville, CA 96130.

Charles E. Hancock,

Acting Chief, Division of Technical Services.

[FR Doc. 79-37227 Filed 12-3-79 8:45 am]

BILLING CODE 4310-84-M

Fish and Wildlife Service

Endangered Species Permit; Receipt of Application

Applicant: Benson's Wild Animal Park, 27 Kimball Hill Road, Hudson, New Hampshire 03051.

The applicant requests a permit to euthanize (take) one deformed female captive-born jaguar (*Panthera onca*) for enchancement of survival. The animal suffers from a calcium deficiency and is cross-eyed.

Euthanasia will be conducted by an experienced veterinarian.

Documents and other information submitted with this application are available to the public during normal business hours in Room 601, 1000 N. Glebe Road, Arlington, Virginia, or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2-4943. Interested persons may comment on this application on or before January 3, 1980 by submitting written data, views, or arguments to the Director at the above address. Please refer to the file number when submitting comments.

Dated: November 28, 1979.

Donald G. Donahoo

Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[Doc. 79-37229 Filed 12-3-79; 8:45 am]

BILLING CODE 4310-55-M

Endangered Species Permit; Receipt of Application

Applicant: Dr. Chester L. Yntema, Department of Anatomy, 766 Irving Avenue, Syracuse, New York 13210.

The applicant requests a permit to sacrifice up to 150 leatherback (*Dermochelys coriacea)* sea turtles per

year for the next two years as part of a study to determine the effects of changes in incubation temperatures on sex of hatchlings of this and other turtles species.

Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in Room 601, 1000 N. Glebe Road, Arlington, Virginia, or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2–4954. Interested persons may comment on this application on or before January 3, 1980 by submitting written data, views, or arguments to the Director at the above address. Please refer to the file number when submitting comments.

Dated: November 28, 1979.

Donald G. Donahoo

Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 79-37230 Filed 12-3-79; 8:45 am]

BILLING CODE 4310-55-M

Endangered Species Permit; Receipt of Application

Applicant: U. S. Department of Energy, Savannah River Operations Office, Aiken, South Carolina 29801.

The applicant requests a permit to capture and release American alligator (*Alligator mississippiensis*) for scientific purposes including radio monitoring of movements, body temperatures sperm viability and other information.

Humane care and treatment during transport has been indicated by the applicant.

Documents and other information submitted with this application are available to the public during normal business hours in Room 601, 1000 N. Glebe Road, Arlington, Virginia, or by writing to the Director, U.S. Fish and Wildlife Service (WPO), Washington, D.C. 20240.

This application has been assigned file number PRT 2–4924. Interested persons may comment on this application on or before January 3, 1980 by submitting written data, views, or arguments to the Director at the above address. Please refer to the file number when submitting comments.

Dated: November 28, 1979.

Donald G. Donahoo,

Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 79-37231 Filed 12-3-79; 8:45 am]

BILLING CODE 4310-55-M

Water and Power Resources Service

Muddy Ridge Area, Riverton Unit, Wyoming, Pick-Sloan Missouri Basin Program; Intent To Prepare an Environmental Impact Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior proposes to prepare an Environmental Impact Statement for the Muddy Ridge Area, Riverton Unit, Wyoming. The area is situated in the northern part of the Wind River Basin, in Fremont County.

The statement will address the impacts of the following primary alternatives for development in the Muddy Ridge Area.

1. Irrigation of about 5,600 acres would require diverting water from Wind River through the existing Wyoming Canal. A total of 27,500 acre-feet per year would be diverted and tranported by about 25 miles of new canals and laterals. An extensive drainage system would be required and return flows would enter Fivemile Creek and flow to Boysen Reservoir.

2. The existing Muddy Ridge Canal would be used to supply water from return flows of the Riverton Irrigation Unit for spread irrigation of approximately 900 acres. Sixty thousand acres of rangeland would be improved with practices such as stockwater development, cross fencing, and rest rotation grazing.

Improvements would be designed for the benefit of wildlife habitat, although there would also be benefits to livestock grazing.

The future without a Water and Power Resources Service project will also be addressed.

A scoping meeting was held April 26, 1979, in Riverton, Wyoming.

Interested public entities and individuals may obtain information on the project and provide input to the draft environmental statement, which is expected to be completed in mid-1980, by contacting: Derwood C. Mercer, Chief, Field Planning Branch, Water and Power Resources Service, Upper Missouri Regional Office, P. O. Box 2553, Billings, Montana 59103, Telephone: FTS 585–6193—Commercial (406) 657–6193.

Dated: November 28, 1979.

Aldon D. Nielsen,

Acting Assistant Commissioner.

[FR Doc. 79-37254 Filed 12-3-79; 8:45 am]

BILLING CODE 4310-09-M

Heritage Conservation and Recreation Service

National Register of Historic Places; Additions, Deletions, and Corrections

By notice in the **Federal Register** of February 6, 1979. Part II, there was published a list of the properties included in the National Register of Historic Places. Further notice is hereby given that certain amendments or revisions in the nature of additions, deletions, or corrections to the previously published list are adopted as set out below.

It is the responsbility of all Federal agencies to take cognizance of the properties included in the National Register as herein amended and revised in accordance with section 106 of the National Historic Preservation Act of 1966, 80 Stat. 16 U.S.C. 470 et seq. (1970 ed.), and the procedures of the Advisory Council on Historic Preservation, 36 CFR Part 800.

Carol Shull,

Acting Keeper of the National Register.

The following list of properties has been added to the National Register of Historic Places since notice was last given in the February 6, 1979, **Federal Register.** National Historic Landmarks are designated by NHL; properties recorded by the Historic American Buildings Survey are designated by HABS; properties recorded by the Historic American Engineering Record has designated by HAER; properties receiving grants-in-aid for historic preservation are designated by G.

ALABAMA

Jefferson County

Birmingham, *Alabama Theatre,* 1811 3rd. Ave., N. (11–13–79)
Birmingham, *Caldwell-Milner Building,* 2015 1st. Ave. N. (11–8–79)
Birmingham, *McAdory Building,* 2013 1st. Ave., N. (11–14–79)

Marengo County

Demopolis, *Demopolis Historic Business District,* Roughly bounded by Capital and Franklin Sts. Desnanette and Cedar Aves. (10–25–79)

ARKANSAS

Calhoun County

Calion vicinity, *Keller Site (Keller Place)* (10–29–79)

CALIFORNIA

Contra Costa County

Richmond vicinity, *Point Richmond Historic District*, Off CA 17 (11–5–79)

Humboldt County

Samoa vicinity, *Humboldt Bay Life-Saving Station*, S of Samoa on Samoa Rd. (10–30–79)

Los Angeles County

Pasadena, *Holly Street Livery Stable*, 110 E. Holly St. (10–25–79)

Mariposa County

Yosemite National Park, *Camp Curry Historic District*, Yosemite Valley (11–1–79)

Merced County

Merced, *Leggett House*, 352 W. 22nd St. (10–25–79)

Orange County

Yorba Linda, *Pacific Electric Railway Company Depot*, 18132 Imperial Hwy. (10–25–79)

San Francisco County

San Francisco, *Girls Club*, 362 Capp St. (11–6–79)
San Francisco, *Lewis Ark (houseboat)*, Hyde St. Pier (11–8–79)
San Francisco, *Tubbs Cordage Company Office Building*, Hyde St. Pier (11–8–79)

Sonoma County

Geyserville, *Geyserville Union School*, Main St. (10–24–79)

COLORADO

Denver County

Denver, *Denver Athletic Club*, 1325 Glenarm Pl. (11–14–79)
Denver, *Fire Station No. 1*, 1326 Tremont Pl. (11–14–79)
Denver, *Neef, Frederick W., House*, 2143 Grove St. (10–25–79)
Denver, *St. Patrick Mission Church*, 3325 Pecos St. (11–14–79)
Denver, *Schlessinger House*, 1544 Race St. (11–14–79)
Denver, *Shorthorn Building*, 2257 Larimer St. (11–14–79)
Denver, *Zang, Adolph J., House*, 1532 Emerson St. (11–14–79)

Larimer County

Fort Collins, *Anderson, Peter, House*, 300 S. Howes St. (10–25–79)

Pueblo County

Pueblo, *Central High School*, 431 E. Pitkin Ave. (11–14–79)
Pueblo, *First Methodist Episcopal Church, South*, 400 Broadway St. (11–14–79)

CONNECTICUT

Hartford County

West Hartford, *Hooker, Sarah Whitman, House*, 1237 New Britain Ave. (11–1–79)

New Haven County

New Haven, *Prospect Hill Historic District*, Off CT 10 (11–2–79)

DELAWARE

Kent County

Little Creek vicinity, *Port Mahon Lighthouse*, NE of Little Creek (10–25–79)

New Castle County

Wilmington vicinity, *Glynrich*, Mill Rd. and Race St. (11–1–79) HABS.

Sussex County

Georgetown, *Brick Hotel*, The Circle (11–13–79)
Georgetown, *Judge's House and Law Office*, 100 and 104 W. Market St. (11–13–79) HABS.
Georgetown, *St. Paul's Episcopal Church*, E. Pine St. (11–13–79)
Georgetown vicinity, *Gyles, Stella Pepper, House*, SW of Georgetown (11–13–79)

GEORGIA

De Kalb County

Atlanta vicinity, *Druid Hills Historic District*, U.S. 29/78 (10–25–79)

Houston County

Henderson vicinity, *Davis-Felton Plantation*, NW of Henderson on Felton Rd. (11–13–79)

Richmond County

Augusta, *Reid-Jones-Carpenter House*, 2249 Walton Way (11–13–79) HABS.

GUAM

Naval Station, *Orote Historical Complex*, Orote Point (10–23–79)

IDAHO

Adams County

New Meadows, *Meadows Schoolhouse*, ID 55 (10–30–79)

Canyon County

Parma, *Stewart, A. H., House (Hotel Parma)*, 3rd St. and Bates Ave. (10–25–79)

Kootenai County

Coeur d'Alene, *Fort Sherman Buildings*, North Idaho Junior College campus (10–25–79)

Washington County

Weiser, *Intermountain Institute*, Paddock Ave. (11–1–79)

ILLINOIS

Du Page County

Wheaton, *Blanchard Hall*, Wheaton College campus (11–14–79)

INDIANA

Elkhart County

Elkhart, *Bickel, Emmanuel C., House*, 614 Bower St. (11–14–79)

Grant County

Fairmount, *Patterson, J. W., House*, 203 E. Washington St. (11–14–79)

Marion County

Indianapolis, *Schnull-Rauch House*, 3050 N. Meridian St. (11–14–79)

Shelby County

Morristown, *Junction Railroad Depot*, U.S. 52 (11–14–79)

Wabash County

North Manchester, *Noftzger-Adams House*, 102 E. 3rd St. (11–14–79)

MAINE

York County

Kittery Point, *Howells, William Dean, House*, Pepperrell Rd. (10–25–79)

MARYLAND

Baltimore (independent city)

Cummins Memorial Church, 210 W. Lanvale St. (10–31–79).

Carroll County

Westminster vicinity, *Royer, Christian, House*, N of Westminster (11–7–79).

Harford County

Abingdon vicinity, *Woodside*, NW of Abingdon at 400 Singer Rd. (11–1–79).

Talbot County

Bellevue, *Clay's Hope*, Bellevue Rd. (10–31–79)
Easton vicinity, *Hope House*, NW of Easton (11–1–79).

Washington County

Hagerstown vicinity, *Old Forge Farm*, E of Hagerstown (11–7–79).
Hagerstown vicinity, *Rohrer House*, E of Hagerstown (11–7–79).

MASSACHUSETTS

Barnstable County

Chatham vicinity, *Monomoy Point Lighthouse*, Monomoy Island (11–1–79).

Essex County

Lawrence, *Downtown Lawrence Historic District*, Roughly bounded by MA 110, Methuen, Lawrence and Jackson Sts. (11–1–79).

Middlesex County

Newton, *Winslow-Haskell Mansion*, 53 Vista Ave. (10–25–79).

Worcester County

Gardner, *First Minister's House*, 186 Elm St. (11–14–79).
Gardner, *Gardner News Building*, 309 Central St. (11–14–79).
Gardner, *Smith, F. W., Silver Company*, 60 Chestnut St. (11–14–79).

MICHIGAN

Wayne County

Detroit, *Columbia (steamer)*, 661 Civic Center Dr. (11–2–79).
Detroit, *Ste. Claire (steamer)*, 661 Civic Center Dr. (11–2–79).

MINNESOTA

Goodhue County

Red Wing, *Gladstone Building*, 309 Bush St. (11–14–79).
Red Wing, *Kappel Wagon Works*, 221 W. 3rd. St. (11–14–79).

Red Wing, *Keystone Building*, 409 Main St. (11–14–79).
Red Wing, *Pratt-Tabor House*, 706 W. 4th St. (11–14–79).
Red Wing, *Red Wing City Hall*, W. 4th St. (11–14–79).
Red Wing, *Red Wing Iron Works*, 401 Levee St. (11–14–79).

Washington County

Stillwater, *Nelson School*, 1018 S. 1st St. (10–25–79).

MISSISSIPPI

Adams County

Natchez, *Roos House*, 208 Linton Ave. (11–8–79).

Lafayette County

College Hill, *College Church*, College Hill Rd. (11–13–79).

Warren County

Vicksburg, *Yazoo and Mississippi Valley Depot*, 500 Grove St. (11–13–79).

MISSOURI

Jackson County

Kansas City, *Wholesale District*, Roughly bounded by 6th, Wyandotte, 8th, May, 11th and Washington Sts. (10–25–79).

NEBRASKA

Dawson County

Gothenburg, *Calling, Ernest A., House*, 1514 Lake Ave. (10–25–79).

NEVADA

Douglas County

Glenbrook, *Lake Shore House*, Glenbrook Rd. (10–4–79).

NEW HAMPSHIRE

Carroll County

Moultonborough vicinity, *Windermere*, SW of Moultonborough on Long Island (11–14–79).

Grafton County

Enfield, *Enfield Shaker Historic District*, SR 4A (11–7–79).

Rockingham County

Portsmouth, *Wentworth-Gardner and Tobias Lear Houses*, Mechanic and Gardner Sts. (10–30–79).

NEW JERSEY

Bergen County

Closter, *Demaree, Abram, House*, Schraalenburgh and Old Hooks Rds. (11–1–79).

Hunterdon County

Califon, *Apgar, J. K., Farmhouse*, SR 512 and Guinea Hollow Rd. (11–1–79).
Clinton vicinity, *Van Syckel Corner District*, Van Syckels Corner and Norton Rds. (11–8–79).
Pittstown vicinity, *Lansdown*, NE of Pittstown on SR 2 (11–2–79).

Monmouth County

Long Branch, *House at 364 Cedar Avenue* (11–1–79).

Morris County

Chatham, *Dusenberry House*, 186 Main St. (11–1–79).

Sussex County

Hamburg vicinity, *Lawrence Mansion*, W of Hamburg on NJ 94 (11–2–79).

NEW YORK

Albany County

Menands, *Albany Rural Cemetery*, Cemetery Ave. (10–25–79).

NORTH CAROLINA

Caswell County

Yanceyville vicinity, *Poteat House*, N of Yanceyville on NC 62 (10–24–79).

NORTH DAKOTA

Benson County

Maddock vicinity, *Viking Lutheran Church*, SE of Maddock (11–14–79).

Williams County

Williston, *James Memorial Library*, 621 1st. Ave. W. (11–14–79).

OHIO

Erie County

Vermilion, *VERMILION-HARBOUR TOWN MULTIPLE RESOURCE AREA (Partial Inventory)*. This area includes various properties at various locations. Details available upon request. (11–14–79).

Knox County

FREDERICKTOWN MULTIPLE RESOURCE AREA. (Partial Inventory). This area includes various properties at various locations. Details available upon request.

Seneca County

Flat Rock vicinity, *Henny Barn*, NE of Flat Rock (11–6–79).

OREGON

Clackamas County

Marquam vicinity, *Albright, Daniel, Farm*, E of Marquam (10–30–79).
Oregon City, *Cross, Harvey, House*, 809 Washington St. (10–30–79).

Douglas County

Elkton vicinity, *Brown, Henry, House*, W of Elkton off OR 38 (10–30–79).

Josephine County

Grants Pass, *Redwoods Hotel*, 310 NW. 6th St. (10–25–79).

Lane County

Eugene, *Schaefers Building*, 1001 Williamette St. (10–30–79).
Eugene vicinity, *Campbell, Robert E., House*, E of Eugene at 890 Aspen Dr. (11–1–79).

Wasco County

Shaniko, *Columbia Southern Hotel*, 4th and E Sts. (10–31–79).

PENNSYLVANIA

Allegheny County

Pittsburgh, *Rodef Shalom Temple*, 4905 5th Ave. (11–5–79).

Centre County

Oak Hall, *Oak Hall Historic District*, SR 871 (10–25–79).

Chester County

Strickersville, *Lunn's Tavern*, PA 896 (10–25–79).

Clearfield County

Clearfield, *Murray, Thomas, House*, 120 S. 2nd St. (10–25–79).

Lehigh County

Zionsville vicinity, *Dillingersville Union School and Church*, E of Zionsville on Zionsville Rd. (10–25–79).

Montgomery County

Cheltenham, *Rowland House, 300 Ashbourne Rd. (10–25–79).*

Pike County

Milford vicinity, *Zimmerman, Marie, Farm*, SW of Milford on U.S. 209 (11–1–79).

Snyder County

Selinsgrove, *Selinsgrove Hall and Seibert Hall*, Pine St. (10–25–79).

SOUTH CAROLINA

York County

York, *York Historic District*, SC 5 and U.S. 321 (10–18–79).

SOUTH DAKOTA

Jerauld County

Wessington Springs, *Shakespeare Garden and Shay House*, Off SD 34 (11–14–79).

TENNESSEE

Cheatham County

Kingston Springs, *Kingston Springs Hotel and Buildings*, Kingston Springs Rd. (10–31–79).

Davidson County

Nashville, *Third Baptist Church (Hopewell Missionary Baptist Church and Parsonage)* 906 and 908 Monroe St. (10–31–79).

Polk County

Ocoee *Ocoee Hydroelectric Plant No. 2*, U.S. 64 (10–31–79).

Shelby County

Memphis, *Annesdale-Snowden Historic District*, Roughly bounded by I–255, Lamar Ave. and Heistan Pl. (10–25–79).
Memphis, *Overton Park Historic District*, I–40 (10–25–79).

TEXAS

Bandera County

Bandera, *Bandera County Courthouse and Jail*, Public Sq., 12th and Maple Sts. (10–31–79).

Bexar County

San Antonio, *San Pedro Springs Park*, San Pedro Ave. (11–1–79).

Bosque County

Meridian, *First National Bank Building*, Main and Morgan Sts. (11–7–79).
Meridian vicinity, *Bridges-Johnson House*, 1.6 mi. SW of Meridian off TX 6 (10–25–79).

Bowie County

Texarkana, *Whitaker House*, 517 Whitaker St. (11–7–79).

Edwards County

Rocksprings, *Edwards County Courthouse and Jail*, Public Sq. (11–7–79)

Floyd County

Floydada vicinity, *Floydada Country Club Site*, 7 mi. S of Floydada off U.S. 62 (11–7–79)

Guadalupe County

Seguin, *Hall, Robert, House*, 214 S. Travis St. (10–25–79)

Harrison County

Marshall, *Stinson, John R., House (Gaines, Belle Fry, House)* 313 W. Austin St. (11–7–79)

Marshall, *Turner, James, House*, 406 W. Washington Ave. (11–7–79)

Hidalgo County

Hidalgo, *Old Hidalgo School*, Flora and 4th Sts. (10–24–79)

Hudspeth County

Sierra Blance vicinity, *Johnson, Rod, site (41 HZ 101)* W of Sierra Blanca (11–1–79)

Sierra Blanca vicinity, *Tinaja De Las Palmas Battle Site*, SE of Sierra Blanca (11–7–79)

Jefferson County

Port Arthur, *Rose Hill*, 100 Woodworth Blvd. (10–31–79)

Lee County

Giddings vicinity, *Droemer Brickyard site*, 1 mi. SW of Giddings on Old Serbin Rd. (11–7–79)

Travis County

Austin, *Rather House*, 3105 Duval St. (10–24–79)

Williamson County

Georgetown, *Railroad Produce Depot*, 401 W. 6th St. (11–7–79)

Emery County

Ferron vicinity, *Singleton, Samuel, House*, S of Ferron on UT 10 (11–8–79)

Iron County

Parowan vicinity *Long Flat Site* (11–1–79)

Sanpete County

Mount Pleasant, *Mount Pleasant Commercial Historic District*, U.S. 89 and UT 116 (10–26–79)

Sevier County

Salina vicinity, *Aspen-Cloud Rock Shelters*, NE of Salina (11–1–79)

VERMONT

Chittenden County

Winooski, *Porter Screen Company*, 110 E. Spring st. (11–15–79)

WEST VIRGINIA

Grant County

Petersburg, *Grant County Courthouse*, Virginia Ave. (10–26–79)

Jefferson County

Harpers Ferry, *Harpers Ferry Historic District*, Off U.S. 340 (10–15–79)

WISCONSIN

Dane County

Madison, *Miller House*, 647 E. Dayton St. (11–8–79)

Jefferson County

Watertown, *St. Paul's Episcopal Church*, 413 S. 2nd St. (11–7–79)

Determinations of eligibility are made in accordance with the provisions of 36 CFR 63, procedures for requesting determinations of eligibility, under the authorities in section 2(b) and 1(3) of Executive Order 11593 and section 106 of the National Historic Preservation Act of 1966, as amended, as implemented by the Advisory Council on Historic Preservation's procedures, 36 CFR Part 800. Properties determined to be eligible under section 63.3 of the procedures for requesting determinations of eligibility are designated by (63.3)

Properties which are determined to be eligible for inclusion in the National Register of Historic Places are entitled to protection pursuant to section 106 of the National Historic Preservation Act of 1966, as amended, and the procedures of the Advisory Council on Historic Preservation, 36 CFR Part 800. Agencies are advised that in accord with the procedures of the Advisory Council on Historic Preservation, before an agency of the Federal Government may undertake any project which may have an effect on an eligible property, the Advisory Council on Historic Preservation shall be given an opportunity to comment on the proposal.

The following list of additions, deletions, and corrections to the list of properties determined eligible for inclusion in the National Register is intended to supplement the cumulative version of that list published in February of each year.

CALIFORNIA

Alameda County

Castor Valley, *Crow Creek Bridge*, I–580 (63.3)

Humboldt County

Bayside, *Trinidad Water Tower*, Old Arcata Rd. (63.3)

Shasta County

Lassen National Forest, *Archeological sites, FS 05–06–58–91, 125, 339, and 341*

Solano County

Fairfield, *748 Broadway Building* (63.3)

Trinity County

Douglas City vicinity, *Indian Creek Townsite*, near Indian Creek (63.3)

Yuba County

Honcut vicinity, *Honcut Creek Bridge*, W of Honcut (63.3)

COLORADO

Mesa County

Clifton vicinity, *Anderegg House*, S of Clifton at 498 32 Rd. (63.3)

CONNECTICUT

Fairfield County

Bridgeport, *Marina Park Historic District (63.3)*

Westport, *Beachside Avenue Bridge* (63.3)

New Haven County

East Haven, *Elanthan House*, 147 Hemingway Ave.

East Haven, *Gideon Potter House*, 274 Hemingway Ave. (63.3)

DISTRICT OF COLUMBIA

Washington

Boundary Stone SE No. 5 (also in Prince Georges County, MD)

O Street Market (63.3)

GEORGIA

Ben Hill County

Fitzgerald, *Grand Theatre*, 113—121 Main St. (63.3)

ILLINOIS

Hancock County

Hamilton, *Mississippi River Bridge* (also in Lee County, IA)

Pope County

Archeological Sites 25D3–23(12PO521) and 25D3–24(12PO522)

INDIANA

Delaware County

Muncie, *Federal Building*, High and Charles Sts. (63.3)

IOWA

Harrison County

Lincoln, Abraham, Memorial Bridge, U.S. 30 (also in Washington County, NE)

Jasper County

Newton, *Rainbow Arch Bridge*, W. 8th St. (63.3)

Lee County

Keokuk, *Mississippi River Bridge* (also in Hancock County, IL)

Polk County

Des Moines, *Bankers Trust Building*, 605 Locust St.

Scott County

Davenport, *Village of East Davenport Historic District*

Woodbury County

Sioux City, *Pacific Short Line Bridge*, U.S. 20 (also in Dakota County, NE)

MAINE

Washington County

Jonesport vicinity, *Archeological Site 61–20 (63.3)*

MARYLAND

Montgomery County

Gaithersburg, *Ascension Chapel*, Frederick and Summit Ave.
Gaithersburg, *Fulks, Thomas, House*, 208 S. Frederick Ave.
Gaithersburg, *Grace United Methodist Church*, 1 Walker Ave.
Germantown, *Germantown Historic District (63.3)*

Prince Georges County

Boundary Stone SE No. 5. Reference—see Washington, DC.
Greenbelt, *Greenbelt Historic District*
Temple Hills, *St. Barnabas Episcopal Church*, 5203 St. Barnabas Rd. (63.3)

Talbot County

Easton, *Easton Historic District* (63.3)
Easton, *Stoney Ridge Farm*, Dutchman's Lane

MASSACHUSETTS

Essex County

Andover, *Tyer Rubber Company*, 10—30 Railroad St.
Lynn, *Fabens Building*, 312—344 Union St.

Hampden County

Chicopee, *Polish National Home*, 136—144 Cabot St.

Middlesex County

Newton Upper Falls, *Newton Upper Falls Railroad Station*, Chestnut and Oak Sts. (63.3)

Suffolk County

Boston, *Boston Edison Electric Illuminating Company Building*, 39 Boylston St.
Boston, *Buildings at 113, 101, 91—95, 83—87 Summer Street*
Boston, *Grand Lodge of the Masons*, 186 Tremont St.
Boston, *Proctor Building (Triangle Cigar Store)*
Boston, *Tremont Street Block Between Avery and Boylston Street*

MISSISSIPPI

Hinds County

Jackson, *Section 8 Housing Project Area in Jackson*

MISSOURI

Mississippi County

Charleston, *Mississippi County Courthouse and Jail*

St. Charles County

St. Charles, *Bruns, Norman, House*, 3030 W. Clay Ave.

St. Francois County

Farmington, *St. Francois County Juvenile Center*

Warren County

Warrenton, *Warren County Jail*, 108 W. Boonslick Rd.

MONTANA

Cascade County

Great Falls vicinity, *Archeological Site 24CA74*, E of Great Falls (63.3)

Roosevelt County

Poplar, *Gateway Hotel*, 1st Ave. and A St. (63.3)

NEBRASKA

Dakota County

PACIFIC SHORT LINE BRIDGE. Reference—see Woodbury County, IA. (63.3)

Washington County

LINCOLN, ABRAHAM, MEMORIAL BRIDGE. Reference—see Harrison County, IA.

NEW JERSEY

Essex County

Newark, *Building at 585 Mount Prospect Avenue* (63.3)
Newark, *Building at 599 Mount Prospect Avenue* (63.3)

Hudson County

Jersey City, *Jersey City Medical Center* (63.3)
Jersey City, *Pier 2*, Liberty State Park (63.3)
Jersey City, *Van Vorst Park Historic District* (63.3)

Mercer County

Trenton, *Hog Island Locomotive Gantry Cranes*, Trenton Marine Terminal area (63.3)

Middelsex County

Sayreville vicinity, *Tennent Brook South Site (28–MI–81)* (63.3)

NORTH CAROLINA

Washington County

Plymouth, *Plymouth Railroad Station*

OKLAHOMA

Pushmataha County

Clayton Lake vicinity, *Bug Hill Site (34PU116)* (63.3)

OREGON

Clackamas County

Three Lynx Railroad Grade Site (CL107), Mount Hood National Forest (63.3)

PENNSYLVANIA

Lehigh County

Allentown, *Old Lehigh County Courthouse*, 501 Hamilton St.

RHODE ISLAND

Providence County

Scituate, *Battey-Barden House*, Plainfield Pike
Woonsocket, *Hanora Mills*, 1 Main St. (63.3)

SOUTH DAKOTA

Lake County

Madison, *Main Post Office*, 119 Center St.

TEXAS

Bexar County

San Antonio, *Archeological Site 41BX1 North*

Live Oak County

Tilden vicinity, *Choke Canyon Reservoir Archeological District* (also in McMullen County) (63.3)

McMullen County

CHOKE CANYON RESERVOIR ARCHEOLOGICAL DISTRICT. Reference—see Live Oak County.

McCulloch County

Brady vicinity, *Saltwater Creek Floodwater Retardation Structure 6A Archeological District* (63.3)

UTAH

BRYCE CANYON NATIONAL PARK MULTIPLE RESOURCE AREA. This area includes various properties at various locations. Details available upon request.

WEST VIRGINIA

Cabell County

Huntington, *U.S. Post Office and Courthouse*, 9th St. and 5th Ave. (63.3)

Marshall County

Moundsville, *U.S. Post Office (Federal Building)*, Lafayette and 7th Sts. (63.3)

Mercer County

Bluefield, *U.S. Post Office and Courthouse (Kee Federal Building)*, 601 Federal St. (63.3)

[FR Doc. 79–36861 Filed 12–3–79; 8:45 am]
BILLING CODE 4310–03–M

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the Heritage Conservation and Recreation Service before November 23, 1979. Pursuant to section 60.13 of 36 CFR Part 60, written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded to the National Register, Heritage Conservation and Recreation Service, U.S. Department of the Interior, Washington, DC 20243. Written comments or a request for additional time to prepare comments should be submitted by December 14, 1979.

Carol Shull,

Acting Chief, Registration Branch.

CALIFORNIA

San Bernardino County

Upland, *Old San Antonio Hospital*, 792 W. Arrow Hwy.

COLORADO

Boulder County

Ward vicinity, *Denver, Boulder and Western Railway Historic District, CO 72*

NEW MEXICO

San Miguel County

Las Vegas, *Adele Ilfeld Auditorium,* New Mexico Highlands University campus

PENNSYLVANIA

Lebanon County

Schaefferstown vicinity, *Bobb House,* NE of Schaefferstown

TENNESSEE

HUNT, REUBEN H., BUILDINGS IN HAMILTON COUNTY THEMATIC RESOURCES. Reference—see individual listings under Hamilton County.

Hamilton County

Chattanooga, *Brainerd Junior High School (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 4201 Cherryton Dr.

Chattanooga, *Carnegie Public Library (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 200 E. 8th St.

Chattanooga, *Chattanooga Bank Building (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 8th St.

Chattanooga, *Chattanooga Electric Railway (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 211–241 Market St.

Chattanooga, *First Baptist Church (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 317 Oak St.

Chattanooga, *Hamilton County Courthouse (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* Georgia Ave. and 6th St.

Chattanooga, *Hardy, Richard, Junior High School (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 2115 Dodson Ave.

Chattanooga, *Highland Park Methodist Episcopal Church (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* Bailey Ave.

Chattanooga, *James Building (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 735 Broad St.

Chattanooga, *Medical Arts Building (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* McCallie Ave.

Chattanooga, *Municipal Building (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* E. 11th St.

Chattanooga, *News-Pound Building (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* E. 11th St.

Chattanooga, *Northside United Presbyterian Church (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 923 Mississippi Ave.

Chattanooga, *Second Presbyterian Church (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 700 Pine St.

Chattanooga, *Soldiers and Sailors Memorial Auditorium (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* McCallie Ave.

Chattanooga, *Tivoli Theater (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 709 Broad St.

Chattanooga, *Trinity Methodist Episcopal Church (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* McCallie Ave.

Chattanooga, *U.S. Post Office (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* Georgia Ave.

Chattanooga, *Willard, Frances, House (Hunt, Reuben H., Buildings in Hamilton County Thematic Resources)* 615 Lindsay St.

Hardeman County

Bolivar, *North Main Street Historic District,* N. Main, Sycamore, Jefferson, Washington and Water Sts.

Shelby County

Memphis, *U.S. Marine Hospital Historic District,* 360 and 374 W. California Ave.

TEXAS

Bexar County

San Antonio, *San Antonio Casino Club Building,* 102 W. Crockett St.

Ector County

Odessa, *White-Pool House,* 112 E. Murphy St.

Fannin County

Ladonia, *Haden House,* 603 W. Bonham St.

Hill County

Hillsboro, *Missouri-Kansas-Texas Company Railroad Station,* Covington, St.

[FR Doc. 79-36860 Filed 12-3-79; 8:45]

BILLING CODE 4310-03-M

INTERNATIONAL COMMUNICATION AGENCY

U.S. Advisory Commission on Public Diplomacy (Formerly, U.S. Advisory Commission on International Communication, Cultural, and Educational Affairs); Open Meeting

As previously announced, the U.S. Advisory Commission on Public Diplomacy will conduct an open meeting on December 13, 1979, in Room 600, 1750 Pennsylvania Avenue NW., Washington, D.C., 9 a.m. to 5 p.m.

The topics covered will be Congressional and Public Liaison, Availability of USICA Products in the United States, and Research in European Opinion. On December 14, 1979, a review of USICA programs in the Middle East will be held in closed session from 9 a.m. to 11 a.m. Since space is limited, please call Miss Elizabeth Fahl, 724–9974, if you are interested in attending the meeting.

Jane S. Grymes,

Management Analyst, Management Analysis/Regulations Staff, Associate Directorate for Management, International Communication Agency.

[FR Doc. 79-37218 Filed 12-3-79; 8:45 am]

BILLING CODE 8230-01-M

DEPARTMENT OF LABOR

Steel Tripartite Committee Working Group on Labor and Community Adjustment Assistance; Notice of Meeting

Note.—This document originally appeared in the **Federal Register** for Monday, December 3, 1979. It is reprinted in this issue to meet the Tuesday/Friday publication schedule assigned to the Labor Department.

The Steel Tripartite Committee was established under the Federal Advisory Committee Act, 5 U.S.C. App. (1976) to advise the Secretary of Labor and Secretary of Commerce on international and domestic issues affecting the U.S. steel industry, labor and public.

Notice is hereby given that the Steel Tripartite Committee's Working Group on Labor and Community Adjustment Assistance will meet at 10:00 A.M., on December 5, 1979, in room S 2217, U.S. Department of Labor, 200 Constitution Ave., N.W., Washington, D.C. 20210.

Items to be discussed are the labor and community adjustment assistance impact of the recent decision by the United States Steel Corporation and the Jones & Laughlin Steel Corporation to close a number of steel and steel-related facilities. Due to the emergency nature of the situation, insufficient time was available to give 15 days advance notice of the Working Group meeting. The public is invited to attend. A limited number of seats will be available to the public on a first-come basis.

For additional information contact Mr. David L. Mallino, Executive Secretary, Steel Tripartite Committee, Bureau of International Labor Affairs, U.S. Department of Labor, Washington, D.C., 20210, telephone (202) 523–7481.

Official records of the meeting will be available for public inspection at N 5631, U.S. Department of Labor, Washington, D.C. 20210.

Signed at Washington, D.C. this 29th day of November 1979.

Herbert N. Blackman,

Deputy Under Secretary for International Affairs (Acting) U.S. Department of Labor.

[FR Doc. 79-37253 Filed 11-30-79; 8:45 am]

BILLING CODE 4510-28-M

Employment and Training Administration

Employment Transfer and Business Competition Determinations Under the Rural Development Act; Notice of Applications

The organizations listed in the attachment have applied to the Secretary of Agriculture for financial assistance in the form of grants, loans, or loan guarantees in order to establish or improve facilities at the locations listed for the purposes given in the attached list. The financial assistance would be authorized by the Consolidated Farm and Rural Development Act, as amended, 7 USC 1924(b), 1932, or 1942(b).

The Act requires the Secretary of Labor to determine whether such Federal assistance is calculated to or is likely to result in the transfer from one area to another of any employment or business activity provided by operations of the applicant. It is permissible to assist the establishment of a new branch, affiliate or subsidiary, only if this will not result in increased unemployment in the place of present operations and there is no reason to believe the new facility is being established with the intention of closing down an operating facility.

The Act also prohibits such assistance if the Secretary of Labor determines that it is calculated to or is likely to result in an increase in the production of goods, materials, or commodities, or the availability of services or facilities in the area, when there is not sufficient demand for such goods, materials, commodities, services, or facilities to employ the efficient capacity of existing competitive commercial or industrial enterprises, unless such financial or other assistance will not have an adverse effect upon existing competitive enterprises in the area.

The Secretary of Labor's review and certification procedures are set forth at 29 CFR Part 75. In determining whether the applications should be approved or denied, the Secretary will take into consideration the following factors:

1. The overall employment and unemployment situation in the local area in which the proposed facility will be located.

2. Employment trends in the same industry in the local area.

3. The potential effect of the new facility upon the local labor market, with particular emphasis upon its potential impact upon competitive enterprises in the same area.

4. The competitive effect upon other facilities in the same industry located in other areas (where such competition is a factor).

5. In the case of applications involving the establishment of branch plants or facilities, the potential effect of such new facilities on other existing plants or facilities operated by the applicant.

All persons wishing to bring to the attention of the Secretary of Labor any information pertinent to the determinations which must be made regarding these applications are invited to submit such information in writing within two weeks of publication of this notice. Comments received after the two-week period may not be considered. Send comments to: Administrator, Employment and Training Administration, 601 D Street NW., Washington, D.C. 20013.

Signed at Washington, D.C. this 29th day of November 1979.

Earl T. Klein,

Director, Office of Program Services.

Applications received during the week ending December 1, 1979.

Name of applicant and location of enterprise: Glover, Inc., Rosewell, New Mexico; principal product or activity: Processing of carcass—beef and pork.

[FR Doc. 79-37219 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-30-M

Reallocation of Funds

AGENCY: Employment and Training Administration.

ACTION: Notice of Reallocated Titles II-D and VI Funds Redistributed to Comprehensive Employment and Training Act (CETA) Prime Sponsors.

SUMMARY: Pursuant to 20 CFR 676.47, the Department of Labor announces the redistribution of funds reallocated under Titles II-D and VI of the Comprehensive Employment and Training Act (CETA).

FOR FURTHER INFORMATION CONTACT: Robert Anderson, Administrator, Office of Comprehensive Employment Development, 601 D Street, NW., Room 5010, Washington, D.C. 20213, Telephone: 202-376-6254.

SUPPLEMENTARY INFORMATION: The following CETA prime sponsors received the amounts indicated of reallocated Titles II-D and VI funds. The Department of Labor reviewed the operations of these prime sponsors and determined that they could effectively utilize the amounts indicated prior to the end of fiscal year 1979.

	Title II-D	Title VI
Lowell Consortium, Mass	0	$150,000
San Juan Municipio, Puerto Rico	0	1,689,945
Balance-of-State, W. Va	0	700,000
Henrico Consortium, Va	0	27,000
Baltimore Consortium, Md	0	504,825
Balance-of-State, Pa	$1,300,000	0
Mercer County, Pa	494,604	0
York County, Pa	45,000	0
Balance-of-State, Ga	600,000	400,000
City of Raleigh, N.C	0	160,000
Tampa/Hillsborough Csrt., Fla	165,400	187,800
Okaloosa County, Fla	50,000	75,000
St. Joseph County, Ind	0	275,000
City of South Bend, Ind	0	326,000
South West Indiana Consortium	0	260,000
St. Clair County, Mich	0	717,803
City of Duluth, Minn	0	305,000
Okron Tri-County Csrt., Ohio	160,000	240,000
Canton/Stark/Wayne Csrt., Ohio	0	541,000
Trumball County, Ohio	0	56,000
Lorain County, Ohio	0	432,000
Central Texas Consortium	180,000	0
Webb County, Tex	250,000	500,000
Baton Rouge, La	300,000	0
Quachita Parish, La	400,000	0
Comanche County, Okla	0	295,972
Kansas City, Csrt., Mo	700,000	1,300,000
City of Springfield, Mo	0	80,000
Balance-of-State, Mo	0	1,800,000
Boulder County, Colo	0	50,000
Balance-of-State, Nev	325,000	375,000
Shasta County, Calif	0	196,000
Santa Barbara County, Calif	0	112,688

Signed at Washington, D.C., this 19th day of November, 1979.

Charles B. Knapp,

Deputy Assistant Secretary for Employment and Training.

[FR Doc. 79-37088 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-30-M

Voluntary Reallocation of Funds

AGENCY: Employment and Training Administration.

ACTION: Final Notice of the Voluntary Reallocation of Funding Under Titles II-D and VI of the Comprehensive Employment and Training Act (CETA).

SUMMARY: Pursuant to 20 CFR 676.47, the Department of Labor announces the voluntary reallocation of Titles II-D and VI funds in the amounts and from the prime sponsors indicated below.

FOR FURTHER INFORMATION CONTACT: Robert Anderson, Administrator, Office of Comprehensive Employment Development, 601 D Street, N.W., Room 5010, Washington, D.C. 20213, Telephone: 202-376-6254.

SUPPLEMENTARY INFORMATION: The prime sponsors listed below advised the Department of Labor that they had excess funds available under Titles II-D and VI of their fiscal year 1979 CETA grants and that they would be unable to effectively utilize these funds prior to the end of fiscal year 1979. They further advised that they were agreeable to voluntary reallocation of these funds.

The Department of Labor Regional Offices determined that the prime sponsors listed below had made every effort to utilize the available funds. However, due to such factors as declining unemployment rates, the prime

sponsors have been unable to recruit a sufficient number of individuals which meet the required eligibility requirements. The Governor, the general public and other prime sponsors were provided with 30 days notice to provide comments to the Regional Offices regarding the reallocation of these funds.

	Title II–D	Title VI
Fulton County, Ga	$150,000	$175,000
Cobb County, Ga	194,773	72,215
Middle Georgia Consortium	891,932	296,261
De Kalb County, Ga	234,000	0
Pasco County, Fla	79,000	0
Seminole County, Fla	69,500	0
Orange/Orlando Csrt., Fla	76,050	40,950
Balance-of-State, Fla	239,500	239,000
City of Chattanooga, Tenn	200,000	210,000
Balance-of-State, Tenn	0	2,210,000
Wake County, N.C	245,000	260,000
City of Charlotte, N.C	0	550,000
Kane/De Kalb Consortium, Ill	472,830	453,090
McLean County, Ill	250,000	150,000
Du Page County, Ill	893,047	1,200,000
Balance-of-State, Ind	0	3,500,000
City of Warren, Mich	0	400,000
Balance-of-State, Ohio	0	550,000
Fort Worth Consortium, Tex	1,866,434	0
North Texas Consortium	387,640	95,000
Harris County, Tex	1,000,000	0
Oklahoma County, Okla	0	295,972
City of Torrance, Calif	0	140,540
Imperial County, Calif	654,440	1,865,404
Northern Marianas	477,740	161,939

Signed at Washington, D.C., this 19th day of November, 1979.

Charles B. Knapp,

Deputy Assistant Secretary for Employment and Training.

[FR Doc. 79-37087 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-30-M

Reallocation of Funds

AGENCY: Employment and Training Administration.

ACTION: Final Notice of Funds Reallocated Under titles II–D and VI of the Comprehensive Employment and Training Act (CETA).

SUMMARY: Pursuant to 20 CFR 676.47, the Department of Labor announces the reallocation of Titles II–D and VI funds in the amounts and from the prime sponsors indicated below.

FOR FURTHER INFORMATION CONTACT: Robert Anderson, Administrator, Office of Comprehensive Employment Development, 601 D Street, N.W., Room 5010, Washington, D.C. 20213, Telephone: 202–376–6254.

SUPPLEMENTARY INFORMATION: The Department of Labor determined, by reviewing actual enrollments with planned enrollments and rates of expenditures, that the CETA programs listed below were underutilizing available funds. The prime sponsors were provided with an opportunity to increase their performance before a final decision was made with respect to reallocation. The respective Governors, the general public and other prime sponsors were advised of the proposed reallocation of funds in the July 13, 1979, and the August 7, 1979, **Federal Registers.**

At the end of 30 days from the date of notice to the prime sponsors, the Department again reviewed the prime sponsor enrollments. The Department found, in the case of the prime sponsors listed below, that the amount of funds indicated for each prime sponsor could not effectively be utilized by the prime sponsor prior to the end of Fiscal Year 1979. As a result, the Department took final reallocation actions with respect to these prime sponsors. Prime sponsors which were listed in the July 31 and August 7 **Federal Registers,** and which are not listed below, were found to have improved their performance to the point where no reallocations were required.

	Title II–D	Title VI
Brockton Consortium, Mass	$899,733	$443,601
Hampden County Csrt., Mass	174,938	0
Westmoreland County, Penn	239,000	0
Fayette County, Penn	235,000	0
Beaver County, Penn	129,000	236,000
Washington County, Penn	271,000	245,000
City of Pittsburgh, Penn	147,000	479,000
Lancaster/Lebanon Csrt., Penn	0	225,600
Berks County, Penn	0	148,000
Balance-of-State, Virginia	0	2,920,000
Prince William County, Virginia	94,000	110,000
City of Alexandria, Virginia	167,000	83,000
Southeastern Tidewater Area Manpower Authority Consortium, Va	145,000	0
Northern Virginia Consortium	391,000	238,000
Macon County, Illinois	194,940	0
Champaign Consortium, Illinois	48,444	0
Tippecanoe County, Indiana	106,772	165,038
City of Dearborn, Michigan	0	200,000
Genessee/Flint/Shiawasee/Lapeer Consortium, Michigan	394,825	443,713
City of Livonia, Michigan	100,678	0
Hennepin County, Minnesota	500,000	0
Dakota County, Minnesota	10,000	0
Balance-of-State, Minnesota	0	475,000
Greene County, Ohio	205,530	0
Richland/Morrow Consortium, Ohio	537,680	302,522
Madison/Dane Consortium, Wis	0	80,000
Waukesha/Ozauha/Washington Consortium, Wisconsin	139,958	69,180
Tri-County Consortium, Wis	349,248	371,260
Marathon County, Wisconsin	151,162	100,000
Rock County, Wisconsin	73,758	90,655
Balance-of-State, Wisconsin	1,560,142	0
Southeast Texas Consortium	1,000,000	0
City of Dallas, Texas	1,300,000	700,000
City of Houston, Texas	5,000,000	4,000,000
East Texas Consortium	0	500,000
Black Hawk County, Iowa	51,000	0
Woodbury County, Iowa	286,000	80,000
Balance-of-State, Iowa	645,000	2,565,000
Johbnson/Leavenworth Csrt., Kansas	327,000	388,000
Kansas City/Wynadotte Csrt., Kans	393,000	473,000
City of Wichita, Kansas	277,000	0
Balance-of-State, Kansas	434,000	536,000
Jackson County, Missouri	22,000	125,000
St. Louis County, Missouri	242,000	0
Balance-of-State, Nebraska	1,118,000	920,000
Jefferson County, Colorado	383,000	306,500
Los Angeles County, California	2,364,519	0
Balance-of-State, California	1,217,620	0
County of Monterey, California	1,237,195	0

Signed at Washington, D.C., this 19th day of November, 1979.

Charles B. Knapp

Deputy Assistant Secretary for Employment and Training.

[FR Doc. 79-37086 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-30-M

Office of the Secretary

[TA-W-6089]

Alba Dress Co.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on September 24, 1979 in response to a worker petition received on September 19, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing women's dresses at Alba Dress Company, New Haven, Connecticut. The investigation revealed that the plant primarily produces women's suits and dresses. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Imports of women's and misses' dresses decreased absolutely in the first six months of 1979 compared to the same period in 1978. The ratio of imports to domestic production was less than 5% in 1977 and 1978.

Imports of women's, misses' and children's suits decreased absolutely in the first six months of 1979 compared to the same period in 1978.

Alba Dress Company is a clothing contractor. Most of its business has been with one manufacturer. This manufacturer reduced orders with Alba Dress in response to their own dress and suit sales declines. This manufacturer does not import suits or dresses or utilize foreign contractors. The Department conducted a survey of some

of the customers of this manufacturer. This survey revealed that a number of these customers had decreased their purchases of dresses and suits from this manufacturer in 1978 compared to 1977 and in the first nine months of 1979 compared to the same period in 1978. While some of these customers increased their purchases of imports, they also increased purchases with other domestic sources. Imports as a percent of their total purchases decreased in both periods.

Conclusion

After careful review, I determine that all workers of Alba Dress Company, New Haven, Connecticut, are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 23d day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37259 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6119]

Amy Ann, Inc.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 1, 1979 in response to a worker petition received on September 24, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers of Amy Ann, Incorporated, Tremont, Pennsylvania, a contractor of dresses. The investigation revealed that the petition was submitted by three workers. In the following determinations, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Imports of women's and misses' dresses increased in 1978 as compared to 1977, but decreased during the first six months of 1979 as compared to the same period in 1978.

Results of a U.S. Department of Labor survey of Amy Ann's sole customer, a women's wear manufacturer, indicated that sales of dresses by this manufacturer to its own retail trade customers increased in 1978 as compared to 1977, and during the first nine months of 1979 as compared to the same period in 1978. This manufacturer reported that it did not contract work overseas during the two periods surveyed.

Conclusion

After careful review, I determine that all workers of Amy Ann, Incorporated, Tremont, Pennsylvania are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37261 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6120]

Arte Knitwear Corp.; 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibilty requirements of Section 222 of the Act must be met.

The investigation was initiated on October 1, 1979 in response to a worker petition received on September 24, 1979 which was filed on behalf of workers and former workers producing ladies' knit sweaters at Arte Knitwear Corporation, Brooklyn, New York. It is concluded that all of the requirements have been met.

U.S. imports of women's, misses' and children's sweaters increased relative to domestic production in 1978 compared to 1977. The ratio of imports to domestic production was 115.8 percent in 1978, and imports of women's, misses' and children's sweaters accounted for 53.7 percent of apparent U.S. consumption in 1978.

A survey conducted by the Department revealed that manufacturers for whom Arte Knitwear Corporation produced ladies' sweaters decreased orders with the subject firm and increased imports of ladies' sweaters in 1978 compared to 1977, and in the first eight months of 1979 compared to the same period in 1978.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with ladies' sweaters produced at Arte Knitwear Corporation, Brooklyn, New York contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Arte Knitwear Corporation, Brooklyn, New York who became totally or partially separated from employment on or after September 20, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Officer of Management, Administration and Planning.

[FR Doc. 79-37262 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6170]

Buffalo Brake Beam Co.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 10, 1979, in response to a worker petition received on October 3, 1979 which was filed on behalf of workers and former workers producing railway car parts, brake beams, ladders, sill steps and connectors. The investigation revealed that the plant produces brake beams. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Evidence developed during the course of the investigation revealed that imports of railroad brake beams are negligible.

Industry sources indicate that stringent product requirements established by the American Association of Railroads (AAR) hinders foreign competition. For foreign producers to sell railroad brake beams in the U.S., they would be required to go through a multitude of tests before gaining approval by the AAR.

Buffalo Brake Beam Company ships some unfinished brake beams to its plant in Hamilton, Ontario, Canada. These beams are finished at the Hamilton plant and sold exclusively in the Canadian market. None of the brake beams finished in Canada are shipped into the U.S. market.

Sales and production of brake beams by the Lackawanna, New York plant of Buffalo Brake Beam Company increased in 1978 compared to 1977 and increased in the January to September period of 1979 compared to the same period in 1978.

Conclusion

After careful review, I determine that all workers of the Lackawanna, New York plant of Buffalo Brake Beam Company are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., the 28th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37285 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6176]

C. N. Wilcher Mining, Inc.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 10, 1979, in response to a worker petition received on October 3, 1979 which was filed on behalf of workers and former workers producing metallurgical coal and coke at C. N. Wilcher Mining, Incorporated, Charleston, West Virginia. The investigation revealed that the workers mine metallurgical coal. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of metallurgical coal decreased absolutely and relative to domestic production during the first half of 1979 compared with the first half of 1978.

Coke is metallurgical coal at a later stage of processing. Since a domestic article may be "directly competitive" with an imported article at a later stage of processing, imports of coke can be considered in determining import injury to workers producing metallurgical coal at C. N. Wilcher Mining, Incorporated.

U.S. imports of coke decreased in terms of quantity absolutely and relative to domestic production during the first half of 1979 compared with the first half of 1978.

C. N. Wilcher Mining, Incorporated began mining metallurgical coal in January 1979. The firm's coal production is processed and sold by another coal company. The Department conducted a survey of that company's primary and secondary customers for their purchases of coal and coke. The respondents reported they did not increase purchases of imported coal or coke and decrease purchases of domestic coal or coke during the period 1977 through September 1979.

Conclusion

After careful review, I determine that all workers of C. N. Wilcher Mining, Incorporated, Charleston, West Virginia are denied eligibilty to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37286 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6123, 6134]

Eastern Plastics of Maine, Inc., and York Heel of Maine, Inc.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigations were initiated on October 1, 1979 in response to a worker petition received on September 13, 1979 which was filed on behalf of workers formerly producing bottoms for shoes at York Heel of Maine, Incorporated; Sanford, Maine (TA-W-6134) and also in response to a petition received on September 18, 1979, which was filed by the Amalgamated Cothing and Textile Workers Union on behalf of workers formerly producing plastic heels and soles at an affiliated company Eastern Plastics of Maine, Incorporated; Sanford, Maine (TA-W-6123). The investigation revealed that York Heel produces urethane heels and soles for shoes. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

The Department conducted a survey of some of the customers buying heels and bottoms from York Heel and Eastern Plastics. Most of the customers did not purchase any imports in 1977, 1978 or 1979. Those customers which decreased purchases from York Heel and Eastern Plastics and increased imports represented an insignificant proportion of the firm's decline in sales in the first nine months of 1979. One of the major customers also indicated that they would decrease imports and rely on domestic sources for future purchases.

Conclusion

After careful review, I determine that all workers of Eastern Plastics of Maine, Incorporated and York Heel of Maine, Incorporated; Sanford, Maine are denied eligibility to apply for adjustment

assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 28th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37287 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6077]

Esther Dress Co., Inc.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibilty requirements of Section 222 of the Act must be met.

The investigation was initiated on September 21, 1979 in response to a worker petition received on September 17, 1979 which was filed by the International Ladies' Garment Workers Union on behalf of workers and former workers producing women's dresses at Esther Dress Company, Incorporated, Waterbury, Connecticut. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like a directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of women's and misses' dresses decreased absolutely in the first half of 1979 compared to the same period of 1978. The ratio of imports to domestic production of dresses was below 5 percent in 1977 and 1978.

A survey of the manufacturer which accounts for a large proportion of the subject firm's contracts revealed that the manufacturer does not purchase imported dresses and does not employ offshore contractors to produce dresses. A survey of the customers of this manufacturer revealed that imports declined as a percentage of the customers' total purchases of dresses in 1978 compared to 1977 and in the first eight months of 1979 compared to the same period of 1978.

Conclusion

After careful review, I determine that all workers of Esther Dress Company, Incorporated, Waterbury, Connecticut are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37288 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6026]

Florsheim Shoe Co.; Affirmative Determination Regarding Application for Reconsideration

On October 31, and November 2, 1979, former workers and the petitioning union requested administrative reconsideration of the Department of Labor's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance for workers and former workers of the Florsheim Shoe Company, Chaffee, Missouri. This determination was published in the **Federal Register** on October 30, 1979, (44 FR 62377).

The former workers and the petitioning union claim that the Department used an appropriate subdivision that did not accurately describe the affected worker group at the Florsheim Shoe Company, Chaffee, Missouri.

Conclusion

After review of the application, I conclude that the claim of the petitioners mentioned above is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, D.C., this 28th day of November 1979.

James F. Taylor,

Director, Office of Managment, Administration and Planning.

[FR Doc. 79-37269 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5889]

Goodyear Tire & Rubber Co., Inc.; Affirmative Determination Regarding Application for Reconsideration

By letter of November 14, 1979, the petitioning union requested administrative reconsideration of the Department of Labor's Negative Determination Regarding Eligibility To Apply for Worker Adjustment Assistance in the case of workers and former workers of Goodyear Tire and Rubber Co., Inc., Los Angeles, California. The determination was published in the **Federal Register** on October 30, 1979, (44 FR 62377).

The petitioning union raised one basic issue in its application. It claims that the fact that Goodyear may be increasing production at another location while decreasing output at Los Angeles is a reflection of the special impact that imported radials have had on the Western market. Goodyear's expansion elsewhere, it claims, is in radial tires, not bias. The Los Angeles plant is only equipped to produce bias tires. It was the Los Angeles plant's inability to compete with imports which resulted in the decision to close by early 1980. In support of this analysis, the petitioner cited the announcement of the plant's closing by Goodyear Board Chairman Pilliod on August 10, 1979.

Conclusion

After review of the application, I conclude that the claim of the petitioning union is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Officer of Management, Administration and Planning.

[FR Doc. 79-37270 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6141]

Joey Dress Co.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 2, 1979 in response to a worker petition received on September 27, 1979 which was filed on behalf of workers and former workers producing ladies' sportswear, dresses and shirts at Joey Dress Company, Weaver, Alabama. The investigation revealed that the plant produces women's skirts, dresses,

pantsuits and blouses. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of women's, misses' and children's skirts decreased absolutely during the January–June period of 1979 compared to the corresponding period of 1978.

U.S. imports of women's and misses' dresses declined absolutely during the January–June period of 1979 compared to the corresponding period of 1978.

U.S. imports of women's misses' and children's suits decreased absolutely during the January–June period of 1979 compared to the corresponding period of 1978.

U.S. imports of women's, misses' and children's blouses and shirts decreased absolutely during the January–June period of 1979 compared to the corresponding period of 1978.

A Departmental survey was conducted with the manufacturers for whom Joey Dress Company received contract work. They survey revealed that the manufacturers did not import women's skirts, dresses, pantsuits or blouses nor did they contract foreign sources for the production of women's skirts, dresses, pantsuits or blouses during 1977, 1978 or the first ten months of 1979. The manufacturers reported increasing contract orders with other domestic contractors during the January–October period of 1979 as compared to the corresponding period of 1978. The manfacturers also reported that their sales increased during the January–October period of 1979 as compared to the corresponding period of 1978.

Total company sales of women's skirts, dresses, pantsuits and blouses increased in quantity and value during the fourth quarter of 1978 compared to the fourth quarter of 1977 and in the January–October period of 1979 as compared to the corresponding period of 1978.

Average employment of production workers and average hours worked at Joey Dress Company increased during the fourth quarter of 1978 compared to the fourth quarter of 1977 and in the January–September period of 1979 compared to the January–September period of 1978. The average number of workers in each month during the January through September period of 1979 was above the corresponding month of the January through September period of 1978.

Conclusion

After careful review, I determine that all workers of Joey Dress Company, Weaver, Alabama are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37271 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6358]

Kramer Beef Co.; Termination of Investigation

In accordance with Section 223 of the Trade Act of 1974 (19 USC 2273) the Department of Labor herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on November 13, 1979 in response to a worker petition received on October 29, 1979 which was filed on behalf of wokers and former workers at Kramer Beef Co., Scranton, Pennsylvania.

Evidence developed during the course of the investigation revealed that Kramer Beef Co., Scranton, Pennsylvania was permanently closed and all employees were separated before October 15, 1978, one year prior to the date of the petition.

Signed at Washington, D.C. this 23rd day of November 1979.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 79-37272 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6107]

Lady Carlton Coat Co., Inc.; 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on September 25, 1979 in response to a worker petition received on September 17, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing ladies' coats and raincoats at the Stamford, Connecticut plant of the Lady Carlton Coat Company, Inc. It is concluded that all of the requirements have been met.

Imports of women's , girls' and infants' raincoats and women's, misses' and children's coats and jackets increased absolutely and relative to domestic production in 1978 compared to 1977.

The Lady Carlton Coat Company began importing ladies' raincoats in 1979. Lady Carlton's domestic production of ladies' coats and raincoats declined in the first three quarters of 1979 compared to the same period in 1978.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increase of imports of articles like or directly competitive with ladies' coats and raincoats produced at the Stamford, Connecticut plant of the Lady Carlton Coat Company, Inc. contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of the Stamford, Connecticut plant of the Lady Carlton Coat Company, Inc. who became totally or partially separated from employment on or after December 1, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 23rd day of November 1979.

James F. Taylor,

Director, Office of Managment, Administration and Planning.

[FR Doc. 79-37273 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6066]

Lee Tire & Rubber Co.; 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibilty requirements of Section 222 of the Act must be met.

The investigation was initiated on September 20, 1979 in response to a worker petition received on September 17, 1979 which was filed by the United Rubber, Cork, Linoleum and Plastic Workers of America on behalf of workers and former workers producing passenger car tires and truck tires at Lee Tire and Rubber Company, Conshohocken, Pennsylvania. The investigation revealed that the plant produces primarily passenger car tires. It is concluded that all the requirements have been met.

U.S. imports of passenger car tires increased relative to domestic production in 1978 compared to 1977 and increased absolutely and relatively in the first half of 1979 compared to the same period of 1978.

The Department surveyed major customers of Lee Tire and Rubber Company that had decreased their purchases of passenger car tires from the subject firm. The survey revealed that customers accounting for a significant proportion of Lee's sales, increased purchases of imported passenger car tires while decreasing purchases from the subject firm in the first three quarters of 1979 compared to the same period of 1978.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with passenger car tires produced at Lee Tire and Rubber Company, Conshohocken, Pennsylvania contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Lee Tire and Rubber Company, Conshohocken, Pennsylvania who became totally or partially separated from employment on or after September 1, 1979 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 28th day of November 1979.

James F. Taylor,

Director, Officer of Management, Administration and Planning.

[FR Doc. 79-37274 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6335]

Maclin-Zimmer-McGill Tobacco Co.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of section 222 of the Act must be met.

The investigation was initiated on November 6, 1979 in response to a worker petition on November 2, 1979 which was filed on behalf of workers and former workers producing semiprocessed tobacco at the Maclin-Zimmer-McGill Tobacco Company, Petersburg, Virginia. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Evidence developed during the course of the investigation revealed that the Maclin-Zimmer-McGill Tobacco Company, Inc., is a major exporter of semi-processed tobacco, and that decreases in sales by the subject firm during the first ten months of 1979 compared to 1978 are attributable to decreases in export sales by the company.

Conclusion

After careful review, I determine that all workers of Maclin-Zimmer-McGill Tobacco Company, Incorporated, Petersburg, Virginia are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37275 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6164]

Mar Mac Manufacturers, Inc.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 9, 1979 in response to a worker petition received on October 2, 1979 which was filed on behalf of workers and former workers producing ladies' and men's slacks and shorts at Mar Mac Manufacturers, Inc., Baltimore, Maryland. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Employment at Mar Mac Manufacturers, Inc. increased in each quarter of 1978 and in the first three quarters of 1979 when compared to the same quarter of the previous year. There were no significant employment declines at the subject firm subsequent to the earliest possible impact date.

Conclusion

After careful review, I determine that all workers of Mar Mac Manufacturers, Inc., Baltimore, Maryland are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37276 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6098]

Mode Manufacturing Co., Inc.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibilty to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on September 24, 1979 in response to a worker petition received on September 19, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing women's dresses at Mode Dress Company, New Haven, Connecticut. The investigation revealed that the correct corporate title is Mode Manufacturing Company, Incorporated. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of women's, misses', and children's dresses decreased absolutely during the first half of 1979 compared with the same period in 1978. The ratio of imports to domestic production was less than 5% in 1977 and 1978.

The Department surveyed the manufacturer for whom Mode Manufacturing Company, Incorporated did contract work. That manufacturer did not purchase imported dresses or utilize foreign contractors but reported that it had experienced declining sales of women's dresses druing the period under investigation. Customers of that manufacturer who were surveyed reported that they had decreased purchases of women's dresses from the manufacturer. Although some of the customers purchased imported dresses, they also increased their reliance on other domestic sources for similar items during the relevant period. These customers reported that imported dresses represented an insignificant proportion of their total dress purchases. The percentage of imports to total dress purchases decline during the period under investigation.

Conclusion

After careful review, I determine that all workers of Mode Manufacturing Company, Incorporated, New Haven, Connecticut are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C. this 23rd day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37277 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6099]

Norman Dress Co., Inc.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on September 24, 1979 in response to a worker petition received on September 19, 1979 which was filed by the International Ladies' Garment Workers' Union on behalf of workers and former workers producing women's dresses at Norman Dress Company, Incorporated, New Haven, Connecticut. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Imports of women's and misses' dresses decreased absolutely in the first six months of 1979. The ratio of imports to domestic production was less than 5% in 1977 and 1978.

The Department surveyed the manufacturer for whom Norman Dress Company, Incorporated did contract work. That manufacturer did not purchase imports, or utilize foreign contractors but reported that it had experienced decreased sales of women's dresses during the period under investigation. Customers of that manufacturer who were surveyed reported that they had decreased purchases of women's dresses from the manufacturer. Although some of these customers purchased imported dresses, they also increased their reliance on other domestic sources for similar items during the relevant period. These customers reported that imported dresses represented an insignificant proportion of their total dress purchases. The percentage of imports to total dress purchases declined during the period under investigation.

Conclusion

After careful review, I determine that all workers of Norman Dress Company, Incorporated, Bridgeport, Connecticut are denied eligibilty to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., the 23rd day of November 1979.

James F. Taylor,

Director, Office of Management Administration and Planning.

[FR Doc. 79-37278 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6108]

Northampton Textile Co.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibilty requirements of Section 222 of the Act must be met.

The investigation was initiated on September 25, 1979 in response to a worker petition received on September 24, 1979 which was filed by three individual workers on behalf of workers and former workers weaving furniture fabric at Northampton Textile Company, Mt. Holly, New Jersey. During the course of the investigation, it was revealed that some of the employees of Northampton Textile Company worked at Alexander

Plush Company, Mt. Holly, New Jersey, a wholly owned subsidiary of Northampton Textile Company. In the following determinations, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separation, or threat thereof, and to the absolute decline in sales or production.

The ratio of U.S. imports of finished fabric to domestic production was 2.0 percent in 1978. U.S. imports decreased absolutely in the first six months of 1979 when compared with the same period in 1978.

A sample of customers of Northampton Textile Company, representing both fabric converters and manufacturers of finished furniture, were surveyed by the Department of Labor. Most of the customers responding to the survey did not purchase imported fabric. The customers who reduced purchases from the subject firm while increasing purchases of imported fabric, also increased their purchases of fabric from other domestic manufacturers. These customers represented an insignificiant proportion of Northampton Textile's sales.

Conclusion

After careful review, I determine that all workers of Northampton Textile Company, Mt. Holly, New Jersey, are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 23rd day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37279 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6196]

Northeast Shoe Co.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 15, 1979, in response to a worker petition received on October 10, 1979, which was filed on behalf of workers and former workers producing ladies' casual shoes at Northeast Shoe Company, Pittsfield, Maine. The investigation revealed that the plant produces primarily ladies casual shoes. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Company sales and plant production of ladies' casual shoes increased in both quantity and value from 1977 to 1978 and in the January–September period of 1979, ccmpared with the same period in the previous year. Declines in company sales and plant production in the third quarter of 1979, compared with the same period in the previous year, were seasonal declines, associated with the changeover from the Fall season to the Spring season in the ladies' footwear manufacturing industry. Average employment at the plant was higher in the third quarter of 1979 than in the same quarter of the previous year.

In the fourth quarter of 1978, total separations at the plant were approximately equal to total accessions. Average production employment increased in the January–October period of 1979, compared with the same period in the previous year. Average employment was higher than the previous year in each month from February–October, 1979. No certification may apply to any worker whose last total or partial separation from Northwest Shoe Company occurred before October 2, 1978, one year prior to the date of petition.

Conclusion

After careful review, I determine that all workers of Northeast Shoe Company, Pittsfield, Maine are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37280 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-5881]

Perry Knit, Inc.; Affirmative Determination Regarding Application for Reconsideration

On October 17, 1979, the petitioning company requested administrative reconsideration of the Department of Labor's Negative Determination Regarding Eligibility to Apply for Worker Adjustment Assistance for workers and former workers of Perry Knit, Inc., Union City, New Jersey. This determination was published in the **Federal Register** on October 19, 1979 (44 FR 60430).

The petitioning company claims that since the U.S. Department of Commerce approved its application for firm adjustment assistance, the Department of Labor should reconsider its denial of the application filed on behalf of workers and former workers of Perry Knit, Inc., Union City, New Jersey, for trade adjustment assistance.

Conclusion

After review of the application, I conclude that the claim of the petitioning company is of sufficient weight to justify reconsideration of the Department of Labor's prior decision. The application is, therefore, granted.

Signed at Washington, D.C., this 28th day of November 1979.

James F. Taylor,

Director, Office of Managment Administration and Planning.

[FR Doc. 79-37281 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-4835]

Rosita Shoe Corp.; Revised Certification of Eligibility To Apply for Worker Adjustment Assistance

In accordance with Section 223 of the Trade Act of 1974, the Department of Labor issued a Certification of Eligibility to Apply for Worker Adjustment Assistance on April 23, 1979, applicable to all workers of the Rosita Shoe Corporation, Lisbon, New Hampshire. The Notice of Certification was published in the **Federal Register** on May 1, 1979, (44 FR 25530).

On the basis of additional information, the Office of Trade Adjustment Assistance, on its own motion, reviewed the certification. This review revealed that several layoffs of workers occurred in the last quarter of 1978, several months prior to the original impact date of April 1, 1979. The additional information revealed that in order to meet import competition the Rosita Shoe Corporation produced a

smaller mix of styles in the last quarter of 1978 to the same quarter of 1977. This smaller mix of styles increased plant efficiency and resulted in additional layoffs. Production of footwear declined in the fourth quarter of 1978 compared to the previous quarter. Despite a transient increase in output in the first quarter of 1979, Rosita Shoe Corporation closed on May 1, 1979, and all production of shoes was transferred to its Canadian affiliate.

The intent of the certification is to cover all workers of the Rosita Shoe Corporation, Lisbon, New Hampshire, who were affected by the decline in production of women's shoes and boots related to import competition. The certification, therefore, is revised providing a new impact date of October 31, 1978.

The revised certification applicable to TA-W-4835 is hereby issued as follows:

All workers of the Rosita Shoe Corporation, Lisbon, New Hampshire, who became totally or partially separated from employment on or after October 31, 1978, are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 28th day of November 1979.

James F. Taylor,

Director, Office of Management Administration and Planning.

[FR Doc. 79-37282 Filed 12-3-79 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6131]

Samco Manufacturing of Crosby, Inc.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 1, 1979 in response to a worker petition received on September 24, 1979 which was filed by the Amalgamated Clothing and Textile Workers on behalf of workers and former workers producing men's and women's snowmobile suits, and hunting wear at Samco Manufacturing of Crosby, Incorporated, Crosby, Minnesota (TA-W-6131). The investigation revealed that the Crosby plant produces only snowmobile suits. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Snowmobile suit statistics are included with men's and boys' nontailored outer jackets and women's, misses', and children's suits.

U.S. imports of men's and boys' nontailored outer jackets, which includes snowmobile suits, decreased absolutely in the first six months of 1979 compared to the same period in 1978.

U.S. imports of women's, misses', and children's suits, which includes snowmobile suits, decreased in the first six months of 1979 compared to the same period in 1978.

The Department conducted a survey of some customers of Samco Manufacturing of Crosby, Incorporated. This survey revealed that none of these customers purchase imports. One major customer decreased purchases with the subject form in 1979 and increased purchases with other domestic sources. The decrease in purchases by this customer from the subject firm represented more than 100% of the subject firm's sales decrease in 1979. This customer does not purchase imports.

Conclusion

After careful review, I determine that all workers of Samco Manufacturing of Crosby, Incorporated, Crosby, Minnesota are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37283 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6254]

Simpson Trucking Co.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on October 23, 1979, in response to a worker petition received on October 18, 1979, which was filed on behalf of workers and former workers hauling metallurgical coal at Simpson Trucking Company, Gilbert, West Virginia.

Simpson Trucking Company is engaged in providing the service of transporting coal by truck from a customer's mine to a preparation plant.

Thus, workers of Simpson Trucking Company do not produce an article within the meaning of Section 222(3) of the Act. Therefore, they may be certified only if their separation was caused importantly by a reduced demand for their services from a parent firm, a firm otherwise related to Simpson Trucking Company by ownership, or a firm related by control. In any case, the reduction in demand for services must originate at a production facility whose workers independently meet the statutory criteria for certification and that reduction must directly relate to the product impacted by imports.

Simpson Trucking Company and its customers have no controlling interest in one another. The subject firm is not corporately affiliated with any other company.

All workers engaged in transporting coal by truck at Simpson Trucking Company are employed by that firm. All personnel actions and payroll transactions are controlled by Simpson. All employee benefits are provided and maintained by Simpson Trucking Company. Workers are not, at any time, under employment or supervision by customers of Simpson Trucking Company. Thus, Simpson Trucking Company, and not any of its customers, must be considered to be the "workers' firm".

Conclusion

After careful review, I determine that all workers of Simpson Trucking Company, Gilbert, West Virginia are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37284 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6072]

Stauffer Chemical Co., Plastics Division; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on September 20, 1979 in response to a worker petition received on September 17, 1979 which was filed on behalf of workers and former workers producing laminated, embossed, and printed polyvinyl chloride film and vinyl fabric backed wallcoverings at Stauffer Chemical Company, Plastics Division, Passaic, New Jersey. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

U.S. imports of vinyl fabric wallcovering declined absolutely in 1978 from 1977 and in January–June 1979 compared to the same period in 1978. The ratio of imports to domestic production decreased from 2.1 percent in 1977 to 1.6 percent in 1978.

U.S. imports of flexible polyvinyl chloride (PVC) sheet and film decreased absolutely in January–June 1979 compared to the same period in 1978. A Department survey revealed that none of the surveyed customers purchased imported laminated, embossed, or printed polyvinyl chloride sheet or film in 1978 or 1979.

Conclusion

After careful review, I determine that all workers of Stauffer Chemical Company, Plastics Division, Passaic, New Jersey are denied eligibility to apply for adjustment assistant under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 28th day of November 1979.

James F. Taylor,

Director, Office of Management Administration and Planning.

[FR Doc. 79-37285 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6088]

Toledo Shingle Co., Inc.; 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance, each of the group eligibility requirements of Section 222 of the Act must be met.

The investigation was initiated on September 21, 1979 in response to a worker petition received on September 18, 1979 which was filed on behalf of workers and former workers producing cedar shingles at Toledo Shingle Company, Incorporated, Toledo, Oregon. It is concluded that all of the requirements have been met.

U.S. Imports of cedar shingles and shakes increased both absolutely and relative to domestic production in 1978 from 1977 and increased absolutely in January–June 1979 compared to the same period in 1978.

A customer survey revealed that some customers reduced purchases from the subject firm and increased purchases of imported cedar shingles in 1978 compared to 1977.

Conclusion

After careful review of the facts obtained in the investigation, I conclude that increases of imports of articles like or directly competitive with the cedar shingles produced at Toledo Shingle Company, Incorporated, Toledo, Oregon contributed importantly to the decline in sales or production and to the total or partial separation of workers of that firm. In accordance with the provisions of the Act, I make the following certification:

All workers of Toledo Shingle Company, Incorporated, Toledo, Oregon who became totally or partially separated from employment on or after September 11, 1978 are eligible to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 26th day of November 1979.

James F. Taylor,

Director, Office of Management, Administration and Planning.

[FR Doc. 79-37286 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6074]

U.S. Steel Corp., Duluth Works; Termination of Investigation

Pursuant to Section 221 of the Trade Act of 1974, an investigation was initiated on September 20, 1979 in response to a worker petition received on September 18, 1979 which was filed by the United Steelworkers of America on behalf of workers and former workers producing metallurgical coke at the Duluth Works of the U.S. Steel Corporation in Duluth, Minnesota.

All employees of the Duluth Works of the U.S. Steel Corporation in Duluth, Minnesota separated on or after December 23, 1975 and on or before September 19, 1979 were certified eligible to apply for adjustment assistance benefits on September 19, 1977 (TA–W–1561). All production at the Duluth Works was terminated in May 1979 and all production workers were separated in or before August 1979. The only employees remaining at the Duluth Works were retained to administer company benefits to laid off workers. These employees are expected to be laid off in or before June 1980. As the intent of TA–W–1561 was to cover all employees of the Duluth Works, a new investigation would serve no purpose. Therefore, it is recommended that this investigation be terminated.

Signed at Washington, D.C. this 27th day of November 1979.

Harold A. Bratt,

Acting Director, Office of Trade Adjustment Assistance.

[FR Doc. 79-37287 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6146]

Vermont Heel Co., Inc.; Negative Determination 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 herein presents the results of an investigation regarding certification of eligibility to apply for worker adjustment assistance.

In order to make an affirmative determination and issue a certification of eligibility to apply for adjustment assistance each of the group eligibilty

requirements of Section 222 of the Act must be met.

The investigation was initiated on October 2, 1979 in response to a worker petition received on September 27, 1979 which was filed on behalf of workers and former workers producing men's, women's and children's wooden clogs, wooden wedges and wooden heels at Vermont Heel Company, Incorporated, White River Junction, Vermont. The investigation revealed that the plant produced wooden soles, heels and wedges for shoes. In the following determination, without regard to whether any of the other criteria have been met, the following criterion has not been met:

That increases of imports of articles like or directly competitive with articles produced by the firm or appropriate subdivision have contributed importantly to the separations, or threat thereof, and to the absolute decline in sales or production.

Vermont Heel Company produced wooden soles, heels and wedges for shoes. These products are included in the category Nonletter Bottom Stock Materials for Footwear.

U.S. imports of nonleather bottom stock materials for footwear increased absolutely and relative to domestic production in 1978 compared to 1977 and in the first six months of 1979 compared to the like period of 1978.

The Department surveyed all of Vermont Heel's customers of wooden components for shoes. The survey revealed that none of the respondents purchased any imported shoe heels, soles or wedges. All the respondents stated they were purchasing these components from other domestic manufacturers.

Conclusion

After careful review, I determine that all workers of Vermont Heel Company Incorporated, White River Junction, Vermont are denied eligibility to apply for adjustment assistance under Title II, Chapter 2 of the Trade Act of 1974.

Signed at Washington, D.C., this 28th day of November 1979.

James F. Taylor,

Director, Officer of Management, Administration and Planning.

[FR Doc. 79-37288 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

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, Bureau of International Labor Affairs, has instituted investigations pursuant to Section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90. 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.

Pursuant to 29 CFR 90.13, 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 December 14, 1979.

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 December 14, 1979.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 29th day of October 1979.

Harold A. Bratt,

Acting Director, Office of Trade Adjustment Assistance.

Appendix

Petitioner: Union/Workers or former workers of	Location	Date received	Date of petition	Petition No.	Articles produced
Big Smith Manufacturing Co. (ACTWU)	Carthage, Mo	10/9/79	10/2/79	TA-W-6,273	Overalls, coveralls, shirts, jeans, and jackets.
Big Smith Manufacturing Co. (ACTWU)	Neosho, Mo	10/9/79	10/2/79	TA-W-6,274	Overalls, coveralls, shirts, jeans, and jackets.
Big Smith Manufacturing Co. (ACTWU)	Webb City, Mo	10/9/79	10/2/79	TA-W-6,275	Overalls, coveralls, shirts, jeans, and jackets.
Big Smith Manufacturing Co. (ACTWU)	St. Joseph, Mo	10/9/79	10/2/79	TA-W-6,276	Overalls, coveralls, shirts, jeans, and jackets.
Big Smith Manufacturing Co. (ACTWU)	Columbus, Kan	10/9/79	10/2/79	TA-W-6,277	Overalls, coveralls, shirts, jeans, and jackets.
Big Smith Manufacturing Co. (ACTWU)	Oskaloosa, Iowa	10/9/79	10/2/79	TA-W-6,278	Overalls, coveralls, shirts, jeans, and jackets.
Big Smith Manufacturing Co. (ACTWU)	Larmar, Mo	10/9/79	10/2/79	TA-W-6,279	Overalls, coveralls, shirts, jeans, and jackets.
Clinchfield Coal Co., Open Fork Mine (UMWA).	Dickenson County, Va	10/10/79	9/25/79	TA-W-6,280	Mining of coal.
Clinchfield Coal Co., Yowling Branch Mine (UMWA).	Russell County, Va	10/10/79	9/25/79	TA-W-6,281	Mining of coal.
Clinchfield Coal Co., Chaney Creek Mine (UMWA).	Russell County, Va	10/10/79	9/25/79	TA-W-6,282	Mining of coal.
Clinchfield Coal Co., Wilder Mine (UMWA)	Russell County, Va	10/10/79	9/25/79	TA-W-6,283	Mining of coal.
Clinchfield Coal Co., Hagy No. 1 Mine (UMWA).	Buchanan County, Va	10/10/79	9/25/79	TA-W-6,284	Mining of coal.
Clinchfield Coal Co., Hagy No. 2 Mine (UMWA).	Buchanan County, Va	10/10/79	9/25/79	TA-W-6,285	Mining of coal.
Clinchfield Coal Co., Smith Gap Mine (UMWA).	Dickenson County, Va	10/10/79	9/25/79	TA-W-6,286	Mining of coal.
Perfect Garment Company, Inc. (ILGWU)	Cambridge, Md	10/24/79	10/17/79	TA-W-6,287	Women's sportswear.
Perfect Garment Company, Inc. (ILGWU)	Baltimore, Md	10/24/79	10/17/79	TA-W-6,288	Women's sportswear.
Perfect Garment Company, Inc. (ILGWU)	Grasonville, MD	10/24/79	10/17/79	TA-W-6,289	Women's sportswear.
Perfect Garment Company, Inc. (ILGWU)	Secretary, Md	10/24/79	10/17/79	TA-W-6,290	Women's sportswear.

[FR Doc. 79-37284 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

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, Bureau of International Labor Affairs, has instituted investigations pursuant to Section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivision.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90. 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.

Pursuant to 29 CFR 90.13, 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 December 14, 1979.

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 December 14, 1979.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C., this 27th day of November 1979.

Harold A. Bratt,

Acting Director, Office of Trade Adjustment Assistance.

Appendix

Petitioner: Union/workers or former workers of—	Location	Date received	Date of petition	Petition No.	Articles produced
Badin Apparel, Inc. (ILGWU)	Miami, Fla	11/21/79	11/15/79	TA-W-6,455	Women's blouses, pants, blazers, tenniswear—knitted cloth.
Custom Casuals, Inc. (ILGWU)	New York, N.Y.	11/13/79	11/5/79	TA-W-6,456	Women's dresses, ensembles, and suits.
Giamo, Inc. (ILGWU)	Miami, Fla	11/21/79	11/15/79	TA-W-6,457	Women's blouses, pants, blazers, tenniswear—knitted cloth.
S. Abraham & Co., Inc. (United Garment Workers of America).	Philadelphia, Pa	11/21/79	11/8/79	TA-W-6,458	Uniforms.
Silco Specialities Inc. (workers)	Wilkes-barre, Pa	11/21/79	11/14/79	TA-W-6,459	Ladies; plastic handbags.
Stafford Garment Manufacturing Corp. (workers).	Fall River, Mass	11/14/79	11/9/79	TA-W-6,460	Women's housecoats, blouses, dresses, skirts, and suits.
T.T. Mallo, Ltd (ILGWU)	New York, N.Y.	11/13/79	11/5/79	TA-W-6,461	Women's rainwear.
U.S. Steel Corp., Gary Works (USWA)	Gary, Ind	11/21/79	11/15/79	TA-W-6,462	Galvanized steel products (bars, plates, and sheets).

[FR Doc. 79-37263 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

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, Bureau of International Labor Affairs, has instituted investigations pursuant to Section 221(a) of the Act and 29 CFR 90.12.

The purpose of each of the investigations is to determine whether absolute or relative increases of imports of articles like or directly competitive with articles produced by the workers' firm or an appropriate subdivision thereof have contributed importantly to an absolute decline in sales or production, or both, of such firm or subdivision and to the actual or threatened total or partial separation of a significant number or proportion of the workers of such firm or subdivison.

Petitioners meeting these eligibility requirements will be certified as eligible to apply for adjustment assistance under Title II, Chapter 2, of the Act in accordance with the provisions of Subpart B of 29 CFR Part 90. 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.

Pursuant to 29 CFR 90.13, 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 December 14, 1979.

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 December 14, 1979.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Bureau of International Labor Affairs, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Signed at Washington, D.C. this 27th day of November 1979.

Harold A. Bratt,

Acting Director, Office of Trade Adjustment Assistance.

Appendix

Petitioner: Union/workers or former workers of—	location	Date received	Date of petition	Petition No.	Articles produced
Allied Chemical Corporation, Harewood Division (workers).	Montgomery, W. Va	11/14/79	11/7/79	TA-W-6,439	Metallurgical coal.
Big Valley Coal Company (workers)	Bergoo, W. Va	11/5/79	10/30/79	TA-W-6,440	Metallurgical coal.
C & E Coal Co. (company)	Greenwood, Ark	11/13/79	11/8/79	TA-W-6,441	Metallurgical coal.
Cheryl Dress Corp. (workers)	Fall River, Mass	11/20/79	11/13/79	TA-W-6,442	Ladies' dresses, skirts, vests, shirts, pants, and jackets.
Empire Button Manufacturing Co., Inc. (ILGWU).	Union City, N.J	11/12/79	11/8/79	TA-W-6,443	Buttons.
Itmann Coal Co., Mine No. 1 (UMWA)	Wyoming County, W. Va	10/29/79	10/22/79	TA-W-6,444	Metallurgical coal.
Itmann Coal Co., Mine No. 2 (UMWA)	Wyoming County, W. Va	10/29/79	10/22/79	TA-W-6,445	Metallurgical coal.
Itmann Coal Co., Mine No. 3 (UMWA)	Wyoming County, W. Va	10/29/79	10/22/79	TA-W-6,446	Metallurgical coal.
Itmann Coal Co., Mine No. 4 (UMWA)	Wyoming County, W. Va	10/29/79	10/22/79	TA-W-6,447	Metallurgical coal.
Itmann Coal Co., Preparation Plant (UMWA)	Wyoming County, W. Va	10/29/79	10/22/79	TA-W-6,448	Cleaning of coal.
McDonnell Astronautics Company (IAMAW)	St. Louis, Mo	11/14/79	11/8/79	TA-W-6,449	F-15 aircraft doors.
McDonnell Douglas Aircraft Co. (IAMAW)	St. Louis, Mo	11/14/79	11/8/79	TA-W-6,450	F-15 aircraft doors.
Sportscoach of America (workers)	Chatsworth, Calif	11/14/79	11/7/79	TA-W-6,451	Motor homes.
Sting Bee (ILGWU)	Long Island City, N.Y	11/2/79	10/26/79	TA-W-6,452	Children's sportswear.
Tidy Products Company (workers)	Columbia, Pa	11/6/79	10/23/79	TA-W-6,453	Infants and children's outerwear.
Youngstown Sheet & Tube Co., Indiana Harbor Works (USWA).	East Chicago, Ind	11/15/79	11/9/79	TA-W-6,454	Galvanized carbon steel, sheet and hot and cold rolled carbon steel, sheet and strip.

[FR Doc. 79-37260 Filed 12-3-79; 8:45 am]

BILLING CODE 4510-28-M

NUCLEAR REGULATORY COMMISSION

Advisory Committee on Reactor Safeguards, Subcommittees on Waste Management and Fuel Cycle; Meeting

The ACRS Subcommittees on Waste Management and Fuel Cycle will hold a joint meeting starting at 8:30 a.m. on Wednesday, December 19, 1979 in Room 1046, 1717 H St., N.W., Washington, D.C. 20555 to continue their review of the NRC waste management/fuel cycle research and technical assistance programs. In addition, representatives of the Environmental Protection Agency (EPA), the United States Geological Survey (USGS), and the Department of Energy (DOE) will brief the Subcommittees on their waste management work.

The Subcommittees will be considering portions of the budget and program of the Office of Nuclear Regulatory Research. Since the NRC budget proposals are now part of the President's budget—not yet submitted to Congress—public disclosure of budgetary information is not permitted. See OMB Circular A-10. The ACRS, however, is required by Section 5 of the 1978 NRC Authorization Act to review the NRC research program and budget and report the results of the review to Congress. In order to perform this review, the ACRS must be able to engage in frank discussion with members of the NRC Staff. For the reason just stated, a discussion would not be possible if held in public session.

I have determined, therefore, that it is necessary to close this meeting to prevent frustration of this aspect of the ACRS' statutory responsibilities, in accordance with Exemption 9(B) to the Government in the Sunshine Act (522b(c)(9)(B)).

Further information can be obtained by a prepaid telephone call to the Designated Federal Employee for this meeting, Mr. Ragnwald Muller (telephone 202/634-1413) between 8:15 am. and 5:00 pm., EST.

Dated: November 28, 1979.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 79-37042 Filed 12-3-79; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. STN 50-482A]

Kansas Gas and Electric Co., et al.; Notice of Receipt of Additional Antitrust Information: Time for Submission of Views on Antitrust Matters

Note.—This document was originally published in the issue of November 13, 1979. It is reprinted at the request of the Nuclear Regulatory Commission.

Kansas Gas and Electric Company, pursuant to Section 103 of the Atomic Energy Act of 1954, as amended, filed on September 11, 1979, information requested by the Attorney General for Antitrust Review as required by 10 CFR Part 50, Appendix L. The information concerns the addition of Kansas Electric Power Cooperative, Inc. as an owner of the Wolf Creek Generating Station, Unit No. 1 located in Coffey County, Kansas.

The information was filed in connection with Kansas Gas and Electric Company and Kansas City Power and Light Company's application for an amendment to Construction Permit No. CPPR-147 to the Wolf Creek Generating Station, Unit No. 1. Construction Permit No. CPPR-147 was issued on May 17, 1977 and construction of the plant is underway.

The original notice of receipt of application for construction permit and operating license included the antitrust aspects of the application and was published in the **Federal Register** on August 30, 1974 (39 FR 31684).

A copy of the Kansas Gas and Electric Company letter, dated September 11, 1979 and above stated documents are available for public examination and copying for a fee at the Commission's Public Document Room, located at 1717 H Street, N.W., Washington, D.C. 20555 and at the Coffey County Courthouse, Burlington, Kansas 66839.

Information in connection with the antitrust review of this application can be obtained by writing to the U.S. Nuclear Regulatory Commission, Washington, D.C., Attention: Antitrust and Indemnity Group, Office of Nuclear Reactor Regulation.

Any person who wishes to have his views on the antitrust matters with respect to Kansas Electric Power Cooperative, Inc. presented to the Attorney General for consideration should submit such views to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention:

Chief, Antitrust and Indemnity Group, Office of Nuclear Reactor Regulation on or before January 11, 1980.

Dated at Bethesda, Maryland, this 2nd day of November 1979.

For the Nuclear Regulatory Commission.

Olan D. Parr,

Chief, Light Water Reactors, Branch No. 3, Division of Project Management.

[FR Doc. 79-34706 Filed 11-30-79; 8:45 am]

BILLING CODE 7590-01-M

DEPARTMENT OF STATE

[PN 696]

Determination on International Security Assistance Programs for Fiscal Year 1980

In accordance with Section 502B of the Foreign Assistance Act of 1961, as amended (the Act), I have reviewed the international security assistance programs of the United States for the fiscal year 1980 in order to assure that:

(1) All security assistance programs are consistent with the provisions of Section 502B of the Act concerning the promotion and advancement of human rights and the avoidance of United States identification with human rights violations, and

(2) With respect to those countries where human rights conditions give rise to the most serious concerns, the security assistance provided by the United States is warranted in each case by extraordinary circumstances involving the national security interests of the United States.

On the basis of this review, I certify that these security assistance programs are in compliance with the requirements of section 502B of the Act.

This determination shall be reported to the Congress and published in the Federal Register as required by law.

Dated: November 17, 1979.

Warren Christopher,

The Deputy Secretary.

[FR Doc. 79-37111 Filed 12-3-79; 8:45 am]

BILLING CODE 4710-01-M

DEPARTMENT OF THE TREASURY

[Supplement to Department Circular; Public Debt Series—No.29-79]

Treasury Notes of Series C-1985; Interest Rate

Washington, November 28, 1979.

The Secretary announced on November 27, 1979, that the interest rate on the notes designated Series C-1985, described in Department Circular—Public Debt Series—No. 29-79, dated November 21, 1979, will be 10⅜ percent. Interest on the notes will be payable at the rate of 10⅜ percent per annum.

Paul H. Taylor,

Fiscal Assistant Secretary.

Supplementary Statement

The announcement set forth above does not meet the Department's criteria for significant regulations and, accordingly, may be published without compliance with the Departmental procedures applicable to such regulations.

[FR Doc. 79-37121 Filed 12-3-79; 8:45 am]

BILLING CODE 4810-40-M

INTERSTATE COMMERCE COMMISSION

[Notice No. 151]

Assignment of Hearings

November 28, 1979.

Cases assigned for hearing, postponement, cancellation or oral argument appear below and will be published only once. This list contains prospective assignments only and does not include cases previously assigned hearing dates. The hearings will be on the issues as presently reflected in the Official Docket of the Commission. An attempt will be made to publish notices of cancellation of hearings as promptly as possible, but interested parties should take appropriate steps to insure that they are notified of cancellation or postponements of hearings in which they are interested.

MC 134405 (Sub-56F), Bacon Transport Company, now assigned for hearing on December 17, 1979, at Dallas, Texas is postponed indefinitely.

MC-112304 (Sub-169F), Ace Doran Hauling & Rigging Co., now assigned for hearing on November 27, 1979 (1 day) at Kansas City, MO is transferred to Modified Procedure.

MC-117815 (Sub-289F), Pulley Freight Lines, Inc., now assigned for hearing on November 28, 1979 (3 Days) at Kanses City, MO is transferred to Modified Procedure.

MC 531 (Sub-380F), Younger Brothers, Inc., now being assigned for hearing on February 26, 1980 (2 Days), at New Orleans, LA. in a hearing room to be designated later.

MC 145370 (Sub-1F), Pharr Brothers, Inc., now being assigned for hearing on February 28, 1980 (2 Days), at New Orleans, LA. in a hearing room to be designated later.

MC 87103 (Sub-27F), Miller Transfer and Rigging Co., A Corporation, now assigned for hearing on November 28, 1979 at Columbus, OH. is canceled and transferred to Modified Procedure.

MC 15975 (Sub-12F), Buske Lines, Inc., now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

MC 42261 (Sub-144F), Langer Transport Corporation, now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

MC 95540 (Sub-1072F), Watkins Motor Lines, Inc., now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

MC 115311 (Sub-327F), J&M Transportation Company, Inc., now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

MC 119632 (Sub-99F), Reed Lines, Inc., now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

MC 119726 (Sub-157F), N.A.B. Trucking Co., Inc., now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

MC 128273 (Sub-331F), Midwestern Distribution, Inc., now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

MC 141124 (Sub-36F), Evangelist Commercial Corp., now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

MC 142559 (Sub-82F), Brooks Transportation, Inc., now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

MC 145152 (Sub-43F), Big Three Transportations, Inc., now being assigned for hearing on January 28, 1980 (10 Days), at the Holiday Inn Central, 111 W. Fortune, Tampa, FL.

AB 43 (Sub-56F), Illinois Central Gulf Railroad Company Abandonment near Kevil and Barlow in Ballard and McCracken Counties, Kentucky now assigned for hearing on December 3, 1979 at Paducah, Ky. will be held at the Paducah City Hall, 300 South Fifth Street, City Hall Building, Courtroom Basement, Paducah, KY.

MC 142703 (Sub-13F), Intermodal Transportation Services, Inc., now assigned for hearing on December 10, 1979 at Columbus, OH. will be held at the Federal Building and U.S. Courthouse, Room 426 (conference room), 85 Marconi Boulevard, Columbus, OH.

MC 142703 (Sub-14F), Intermodal Transportation Service, Inc., now assigned for hearing on December 10, 1979 at Columbus, OH. will be held at the Federal Building and U.S. Courthouse, Room 426 (conference room), 85 Marconi Boulevard, Columbus, OH.

MC 124211 (Sub-356F), Hilt Truck Line, Inc., now assigned for hearing on December 10, 1979 at Omaha, NE. is canceled and transferred to Modified Procedure.

MC 139906 (Sub-33F), Interstate Contract Carrier Corp., now assigned for hearing on December 11, 1979 at Los Angeles, CA. is canceled and transferred to Modified Procedure.

MC 97457 (Sub-8F), Warner & Sons Trucking Company, A Corporation, now assigned for hearing on December 10, 1979 at Lansing, MI. is canceled and transferred to Modified Procedure.

MC 128616 (Sub-26F), Gelco Courier Services, Inc., now assigned for hearing on December 3, 1979 at Cincinnati, OH. is canceled and Application Dismissed.
MC 55896 (Sub-105F), R–W Service System, Inc., now being assigned for hearing on January 8, 1980 at the Offices of the Interstate Commerce Commission in Washington, DC.
MC 112801 (Sub-226F), Transport Service Company, now being assigned for hearing on March 3, 1980 (1 Day), at New Orleans, LA. in a hearing room to be designated later.
MC 142207 (Sub-25F), Brannan Systems, Inc., now being assigned for hearing on March 4, 1980 (3 Days), at New Orleans, LA. in a hearing room to be designated later.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79–37187 Filed 12–3–79; 8:45 am]

BILLING CODE 7035–01–M

Fourth Section Applications for Relief

November 29, 1979.

These applications for long-and-short-haul relief have been filed with the I.C.C.

Protests are due at the I.C.C. on or before December 19, 1979.

FSA No. 43772, Southwestern Freight Bureau, Agent No. B–41, Hexamethylene diamine solution, in tank carloads, from Orange and Bloomington, TX to Seaford, DE, in supp. 42 to its Tariff ICC SWFB 4616, effective December 24, 1979. Grounds for relief—rate relationship.
FSA No. 43773, Trans-Continental Freight Bureau Agent No. 544, liquefied petroleum gas in tank carloads from Great Falls, Mont. to points in Western Territory, to be published in ICC TCFB 3014–Q. Grounds for relief—market competition, short-line distance formula and grouping.
FSA No. 43774, Trans-Continental Freight Bureau, Agent No. 546, cleaning compounds and other articles, in carloads, from stations in New Jersey and Ohio to stations in California, in its Tariff ICC TCFB 3001. Grounds for relief—improved car utilization.

By the Commission.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79–37190 Filed 12–3–79; 8:45 am]

BILLING CODE 7035–01–M

Motor Carrier Intrastate Application(s)

The following application(s) for motor common carrier authority to operate in intrastate commerce seek concurrent motor carrier authorization in interstate or foreign commerce within the limits of the intrastate authority sought, pursuant to section 10931 (formerly Section 206(a)(6)) of the Interstate Commerce Act. These applications are governed by Special Rule 245 of the Commission's *General Rules of Practice* (49 CFR 1100.245), which provides, among other things, that protests and requests for information concerning the time and place of State Commission hearings or other proceedings, and subsequent changes therein, and any other related matters shall be directed to the State Commission with which the application is filed and shall *not* be addressed to or filed with the Interstate Commerce Commission.

Florida Docket No. 790439–CCT, Filed May 18, 1979. Applicant: HULK HEAVY HAULING & RIGGING, INC., Suite 811, Metcalf Bldg., 100 S. Orange Avenue, Orlando, FL 32801. Representative: James E. Wharton, Suite 811, Metcalf Bldg., 100 S. Orange Avenue, Orlando, FL 32801. Certificate of Public Convenience and Necessity sought to operate a freight service, as follows: Transportaion of: Items which because of their size or weight require the use of special equipment and items too heavy or bulky to be transported by regular route common carriers of general commodities between the following territories: (1) Between points in that portion of Florida bordered on the north by Florida-Georgia State Line and on the northwest by the Suwanee River, on the west by Gulf of Mexico, on the south by a line commencing at Ft. Pierce then over State Road 80 to US 27 then over U.S. 27 to U.S. 441, then over U.S. 441 to the Atlantic Ocean and bordered on the east by the Atlantic Ocean; and (2) Between points in the territory described in No. 1 on the one hand and on the other, all points in Florida. Intrastate, interstate and foreign commerce authority sought. Hearing: Tuesday, December 11, 1979, 9:30 AM, State Office Building, 400 Robinson St., Orlando, FL. Request for procedural information should be addressed to Florida Public Service Commission, Fletcher Building, 101 East Gaines St., Tallahassee, FL 32304, and should not be directed to the Interstate Commerce Commission.

By the Commission.

Agatha L. Mergenovich,

Secretary.

[Doc. 79–37189 Filed 12–3–79; 8:45 am]

BILLING CODE 7035–01–M

Permanent Authority Decisions

The following applications, filed on or after March 1, 1979, are governed by Special Rule 247 of the Commission's *Rules of Practice* (49 CFR 1100.247). These rules provide, among other things, that a petition for intervention, either in support of or in opposition to the granting of an application, must be filed with the Commission within 30 days after the date notice of the application is published in the **Federal Register.** Protests (such as were allowed to filings prior to March 1, 1979) *will be rejected.* A petition for intervention without leave must comply with Rule 247(k) which requires petitioner to demonstrate that it (1) holds operating authority permitting performance of any of the service which the applicant seeks authority to perform, (2) has the necessary equipment and facilities for performing that service, and (3) has performed service within the scope of the application either (a) for those supporting the application, or, (b) where the service is not limited to the facilities of particular shippers, from and to, or between, any of the involved points.

Persons unable to intervene under Rule 247(k) may file a petition for leave to intervene under Rule 247(l) setting forth the specific grounds upon which it is made, including a detailed statement of petitioner's interest, the particular facts, matters, and things relied upon, including the extent, if any, to which petitioner (a) has solicited the traffic or business of those supporting the application, or, (b) where the identity of those supporting the application is not included in the published application notice, has solicited traffic or business identical to any part of that sought by applicant within the affected marketplace. The Commission will also consider (a) the nature and extent of the property, financial, or other interest of the petitioner, (b) the effect of the decision which may be rendered upon petitioner's interest, (c) the availability of other means by which the petitioner's interest might be protected, (d) the extent to which petitioner's interest will be represented by other parties, (e) the extent to which petitioner's participation may reasonably be expected to assist in the development of a sound record, and (f) the extent to which participation by the petitioner would broaden the issues or delay the proceeding.

Petitions not in reasonable compliance with the requirements of the rule may be rejected. An original and one copy of the petition to intervene shall be filed with the Commission indicating the specific rule under which the petition to intervene is being filed, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named.

Section 247(f) provides, in part, that an applicant which does not intend to timely prosecute its application shall promptly request that it be dismissed, and that failure to prosecute an application under the procedures of the Commission will result in its dismissal.

If an applicant has introduced rates as an issue it is noted. Upon request, an applicant must provide a copy of the tentative rate schedule to any protestant.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication.*

Any authority granted may reflect administrative acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

Findings

With the exception of those applications involving duly noted problems (e.g., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each common carrier applicant has demonstrated that its proposed service is required by the present and future public convenience and necessity, and that each contract carrier applicant qualifies as a contract carrier and its proposed contract carrier service will be consistent with the public interest and the transportation policy of 49 U.S.C. 10101. Each applicant is fit, willing, and able properly to perform the service proposed and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulation. Except where specifically noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In those proceedings containing a statement or note that dual operations are or may be involved we find, preliminarily and in the absence of the issue being raised by a petitioner, that the proposed dual operations are consistent with the public interest and the transportation policy of 49 U.S.C. 10101 subject to the right of the Commission, which is expressly reserved, to impose such terms, conditions or limitations as it finds necessary to insure that applicant's operations shall conform to the provisions of 49 U.S.C. 10930(a) [formerly section 210 of the Interstate Commerce Act.]

In the absence of legally sufficient petitions for intervention, on or before January 3, 1980 (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of the decision-notice. To the extent that the authority sought below may duplicate an applicant's other authority, such duplication shall be construed as conferring only a single operating right.

Applicants must comply with all specific conditions set forth in the following decision-notices within 30 days after publication, or the application shall stand denied.

Note.—All applications are for authority to operate as a common carrier, by motor vehicle, in interstate or foreign commerce, over irregular routes, except as otherwise noted.

Volume No. 209

Decided: Oct. 30, 1979.

By the Commission, Review Board Number 3, Members Parker, Fortier and Hill. Member Hill not participating.

MC 11207 (Sub-493F), filed May 16, 1979. Applicant: DEATON, INC., 317 Avenue W, P.O. Box 938, Birmingham, AL 35201. Representative: Kim D. Mann, Suite 1010, 7101 Wisconsin Avenue, Washington, DC 20014. Transporting (1) *iron and steel articles,* and (2) *materials, equipment and supplies* used in the manufacture of the commodities named in (1) above (except commodities in bulk), between Carnegie, PA, on the one hand, and, on the other, points in AL, AR, LA, MS, and TX. (Hearing site: Pittsburgh, PA or Washington, DC.)

MC 26396 (Sub-248F), filed May 16, 1979. Applicant: POPELKA TRUCKING CO., d.b.a. THE WAGGONERS, P.O. Box 31357, Billings, MT 59107. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501. Transporting *galvanized steel,* from the facilities of Mr. Galvanized, Inc., at Farrell, PA, to watertown, SD. (Hearing site: Billings, MT.)

MC 61977 (Sub-19F), filed May 22, 1979. Applicant: ZERKLE TRUCKING COMPANY, a corporation, 2400 Eighth Ave., Huntington, WV 25703. Representative: John M. Friedman, 2930 Putnam Ave., Hurricane, WV 25526. Transporting *composition board and lumber,* between the facilities of Champion International Corporation at Charleston, Catawba, and Orangeburg, SC, and South Boston, VA, on the one hand, and, on the other, points in IL, IL, KY, OH, TN, and WV. (Hearing site: Charleston, WV.)

Note.—Dual operations may be involved.

MC 63417 (Sub-211F), filed May 16, 1979. Applicant: BLUE RIDGE TRANSFER COMPANY, INCORPORATED, P.O. Box 13447, Roanoke, VA 24034. Representative: William E. Bain (same address as applicant). Transporting (1) *fireplaces, air heaters, ventilators, barbecue grills,* and (2) *accessories* used in the installation of the commodities in (1) above, from the facilities of the Mobex Corporation at or near Baltimore, MD, Fullerton, CA, and Union City, TN, to points in the United States (except AK and HI). (Hearing site: Roanoke, VA, or Los Angeles, CA.)

MC 70557 (Sub-10F), filed May 10, 1979. Applicant: NIELSEN BROS. CARTAGE CO., INC., 4619 W. Homer St., Chicago, IL 60639. Representative: Carl L. Steiner, 39 S. LaSalle St., Chicago, IL 60603. Transporting *canned and preserved foodstuffs,* from the facilities of Heinz USA, Div. of H. J. Heinz Co., at or near Greenville, SC, to New Orleans, LA, points in AL, MS, TN, and points in FL on and west of FL Hwy 79, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Miami, FL.)

Note.—Dual operations may be involved.

MC 78687 (Sub-66F), filed May 21, 1979. Applicant: LOTT MOTOR LINES, INC., P.O. Box 751, Moravia, NY 13118. Representative: E. Stephen Heisley, 805 McLachlen Bank Bldg., 666 Eleventh St., N.W., Washington, DC 20001. Transporting (1) *canned and preserved foodstuffs,* and (2) *equipment, materials and supplies* used in the manufacture and distribution of the commodities in (1) above, between the facilities of Seneca Foods, Inc., at points in Cayuga, Ontario, Seneca, Wayne and Yates Counties, NY, on the one hand, and, on the other, those points in the United States in and east of DE, MD, NJ, PA and TX. (Hearing site: Washington, DC, or Rochester, NY.)

MC 95336 (Sub-12F), filed May 21, 1979. Applicant: J. B. WILLIAMS EXPRESS, INC., P.O. Box V, Williamsburgh Station, Brooklyn, NY 11211. Representative: Arthur J. Piken, One Leafrak City Plaza, Flushing, NY 11368. Transporting *salvaged merchandise,* from New York, NY, to points CT, NJ, NY and PA. (Hearing site: New York, NY, or Washington, DC.)

MC 100666 (Sub-475F), filed May 16, 1979. Applicant: MELTON TRUCK LINES, INC., P.O. Box 7666, Shreveport LA 71107. Representative: Wilburn L. Williamson, Suite 615—East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. Transporting (1) *such commodities* as are dealt in or used by manufacturers and dealers of agricultural equipment and machinery, industrial equipment and machinery, and lawn and leisure products (except commodities in bulk), between the

facilities of Deere & Company at points in Black Hawk, Dubuque, Polk, Scott and Wapello Counties, IA, Rock Island County, IL, and Dodge County, WI, on the one hand, and, on the other, points in AL, AR, FL, GA, LA, MS, NC, OK, SC, TN, TX and VA, restricted to the transportation of traffic originating at or destined to the facilities of Deere & Company in the above-named counties, and (2) *materials, equipment and supplies* used in the manufacture and distribution of the commodities described in (1) above, (except commodities in bulk), between points in AL, AR, FL, GA, LA, MS, NC, OK, SC, TN, TX, and VA, restricted to the transportation of traffic originating at or destined to the facilities of Deere & Company dealers. (Hearing site: Chicago, IL, or St. Paul, MN.)

MC 105566 (Sub-192F), filed May 21, 1979. Applicant: SAM TANKSLEY TRUCKING, INC., P.O. Box 1120, Cape Girardeau, MO 63701. Representative: Thomas F. Kilroy, Suite 406, Executive Bldg., 6901 Old Keene Mill Rd., Springfield, VA. Transporting *plastic articles*, from Tustin, CA, to points in IL, IN, KS, KY, MO, NE, OH, and PA. (Hearing site: Los Angeles, CA.)

MC 109397 (Sub-462F), filed May 21, 1979. Applicant: TRI-STATE MOTOR TRANSIT CO., a corporation, P.O. Box 113, Joplin, MO 64801. Representative: A. N. Jacobs (same address as applicant). Transporting (1) *commodities*, the transportation of which because of size or weight requires the use of special equipment, (2) *machinery, parts, and materials and supplies* incidental to the transportation of the commodities in (1) above, (3) *self-propelled articles*, each weighing 15,000 pounds or more, and (4) *machinery, tools, parts, and supplies* moving in connection with the commodities in (3) above, restricted to the transportation of traffic which are transported on trailers, between points in TN, MS, AL, GA, SC, and FL, on the one hand, and, on the other, points in IL, IN, MI, OH, WV, VA, and NC. (Hearing site: Chicago, IL, or Detroit, MI.)

Note.—Applicant intends to substitute single-line service for joint-line service.

MC 111397 (Sub-130F), filed May 21, 1979. Applicant: DAVIS TRANSPORT, INC., 1345 South Fourth Street, Paducah, KY 42001. Representative: H. S. Melton, Jr., P.O. Box 1407, Paducah, KY 42001. Transporting *zinc, zinc oxide, zinc dust, zinc dross, metallic cadmium, and lead sheet*, from the facilities of St. Joe Zinc Company at Josephtown, PA, to St. Louis, MO, and points in IL, IN, KY, and TN. (Hearing site: Louisville, KY, or Washington DC.)

MC 111397 (Sub-13F), filed May 21, 1979. Applicant: DAVIS TRANSPORT, INC., 1345 South Fourth Street, Paducah, KY 42001. Representative: H. S. Melton, Jr., P.O. Box 1407, Paducah, KY 42001. Transporting *such commodities* as are distributed by wholesale grocery warehouses (except commodities in bulk), from points in AL, AR, FL, GA, IL, IN, LA, MO, TN, and TX, to (1) the facilities of M. Livingston & Company at Paducah, Fulton, and Leitchfield, KY, and (2) the facilities of Banks Grocery Company, at Paducah, KY. (Hearing site: Memphis, TN, or Louisville, KY.)

MC 112617 (Sub-436F), filed May 21, 1979. Applicant: LIQUID TRANSPORTERS, INC., 1292 Fern Valley Road, P.O. Box 21395, Louisville, KY 40221. Representative: Charles R. Dunford (same address as applicant). Transporting *chemicals*, in bulk, in tank vehicles, from New Albany, IN, to points in AL, AR, CT, DE, FL, GA, IL, IA, KS, KY, LA, MO, MA, MI, MN, MS, MD, NJ, NY, NC, OH, OK, PA, SC, TN, TX, VA, WV, and WI. (Hearing site: Louisville, KY, or Washington, DC.)

MC 113666 (Sub-170F), filed May 23, 1979. Applicant: FREEPORT TRANSPORT, INC., 1200 Butler Rd., Freeport, PA 16229. Representative: R. Scott Mahood (same address as applicant). Transporting *iron and steel articles*, between Midland, PA, on the one hand, and, on the other, points in IL, IN, MO, NY, NJ, DE, CT, MA, VA, and WI. (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 113666 (Sub-171F), filed May 23, 1979. Applicant: FREEPORT TRANSPORT, INC., 1200 Butler Rd., Freeport, PA 16229. Representative: R. Scott Mahood (same address as applicant). Transporting *ammonium nitrate*, from Edinburg, PA, to points in PA, restricted to the transportation of traffic having a prior movement by rail. (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 115826 (Sub-449F), filed April 15, 1979, and previously noticed in the **Federal Register** issue of October 4, 1979. Applicant: W. J. DIGBY, INC., 6015 East 58th Ave., Commerce City, CO 80022. Representative: Howard Gore (same address as applicant). Transporting *foodstuffs, commodities* used and dealt in by restaurants and food service companies, and *commodities* used in packaging and processing foodstuffs (except commodities in bulk), from points in CA, IN, LA, MA, NJ, NY, TX, and WI to the facilities of CFS Continental, Inc., at or near Chicago, IL, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations.

Note.—This republication is to correctly reflect the commodity description.

MC 115826 (Sub-479F), filed May 21, 1979. Applicant: W. J. DIGBY, INC., 6015 East 58th Ave., Commerce City, CO 80022. Representative: Howard Gore (same address as applicant). Transporting *meats, and meat products, meat by-products, and articles distributed by meat packing houses*, as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from (1) points in CO (except Denver, Greeley, Colorado Springs), NE, KS, TX, MO, NM, ID, IA, AZ, WA, and CA, to Ogden, UT, and (2) from Ogden, UT, to points in the United States (except AK, HI, AZ, and CA). (Hearing site: Denver, CO.)

MC 116686 (Sub-4F), filed May 23, 1979. Applicant: LONG ISLAND FURNITURE EXPRESS, INC., 1080-B Route 109, N. Lindenhurst, NY 11757. Representative: Roy A. Jacobs, 550 Mamaroneck Ave., Harrison, NY 10528. Transporting *new furniture*, between the facilities of Long Island Furniture Express, Inc., at North Lindenhurst, NY, on the one hand, and, on the other, points in Fairfield, Hartford, Litchfield and New Haven Counties, CT. (Hearing site: New York, NY.)

MC 117686 (Sub-271F), filed May 21, 1979. Applicant: HIRSCHBACH MOTOR LINES, INC., P.O. Box 417, Sioux City, IA 51102. Representative: George L. Hirschbach (same address as applicant). Transporting *canned and preserved foodstuffs*, from the facilities of Heinz USA, Division of H.J. Heinz Company at or near Iown City and Muscatine, IA, to points in MN, ND, and SD, restricted to the transportation of traffic originating at the above named facilities and destined to the above named destination points. (Hearing site: Washington, DC, or Pittsburgh, PA.)

MC 125777 (Sub-248F), filed May 16, 1979. Applicant: JACK GRAY TRANSPORT, INC., 4600 East 15th Avenue, Gary, IN 46403. Representative: Allan C. Zuckerman, 39 South LaSalle Street, Chicago, IL, 60603. Transporting *coke and coke breeze*, in bulk, in dump vehicles, from Erie, PA, and Toledo, OH, to points in CT, DE, IA, IL, IN, KY, MA, MD, ME, MI, MN, MO, NH, NH, NY, OH, PA, RI, VA, VT, WI, WV, and DC. (Hearing site: Chicago, IL.)

MC 129537 (Sub-34F), filed May 23, 1979. Applicant: REEVES TRANSPORTATION CO., Rt. 5-Dews Pond Rd., Calhoun, GA 30701. Representative: John C. Vogt, Jr., 406 N.

Morgan St., Tampa, FL 33602. Transporting (1) *carpeting, floor covering, carpet padding,* and (2) *materials, supplies and equipment* used in the installation and manufacture of the commodities named in (1) above, between points in Floyd, Bartow, Chattooga, Muscogee, Gordon, Whitfield, Murray, Walker, Catoosa and Troup Counties, GA, on the one hand, and, on the other, points in OK. (Hearing site: Oklahoma City, OK.)

MC 129857 (Sub-7F), filed May 17, 1979. Applicant: G.R.M., INC., d.b.a. PORT TERMINAL TRANSPORT, INC., 700 Henry Ford Ave., Long Beach, CA 90801. Representative: Patricia M. Schnegg, 1800 United California Bank Bldg., 707 Wilshire Blvd., Los Angeles, CA 90017. Transporting *automobiles,* between points in CA. (Hearing site: Los Angeles, CA.)

Note.—By this application authority is sought to convert the applicant's present Certificate of Registration to a Certificate of Public Necessity.

MC 134286 (Sub-116F), filed May 18, 1979. Applicant: ILLINI EXPRESS, INC., P.O. Box 1564, Sioux City, IA 51102. Representative: Julie Humbert (same address as applicant). Transporting *dated magazine parts* (except in bulk), from Brookfield, WI, to Old Saybrook, CT. (Hearing site: Sioux City, IA, or Denver, CO.)

MC 134467 (Sub-46F), filed May 21, 1979. Applicant: POLAR EXPRESS, INC., P.O. Box 845, Springdale, AR 72764. Representative: Charles M. Williams, 350 Capitol Life Center, 1600 Sherman St., Denver, CO 80203. Transporting *such merchandise* as is dealt in by retail, discount, department, or variety stores, except commodities in bulk, from points in the United States (except AK, HI, and AR), to the facilities of Wal-Mart Stores, Inc., at or near Bentonville, Searcy, and Ft. Smith, AR. (Hearing site: Little Rock, AR.)

MC 134477 (Sub-354F), filed May 18, 1979. Applicant: SCHANNO TRANSPORTATION, INC., 5 West Mendota Road, West St. Paul, MN 55118 Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. Transporting (1) *toilet preparations,* and (2) *commodities* used in the sale of toilet preparations (except in bulk in (1) and (2) from the facilities of LaMaur, Inc. at Minneapolis, MN, to points in AL, AR, FL, GA, IN, KS, KY, LA, MS, MO, NC, OK, SC, TN, and TX. (Hearing site: St. Paul, MN.)

MC 135797 (Sub-220F), filed May 23, 1979. Applicant: J. B. HUNT TRANSPORT, INC., P.O. Box 130, Lowell AR 72745. Representative: Paul R. Bergant (same address as applicant). Transporting (1) *such commodities* as are dealt in by grocery and food business houses, and (2) *equipment, materials and supplies* used in the conduct of such business, from Stockton, Modesto and Ventura, CA, to points in LA, OK and TX. (Hearing site: Los Angeles, CA, or Washington, D.C.)

MC 138157 (Sub-152F), filed May 21, 1979. Applicant: SOUTHWEST EQUIPMENT RENTAL, INC., d.b.a. SOUTHWEST MOTOR FREIGHT, P.O. Box 9596, Chattanooga, TN 37412. Representative: Patrick E. Quinn (same address as applicant). Transporting *motor vehicle parts and accessories,* from Carson, CA, to those points in the United States in and east of ND, SD, NE, KS, OK and TX. (Hearing site: Los Angeles, CA.)

Note.—Dual operations may be involved.

MC 138206 (Sub-7F), filed May 10, 1979. Applicant: TRULINE CORPORATION, 4455 South Cameron Avenue, Las Vegas, NV 89103. Representative: Robert G. Harrison, 4299 James Drive, Carson City, NV 89701. Transporting *iron and steel products,* (except construction materials and building materials as defined in the *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 279, Appendix VI), between points in Los Angeles, San Bernardino and Riverside Counties, CA, on the one hand, and, on the other, points in NV. (Hearing site: Las Vegas, NV.)

MC 139177 (Sub-3F), filed May 17, 1979. Applicant: MAIERS TRANSFER & STORAGE CO., INC., 515 25th Avenue North, St. Cloud, MN 56301. Representative: Val M. Higgins, 1000 First National Bank Bldg., Minneapolis, MN 55402. To operate as a *contract carrier,* by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *paper and paper products,* from the facilities of Hoerner Waldorf Champion International Corporation at Minneapolis, MN, to points in ND, (2) *commodities* used in the manufacture of paper and paper products (except commodities in bulk), from points in ND to the facilities of Hoerner Waldorf Champion International Corporation at Minneapolis, MN, parts (1) and (2) under continuing contract(s) with Champion International Corporation of Hamilton, OH. (Hearing site: Minneapolis, MN-St. Paul, MN.)

MC 140587 (Sub-16F), filed May 21, 1979. Applicant: CECIL CLAXTON, Route 3, Box 7, Wrightsville, GA 31096. Representative: Ronald K. Kolins, Suite 202, 333 North Fairfax Street, Alexandria, VA 22314. Transporting *packaged petroleum products,* from Congo and St. Marys, WV, to points in GA, FL and AL. (Hearing site: Atlanta, GA.)

MC 143267 (Sub-72F), filed May 24, 1979. Applicant: CARLTON ENTERPRISES, INC., P.O. Box 520, Mantua, OH 44255. Representative: Neal A. Jackson, 1155 15th St. NW., Washington, DC 20005. Transporting *plywood and plywood wall paneling,* from the facilities of Plywood Panels, Inc., at or near Norfolk, VA, to points in CT, MD, NJ, OH, PA, and WV. (Hearing site: Cleveland, OH, or Washington, DC.)

MC 143687 (Sub-10F), filed May 17, 1979. Applicant: DAVID DALE TRANSPORT, INC., 2 Franklin Street, West Medway, MA 02053. Representative: Wesley S. Chused, 15 Court Square, Boston, MA 02108. To operate as a *contract carrier,* by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *cans,* from Peabody, MA, to those points in the United States in and east of MN, IA, MO, OK, and TX (except MA), under continuing contract(s) with Eagle Can Company of Peabody, MA. (Hearing site: Boston, MA.)

MC 144227 (Sub-2F), filed May 21, 1979. Applicant: CARMIL, INC., Hershey, NE 69143. Representative: Lavern R. Holdeman, 521 South 14th St., Suite 500, P.O. Box 82849, Lincoln, NE 68501. Transporting *feed and feed ingredients* (except liquid commodities, in bulk), from Sergeant Bluff, IA, to points in NE on and west of U.S. Hwy 183, restricted to the transportation of shipments originating at the facilities of Farmland Industries, Inc., at or near Sergeant Bluff, IA, and destined to the named destination. (Hearing site: North Platte or Lincoln, NE.)

MC 145026 (Sub-5F), filed May 23, 1979. Applicant: NORTHEAST CORRIDOR EXPRESS, INC., Railroad Ave., Federalsburg, MD 21632. Representative: Dwight L. Koerber, Jr., 805 McLachlen Bank Bldg., 666 Eleventh St. N.W., Washington, DC 20001. Transporting *edible flour compounds* (except in bulk), from Cleveland, OH, to Gloucester and New Beford, MA. (Hearing site: Washington, DC.)

MC 145557 (Sub-6F), filed May 10, 1979. Applicant: LIBERTY TRANSPORT, INC., 4614 South 40th Street, St. Joseph, MO 64503. Representative: Tom B. Kretsinger, 20 East Franklin, Liberty, MO 64068. Transporting (1)(a) *malt beverages* (except commodities in bulk) (b) *advertising materials and supplies,* from points in Jefferson County, CO, to points in IA and MO, and (2) *empty used*

beverage containers for recycling and, (3) *materials and supplies* used in and dealt with by breweries, in the reverse direction. (Hearing site: Denver, CO.)

MC 145636 (Sub-5F), filed May 21, 1979. Applicant: BOB BRINK INCORPORATED, 165 Stueben St., Winona, MN 55987. Representative: Samuel Rubenstein, 301 North Fifth St., Minneapolis, MN 55403. Transporting (1) *metal ware*, and (2) *commodities* which are otherwise exempt for economic regulation under Section 10526(6) (formerly 203 (b)(6) of the Interstate Commerce Act, when moving in mixed loads with commodities named in (1) above, from Winona, MN, to points in AZ, AR, CA, CO, ID, IA, KS, LA, MO, MT, NE, NM, ND, OK, OR, SD, TX, UT, WA and WY. (Hearing site: Minneapolis or St. Paul, MN.)

MC 145726 (Sub-4F), filed May 21, 1979. Applicant: G. P. THOMPSON ENTERPRISES, INC., P.O. Box 146, Midway, AL 36053. Representative: Terry P. Wilson, 420 South Lawrence Street, Montgomery, AL 36104. Transporting *meats, meat products, meat byproducts, and articles distributed by meat-packing houses*, as described in Sections A and C of Appendix I to the Report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), (1) from the facilities utilized by John Morrell & Co. at or near Arkansas City, KS, East St. Louis, IL, Memphis, TN, and Shreveport, LA, to points in AL, FL, GA, MS, NC, SC, and TN, restricted to the transportation of traffic originating at the facilities of John Morrell & Co. (Hearing site: Chicago, IL or East St. Louis, IL.)

MC 146666 (Sub-2F), filed May 16, 1979. Applicant: EDWARD R. CORCORAN, d.b.a. CORCORAN TRUCKING, 1955 Old Hardin Road, P.O. Box 31135, Billings, MT 59107. Representative: Jack H. Blanshan, Suite 200, 205 West Touhy Avenue, Park Ridge, IL 60068. Transporting (1) *bananas*, and (2) *agricultural commodities* exempt from regulation under Section 10526(a)(6) of the Interstate Commerce Act when transported in mixed loads with bananas, from the facilities of Del Monte Banana Co. at Port Hueneme, CA, to points in CO, MN, MT, NE, ND, SD, and WY, restricted to the transportation of traffic having a prior movement by water. (Hearing site: Los Angeles, CA.)

MC 147077 (Sub-2F), filed May 21, 1979. Applicant: Q. T. TUGGLE, d.b.a. CALIFORNIA WESTERN, 3325 Linden Ave., Long Beach, CA 90807. Representative: Milton W. Flack, 4311 Wilshire Blvd., Suite 300, Los Angeles, CA 90010. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *graphic arts machinery and equipment*, and (2) *materials* and *supplies* incidental to the transportation of the commodities in (1) above, between points in the United States (except AK and HI), under a continuing contract(s) with Masthead International, Inc., of Newhall, CA. (Hearing site: Los Angeles, CA.)

MC 147136 (Sub-2F), filed April 23, 1979. Applicant: TOMORROW TRANSPORTS, INC., 1257 Central Ave., Hamilton, OH 45011. Representative: Jerry B. Sellman, 50 West Broad St., Columbus, OH 43215. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), from the facilities of Ohio Valley Shippers Association, at Cincinnati, OH, to points in AZ, CA, FL, GA, NM, OR, TX and WA. (Hearing site: Columbus, OH, or Washington, DC.)

MC 147437F, filed May 21, 1979. Applicant: FORT WORTH CARRIER CORPORATION, Box 18245, Fort Worth, TX 76118. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood Avenue, Fort Smith, AR 72902. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *general commodities* (except commodities in bulk, Classes A and B explosives, household goods as defined by the Commission, and those requiring special equipment), between points in AR, KS, LA, MS, MO, NM, OK, TN, and TX, under continuing contract(s) with Dillard Department Stores, Inc., of Fort Worth, TX, restricted to the transportation of traffic originating at or destined to the facilities of Dillard Department Stores, Inc. (Hearing site: Dallas, TX, or Washington, DC.)

MC 147866F, filed May 22, 1979. Applicant: INDUSTRIAL CONTRACT CARRIERS, INC., 14750 S.W. 72nd Ave., Tigard, OR 97223. Representative: Philip G. Skofstad, P.O. Box 594, Gresham, OR 97030. Transporting *paint* (except in bulk, in tank vehicles), from Salem, OR, to points in CA and WA. (Hearing site: Portland, OR.)

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Decided: Nov. Nov. 9, 1979

By the Commission, Review Board Number 1, Members Carlton, Joyce and Jones.

MC 2900 (Sub-374F), filed May 25, 1979. Applicant: RYDER TRUCK LINES, INC., Ranger Division, 2050 Kings Road, P.O. Box 2408–R, Jacksonville, FL 32203. Representative: John Carter (same address as applicant). Transporting *malt beverages*, between the facilities of Anheuser-Busch, Inc., at Williamsburg, VA, on the one hand, and, on the other, points in AL, AR, CT, DE, FL, GA, IL, IN, KY, LA, ME, MD, MA, MI, MS, MO, NH, NJ, NC, NY, OK, OH, PA, RI, SC, TN, TX, VT, WV, and DC, restricted to the transportation of traffic originating at or destined to the named points. (Hearing site: St. Louis, MO.)

MC 16831 (Sub-29F), filed June 8, 1979. Applicant: MID SEVEN TRANSPORTATION COMPANY, a corporation, 2323 Delaware Ave., Des Moines, IA 50317. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. Transporting (1) *agricultural implements*, (2) *parts and attachments* for agricultural implements, and (3) *materials* used in the manufacture of the commodities in (1) and (2) above, between Ames, IA, on the one hand, and, on the other, points in IL, IN, KY, MI, OH, and WI, restricted to the transportation of traffic originating at or destined to Ames, IA. (Hearing site: Des Moines, IA, or St. Paul, MN.)

MC 17000 (Sub-19F), filed June 5, 1979. Applicant: HOHENWALD TRUCK LINES, INC., P.O. Box 196, Hohenwald, TN 38462. Representative: Robert L. Baker, 618 United American Bank Bldg., Nashville, TN 37219. Transporting *rubber gaskets*, from Lobelville, TN, to points in IL. (Hearing site: Washington, DC, or Nashville, TN.)

MC 52460 (Sub-245F), filed June 6, 1979. Applicant: ELLEX TRANSPORTATION, INC., P.O. Box 9637, 1420 W. 35th St., Tulsa, OK 74107. Representative: Wilburn L. Williamson, Suite 615, East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. Transporting *candy* from Covington, TN to points in AL, AZ, AR, CO, FL, GA, KS, LA, MO, MS, NM, NC, OK, SC, and TX. (Hearing site: Memphis, TN.)

MC 60251 (Sub-13F), filed June 7, 1979. Applicant: P & D TRANSPORTATION, INC., Connell Highway, Newport, RI 02840. Representative: Frederick T. O'Sullivan, P.O. Box 2184, Peabody, MA 01960. Transporting *sailboats*, from points in Newport County, RI to points in AL, CA, CT, DE, FL, GA, IL, IN, LA, ME, MD, MA, MI, MN, MS, NH, NJ, NY, NC, OH, OR, PA, SC, TX, VT, VA, WV, WI, and DC. Condition: Upon issuance of a certificate in this proceeding, MC 143011 issued January 22, 1979, shall be

cancelled. (Hearing site: Providence, RI, or Boston, MA.)

MC 61231 (Sub-147F), filed May 30, 1979. Applicant: EASTER ENTERPRISES, INC., d.b.a. ACE LINES, INC., P.O. Box 1351, Des Moines, IA 50309. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. Transporting *wood fencing, timbers, wood shavings, and posts,* from Gladstone, MI, to points in IL, IN, IA, MN, and WI. (Hearing site: St. Paul, MN.)

MC 61620 (Sub-15F), filed May 30, 1979. Applicant: M & G TRANSPORTATION CO., INC., Gloucester, VA 23061. Representative: Terrell C. Clark, P.O. Box 25, Stanleytown, VA 24168. Transporting *containers, container ends, and container lids,* from Baltimore, MD, to Norfolk and Seaford, VA. (Hearing site: Norfolk, VA, or Washington, DC.)

MC 90870 (Sub-27F), filed May 29, 1979. Applicant: RIECHMANN ENTERPRISES, INC., Route 2, Box 137, Alhambra, IL 62001. Representative: Cecil L. Goettsch, 1100 Des Moines Bldg., Des Moines, IA 50309. Transporting *lumber,* from points in AR, MS, and those in TN west of the Tennessee River, to points in IA, IN, IL, KS, KY, MI, MO, MS, NC, NE, OK, SC, TX, and WI. (Hearing site: Chicago, IL, or Memphis, TN.)

MC 95490 (Sub-49F), filed June 5, 1979. Applicant: UNION CARTAGE COMPANY, a corporation, 9A Southwest Cutoff, Worcester, MA 01604. Representative: Edward J. Kiley, 1730 M Street, N.W., Suite 501, Washington, DC 20036. Transporting *glass containers,* from Dayville, CT, to the facility of Costa Apple Products, at or near Highland, NY. (Hearing site: Boston, MA, or Washington, DC.)

MC 104430 (Sub-58F), filed June 8, 1979. Applicant: CAPITAL TRANSPORT COMPANY, INC., Highway 24 West, P.O. Box 408, McComb, MS 39648. Representative: Fred W. Johnson, Jr., 1500 Deposit Guaranty Plaza, P.O. Box 22628, Jackson, MS 39205. Transporting *petroleum, petroleum products, and liquid chemicals,* in bulk, in tank vehicles, from points in Jefferson Parish, LA, to points in the United States (except AK and HI). (Hearing site: New Orleans, LA, or Jackson, MS.)

MC 105501 (Sub-36F), filed June 4, 1979. Applicant: TERMINAL WAREHOUSE COMPANY, INC., 1851 Raddison Road, N.E., Blaine, MN 55434. Representative: Anthony C. Vance, 1307 Dolley Madison Blvd., McLean, VA 22101. Transporting (1) *bleaches, and cleaning, softening, sizing, scouring, finishing, and bluing products,* and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, (except commodities in bulk), from the facilities of Purex Corp. and its Division, Hilex Corporation, at or near St. Paul, MN, to points in ND, SD, IA, WI, and NE. (Hearing site: Minneapolis, MN, or Washington, DC.)

MC 112520 (Sub-371F), filed June 5, 1979. Applicant: McKENZIE TANK LINES, INC., Post Office Box 1200, Tallahassee, FL 32302. Representative: Thomas F. Panebianco (same address as applicant). Transporting *liquefied petroleum gas,* in bulk, in tank vehicles, from Pascagoula, MS, to Mobile, AL. Condition: The authority granted here is limited in point of time to five (5) years from the date of issuance. (Hearing site: Mobile, AL.)

MC 112520 (Sub-372F), filed June 6, 1979. Applicant: McKENZIE TANK LINES, INC., Post Office Box 1200, Tallahassee, FL 32302. Representative: Thomas F. Panebianco (same address as applicant). Transporting *silicon tetrachloride,* in bulk, from the facilities of Degussa, Inc., at or near Mobile, AL, to Weston, MI. (Hearing site: Mobile, AL.)

MC 114301 (Sub-106F), filed June 14, 1979. Applicant: DELAWARE EXPRESS CO., a corporation, P.O. Box 97, Elkton, MD 21921. Representative: Maxwell A. Howell, 1100 Investment Building, 1511 K Street, NW., Washington, DC 20005. Transporting *plastic materials,* between Greensboro, MD, on the one hand, and, on the other, points in AL, CT, DE, GA, IL, IN, KY, MA, ME, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VA, and VT. (Hearing Site: Washington, DC.)

MC 115331 (Sub-501F), filed June 4, 1979. Applicant: TRUCK TRANSPORT INCORPORATED, 29 Clayton Hills Lane, St. Louis, MO 63131. Representative: J. R. Ferris, 230 St. Clair Ave., East St. Louis, IL 62201. Transporting (1) *rolling processing fluids and lubricating oils,* in bulk, in tank vehicles, and in shipper-owned containers, from the facilities of The Ironsides Co., at Columbus, OH, to points in AL, AR, CT, FL, GA, IL, IN, KY, MD, MI, MO, NJ, NY, NC, OH, PA, SC, TX, TN, VA, WV, and WI, and (2) *materials* used in the manufacture of the commodities in (1) above, in bulk, in tank vehicles, and in shipper-owned containers, from Smackover, AR, Savannah, GA, Itasca, McCook, and Chicago, IL, Ft. Wayne, Hammond, Jefferson and Plymouth, IN, Ashland, KY, Elkridge, MD, Austin, MN, St. Louis, MO, Weehauken, NJ, Buffalo, NY, Bradford, Marcus Hook, Petrolia, Franklin, and Philadelphia, PA, Houston, TX, Norfolk, VA, Milwaukee, Cudahy and Madison, WI, and Lake Charles, LA, to the facilities of The Ironsides Co., at Columbus, OH, restricted in (1) and (2) above, to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Columbus, OH, or Washington, DC.)

MC 115841 (Sub-720F), filed June 4, 1979. Applicant: COLONIAL REFRIGERATED TRANSPORTATION, INC., 9041 Executive Park Drive, Suite 110, Building 100, Knoxville, TN 37919. Representative: D. R. Beeler (same address as applicant). Transporting *gas ranges and electric ranges,* from Murray, KY, to points in MA, MD, NY, NJ, and PA. (Hearing site: Washington, DC.)

MC 116740 (Sub-9F), filed June 6, 1979. Applicant: LEE N. HICKOX, Box 637, Flora, IL 62839. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. Transporting *aluminum wire and rods, steel wire, strand, cable, and empty reels,* from the facilities of Southwire Company, at Hawesville, KY, to Flora, IL, restricted to the transportation of traffic originating at the named origin. (Hearing site: St. Louis, MO, or Chicago, IL.)

MC 117940 (Sub-339F), filed June 6, 1979. Applicant: NATIONWIDE CARRIERS, INC., P.O. Box 104, Maple Plain, MN 55359. Representative: Allan L. Timmerman, 5300 Highway 12, Maple Plain, MN 55359. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), from the facilities used by Tulsa Shippers Association, Inc., at points in NY and NJ to Tulsa, OK. (Hearing site: Tulsa, OK.)

MC 117940 (Sub-340F), filed June 6, 1979. Applicant: NATIONWIDE CARRIERS, INC., P.O. Box 104, Maple Plain, MN 55359. Representative: Allan L. Timmerman, 5300 Highway 12, Maple Plain, MN 55359. Transporting *agricultural chemicals,* (except in bulk), between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Monsanto Company. (Hearing site: St. Louis, MO.)

MC 119741 (Sub-190F), filed June 5, 1979. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Avenue NW, P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson, (same address as applicant). Transporting *frozen foodstuffs,* between Indianapolis, IN, on the one hand, and, on the other, points in AR, CO, IL, IA, KS, MN, MO, NE, ND, OK, SD, TX, and WI, restricted to the transportation of

traffic originating at or destined to the facilities of Monument Distribution Warehouse, Inc., at Indianapolis, IN. (Hearing site: Indianapolis, IN.)

MC 123061 (Sub-129F), filed June 4, 1979. Applicant: LEATHAM BROTHERS, INC., 46 Orange St., P.O. Box 16026, Salt Lake City, UT 84116. Representative: Harry D. Pugsley, 1283 E. South Temple No. 501, Salt Lake City, UT 84102. Transporting *shale rock*, from Richmond and Port Costa, CA, to Bellingham, WA. (Hearing site: Portland, OR, or Seattle, WA.)

MC 127740 (Sub-1F), filed June 4, 1979. Applicant: GUY SEAY, Route 6, Spartanburg, SC 29303. Representative: Mitchell King, Jr., P.O. Box 1628, Greenville, SC 29602. Transporting *dry fertilizer*, (1) from Augusta, GA, to points in NC, SC, TN, and VA, and (2) from points in (a) Spartanburg County, SC, to points in GA, TN, and VA, and (b) Greene County, TN, to points in GA, NC, SC, and VA. (Hearing site: Columbia, SC.)

MC 128951 (Sub-26F), filed June 5, 1979. Applicant: ROBERT H. DITTRICH, doing business as BOB DITTRICH TRUCKING, 1000 N. Front St., New Ulm, MN 56073. Representative: Rodney H. Jeffery, (same address as applicant). Transporting *feed, feed ingredients, and flour*, between points in IA, MN, and NE, on the one hand, and, on the other points, in IA, IL, IN, MN, MO, and NE. (Hearing site: Minneapolis or St. Paul, MN.)

MC 134090 (Sub-7F), filed June 5, 1979. Applicant: ALL BEST TRANSFER AND WAREHOUSE, INC., 107 Trumbull St., Elizabeth, NJ 07206. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. To operate as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *lawn and garden care products*, between the facilities of O. M. Scott & Sons Co., at or near North Brunswick, NJ, and, the facilities of O. M. Scott & Sons Co., at or near Marysville, OH, under continuing contract(s) with O. M. Scott & Sons Co., of Marysville, OH. (Hearing site: Columbus, OH, or New York, NY.)

MC 135070 (Sub-70F), filed June 4, 1979. Applicant: JAY LINES, INC., P.O. Box 30180, Amarillo, TX 79120. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. Transporting *meats, meat products and meat byproducts, and articles distributed by meat-packing houses*, as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the facilities of Farmland Foods, Inc., at or near Garden City, KS, to points in the United States (except AK and HI). (Hearing site: Wichita, KS, or Amarillo, TX.)

Note.—Dual operations may be involved.

MC 135070 (Sub-71F), filed June 4, 1979. Applicant: JAY LINES, INC., P.O. Box 30180, Amarillo, TX 79120. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. Transporting (1) *bananas*, and (2) *agricultural commodities* which are otherwise exempt from economic regulation under 49 U.S.C. 10526 (a)(6) [formerly Section 203(b)(6) of the Interstate Commerce Act], when moving in mixed loads with bananas, from Norfolk, VA, to points in the United States (except AK and HI). (Hearing site: Norfolk, VA, or Amarillo, TX.)

Note.—Dual operations may be involved.

MC 135070 (Sub-72F), filed June 4, 1979. Applicant: JAY LINES, INC., P.O. Box 30180, Amarillo, TX 79120. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. Transporting (1) *Plumbing fixtures and fittings*, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, between the facilities of Kohler Co., at or near (a) Kohler, WI, (b) Brownwood, TX, and (c) Spartanburg, SC, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Milwaukee, WI, or Amarillo, TX.)

Note.—Dual operations may be involved.

MC 135410 (Sub-68F), filed June 4, 1979. Applicant: COURTNEY J. MUNSON, d/b/a MUNSON TRUCKING, P.O. Box 266, Monmouth, IL 61462. Representative: Stephen H. Loeb, Suite 200, 205 West Touhy Ave., Park Ridge, IL 60068. Transporting *envelopes*, from the facilities of Boise Cascade Corporation, at Addison, IL, to points in IA. (Hearing site: Chicago, IL.)

MC 140241 (Sub-54F), filed May 30, 1979. Applicant: DALKE TRANSPORT, INC., Box 7, Moundridge, KS 67107. Representative: Larry E. Gregg, 641 Harrison St., Topeka, KS 66603. Transporting *salt and salt products*, from Lyons and Kanapolis, KS, and points in Reno County, KS, to points in AZ, AR, CO, ID, IL, IN, IA, KY, LA, MN, MS, MO, MT, NE, NM, OH, OK, TN, TX, UT, WI, and WY. (Hearing site: Wichita, KS, or Kansas City, MO.)

MC 143471 (Sub-15F), filed June 6, 1979. Applicant: DAKOTA PACIFIC TRANSPORT, INC., 301 Mt. Rushmore Rd., Rapid City, SD 57701. Representative: J. Maurice Andren, 1734 Sheridan Lake Road, Rapid City, SD 57701. To operate as a *contract carrier*, by motor vehicle, in foreign commerce only, over irregular routes, transporting *lumber*, from ports of entry on the international boundary line between the United States and Canada in WA, ID, MT, ND, and MN to points in IL, IA, MN, NE, ND, SD, and WI, under continuing contract(s) with Weyerhaeuser Company, of Tacoma, WA. (Hearing site: Rapid City or Pierre, SD.)

Note.—Dual operations may be involved.

MC 146001 (Sub-4F), filed June 6, 1979. Applicant: BOB MARGOSIAN, d.b.a. BOB MARGOSIAN TRUCKING: 6885 Avenue 416, P.O. Box 395, Dinuba, CA 93618. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609. Transporting *juice* in containers, *prunes, prune extract, table sauces, dried fruits and edible nuts*, from Yuba City and Stockton, CA, to Phoenix, AZ (Hearing site: Los Angles, CA.)

MC 146461 (Sub-1F), filed June 4, 1979. Applicant: J. H. TRUCKING, INC., Route 4, Box 112, Amarillo, TX 79119. Representative: Edward A. O'Donnell, 1004 29th Street, Sioux City, IA 51104. Tranporting *meats, meat products, and meat byproducts, and articles distributed by meat-packing houses* as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides, and commodities in bulk, in tank vehicles), from the facilities of Booker Custom Packing Co., at (a) Booker, TX and (b) Clovis, NM, to points in the United States (except AK and HI), restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations, except traffic moving in foreign commerce. (Hearing site: Amarillo, TX.)

MC 146520 (Sub-4F), filed June 6, 1979. Applicant: QUALITY TRANSPORT, INC., 4404 West Berteau, Chicago, IL 60641. Representative: William J. Boyd, 2021 Midwest Road, Suite 205, Oak Brook, IL 60521. Transporting (1) *bananas*, and (2) *agricultural commodities* which are otherwise exempt from economic regulation under 49 U.S.C. 10526 (a)(6) [formerly Section 203(b)(6) of the Interstate Commerce Act], when moving in mixed loads with bananas, from Norfolk, VA, to points in IL, IA, IN, KS, KY, MI, MN, MO, ND, NE, OH, SD, and WI. (Hearing site: New York, NY, or Washington, DC.)

Note.—Dual operations may be involved.

MC 146991 (Sub-1F), filed June 4, 1979. Applicant: SILICA SAND TRANSPORT, INC., Box 208, Routes 47 and 71, Yorkville, IL 60560. Representative: Arnold L. Burke, 180 North La Salle Street, Chicago, IL 60601. Transporting

iron and steel articles, from the facilities of Northwestern Steel and Wire Company, at Sterling and Rock Falls, IL, to points in IN, KY, MI, OH, PA, and WI. (Hearing site: Chicago, IL.)

Note.—Dual operations may be involved.

MC 147600F, filed May 17, 1979. Applicant: TROY WALKER, Box 48, So. Pittsburg, TN 37380. Representative: Charles G. Jenkins, P.O. Box 536, Jasper, TN 37347. Transporting *trailers* designed to be drawn by passenger automobiles, in secondary movement, and *buildings,* in sections, from Jasper, TN, to points in TN, AL, and GA. (Hearing site: Jasper or Chattanooga, TN.)

MC 148270F, filed May 16, 1979. Applicant: BRELAR, INC., Post Office Box 796, Greenville, MS 38701. Representative: K. Larry Stivers, 1553 Sunridge Cove, Greenville, MS 38701. Transporting *general commodities* (except those of unusual value, classes A and B explosives, commodities in bulk, household goods as defined by the Commission, and those requiring the use of special equipment), between the facilities of Cascio's Storage and Warehouse, at Greenville, MS, on the one hand, and, on the other, points in AL, AR, FL, GA, IN, IL, KS, KY, LA, MS, NC, OK, SC, TN, and TX. (Hearing site: Jackson, MS.)

Note.—Dual operations may be involved.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-37186 Filed 12-3-79; 8:45 am]

BILLING CODE 7035-01-M

[Docket AB-55 (Sub-30F)]

Seaboard Coast Line Railroad Co. Abandonment in Umatilla, Fla.; Notice of Findings

Notice is hereby given pursuant to 49 U.S.C. 10903 that by a Certificate and Decision decided November 7, 1979, a finding, which is adminstratively final, was made by the Commission, Review Board Number 5, stating that, subject to the conditions for the protection of railway employees prescribed by the Commission in AB-36 (Sub-No. 2), *Oregon Short Line R. Co.-Abandonment Goshen,* 360 I.C.C. 91 (1979), and further SCL shall keep intact all of the right-of-way underlying the track, including all of the bridges and culverts for a period of 120 days from the effective date of the certificate and decision to permit any state or local government agency or other interested party to negotiate the acquisition for public use of all or any portion of the right-of-way, the present and future public convenience and necessity permit the abandonment by the Seaboard Coast Line Railroad Company of a portion of a line or railroad known as the Umatilla Subdivision, extending from railroad milepost ASC-819.05 to milepost ASC-820.62, in Umatilla, FL, a distance of 1.57 miles, in Lake County, FL. A certificate of public convenience and necessity permitting abandonment was issued to the Seaboard Coast Line Railroad Company. Since no investigation was instituted, the requirement of § 1121.38(a) of the Regulations that publication of notice of abandonment decisions in the **Federal Register** be made only after such a decision becomes administratively final was waived. Upon receipt by the carrier of an actual offer of financial assistance, the carrier shall make available to the offeror the records, accounts, appraisals, working papers, and other documents shall be made available during regular business hours at a time and place mutually agreeable to the parties.

The offer must be filed and served no later than December 19, 1979. The offer, as filed, shall contain information required pursuant to Section 1121.38(b)(2) and (3) of the Regulations. If no such offer is received, the certificate of public convenience and necessity authorizing abandonment shall become effective January 18, 1980.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 79-37188 Filed 12-3-79; 8:45 am]

BILLING CODE 7035-01-M

Sunshine Act Meetings

Federal Register
Vol. 44, No. 234
Tuesday, December 4, 1979

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).

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1

[M-257, Amdt. 3; Nov. 29, 1979]

CIVIL AERONAUTICS BOARD.

Notice of addition of item to the November 28, 1979, meeting.

TIME AND DATE: 9:30 a.m., November 28, 1979.

PLACE: Room 1027 (Open), Room 1011 (Closed), 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

SUBJECT: 21a. Great Northern Airlines Service Mail Rate Investigation (Memo 7515-F, BDA).

STATUS: 1-23 Open, 24-Closed.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary, (202) 673-5068.

SUPPLEMENTARY INFORMATION: This item would provide Great Northern a temporary rate for mail service at the inception of its new certificated authority, December 1. Absent our taking action today, the Post Office will not tender mail to GNA, and diminished service to the public as well as a revenue loss to the carrier could result. Due to clerical shortages surrounding the Thanksgiving Holiday, staff was unable to forward the item in time for placement on the sunshine calendar. Accordingly, the following Members have voted that agency business requires that Item 21a be added to the November 28, 1979 agenda and that no earlier announcement of this addition was possible:

Chairman, Marvin S. Cohen
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

[S-2338-79; Filed 11-29-79; 4:29 pm]

BILLING CODE 6320-01-M

2

[M-257, Amdt. 2; Nov. 27, 1979]

CIVIL AERONAUTICS BOARD.

Notice of deletion of item from the November 28, 1979, meeting agenda.

TIME AND DATE: 9:30 a.m., November 28, 1979.

PLACE: Room 1027 (Open), Room 1011 (Closed), 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

SUBJECT: 13. Docket 34772, Cancellation of Rule 1(G), CAB No. 352 (formerly CAB No. 142), and similar tariff rules that state that no employees or agents of carriers have authority to waive or modify tariff provisions (Memo 8503-A 8503-B, BDA, BCP, OGC, BIA, OEA).

STATUS: 1-23 Open, 24- Closed.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary, (202) 673-5068.

SUPPLEMENTARY INFORMATION: Item 13 is being deleted from the November 28, 1979 agenda because the Chairman needs additional time to review this item. Accordingly, the following Members have voted that agency business requires that Item 13 be deleted from the November 28 agenda and that no earlier announcement of this deletion was possible:

Chairman, Marvin S. Cohen
Member, Richard J. O'Melia
Member, Elizabeth E. Bailey
Member, Gloria Schaffer

[S-2339-79 Filed 11-29-79; 4:29 pm]

BILLING CODE 6320-01-M

3

[M-258, Nov. 29, 1979]

CIVIL AERONAUTICS BOARD.

TIME AND DATE: 9:30 a.m., December 6, 1979.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT:

1. Ratification of Items adopted by notation.
2. Docket 30927, petition of World Airways for institution of a Transatlantic Low-Fare Route Proceeding. (Memo No. 9317, BIA, OGC, BLJ).
3. Dockets 36091 and 36196; Applications of American and Braniff for Texas-Eastern Canada exemptions. (BIA, OGC).
4. Dockets 15216, 14882, 15217, 16568, and 15253—Finalization of tentative findings, conclusions and decisions in Order 79-9-63. (Memo No. 9113-A, BIA, OGC).
5. Docket 37052, Application of Flugleidir H.F./Icelandair for a temporary exemption to permit nonstop service between authorized U.S. points and Luxembourg. (BIA, OGC).
6. Docket 35503, Petition of AAFES for a declaratory ruling or an exemption under Section 416(b). (OGC).
7. Docket 36419, Texas-Alberta-Alaska case. (OGC).
8. Docket 36764, *Miami-London Case*, Order on Reconsideration. (OGC).
9. Dockets 30882, 30883, and 33362; *Applications of Southern Air Transport, Inc.* and *Former Large Irregular Air Service Investigation*. (Memo No. 9316, OGC).
10. Dockets 35466, 35645, 32871, 35620, 35637, 35636, 35629, 35618, 35622, 36621, 35605, 35640, 34641, 32885, 32727, and 35627; *Albuquerque Show-Case Investigation;* Applications of USAir, American, Braniff, Continental, Easter, Frontier, Hughes Airwest, Northwest, National, Ozark, Pacific Southwest, Republic, Texas International, TWA, and Western for Albuquerque and beyond domestic markets. (BDA).
11. Dockets 36594 and 36651, Aspen Airways' notice to suspend service at Gunnison, Co., effective December 14, 1979. (Memo No. 9315, BDA, OCCR).
12. Dockets 36445 and 36538, Air Pacific's notice to suspend service at Chico, California. (BDA).
13. Dockets EAS-105 thru EAS-333 and EAS-347; Essential Air Service Determinations for Alaskan Points. (BDA).
14. Docket 34772, Cancellation of Rule 1(G), CAB No. 353 (formerly CAB No. 142), and similar tariff rules that state that no employees or agents of carriers have authority to waive or modify tariff provisions. (Memo No. 8503-A, 8503-B, BDA, BCP, OGC, BIA, OEA).
15. Amendment of Rules of Practice in Enforcement Proceedings to simplify and expedite procedures for settlement, and to conform provisions for withholding of documents to Freedom of Information Act standards. (BCP).

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary, (202) 673-5068.

[S-2345-79 Filed 11-30-79; 1:55 pm]

BILLING CODE 6320-01-M

4

COMMODITY CREDIT CORPORATION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: Published November 26, 1979, 44 FR 67562.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 2 p.m., December 3, 1979.

STATUS: Open.

CHANGE: The meeting has been cancelled.

CONTACT PERSON FOR MORE INFORMATION: Bill Cherry, Secretary, Commodity Credit Corporation, Room 202–W, Administration Building, U.S. Department of Agriculture, Washington, D.C. 20013, Telephone (202) 447–7583.

[S–2343–79; Filed 11–30–79; 11:27 am]

BILLING CODE 3410–05–M

5

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 11:00 on Friday, November 30, 1979, the Federal Deposit Insurance Corporation's Board of Directors will meet in closed session, by vote of the Board of Directors pursuant to sections 552b (c)(6), (c)(8), and (c)(9)(A)(ii) of title 5, United States Code, to consider the following matters:

Application for Federal deposit insurance:

Arlington State Bank, a proposed new bank, to be located approximately 150 feet west of the northwest corner of the intersection of Poly Webb Road and Little Road, Arlington, Texas, for Federal deposit insurance.

Application for consent to merge and to establish branches:

Republic Bank, Gardena, California, an insured State nonmember bank, for consent to merge with California Pacific Bank, Fullerton, California, under the charter and title of Republic Bank, and to establish the two offices of California Pacific Bank as branches of the resultant bank.

Application for consent to a purchase and assumption transaction and to establish a branch:

The Morris County Savings Bank, Morristown, New Jersey, for consent to purchase the assets of and assume the liability to pay deposits made in Bernards State Bank, Bernardsville, New Jersey, and to establish the office of Bernards State Bank as a branch of The Morris County Savings Bank.

In calling the meeting, the Board of Directors determined that Corporation business requires consideration of these matters on less than seven days' notice to the public and that no earlier notice of the meeting was practicable.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550—17th Street, NW., Washington, D.C.

Requests for information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation at (202) 389–4425.

Dated: November 29, 1979.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[S–2340–79 Filed 11–29–79; 4:59 pm]

BILLING CODE 6714–01–M

6

November 30, 1979.

FEDERAL ENERGY REGUALTORY COMMISSION.

TIME AND DATE: November 30, 1979, 10 a.m.

PLACE: 825 North Capitol Street, NE., Washington, D.C. 20426.

MATTERS TO BE CONSIDERED: Conduct of an on-the-record proceeding.

CONTACT PERSON FOR: Kenneth F. Plumb, Secretary.

[S–2348–79 Filed 11–30–79; 2:53 pm]

BILLING CODE 6450–01–M

7

FEDERAL HOME LOAN BANK BOARD.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: FR Vol. 44, Page 69074, November 30, 1979.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 11 a.m., December 5, 1979

PLACE: 1700 G Street, NW., Sixth Floor, Washington, D.C.

STATUS: Open Meeting.

CONTACT PERSON FOR MORE INFORMATION: Franklin O. Bolling (202–377–6677).

CHANGES IN THE MEETING:

The following item has been withdrawn from the agenda for the open meeting.

Regulation on Consolidation and Simplification of Branch Regulations.

The following items have been added to the agenda for the open meeting.

Regulation on Marketable Certificates of Deposits; Brokered Funds.

Regulation on Eurodollar Deposits

No. 277, November 30, 1979.

[S–2347–79; Filed 11–30–79; 2:53 pm]

BILLING CODE 6720–01–M

8

FEDERAL HOME LOAN MORTGAGE CORPORATION.

TIME AND DATE: 2 p.m., December 5, 1979.

PLACE: 1700 G Street NW., Sixth Floor, Washington, D.C.

STATUS: Open Meeting.

CONTACT PERSON FOR MORE INFORMATION: Henry Judy (202–789–4734).

MATTERS TO BE CONSIDERED: Bylaw Amendment on Approval of GMC Offering Materials.

No. 296, November 29, 1979.

[S–2346–79 Filed 11–30–79; 1:55 pm]

BILLING CODE 6720–02–M

9

FEDERAL RESERVE SYSTEM (Board of Governors).

TIME AND DATE: 11 a.m., Friday, December 7, 1979.

PLACE: 20th Street and Constitution Avenue NW., Washington, D.C. 20551.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.
2. Any agenda items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. Joseph R. Coyne, Assistant to the Board; (202) 452–3204.

Dated: November 28, 1979.

Griffith L. Garwood,

Deputy Secretary of the Board.

[S–2342–79 Filed 11–30–79; 11:16 am]

BILLING CODE 6210–01–M

10

INTERSTATE COMMERCE COMMISSION.

TIME AND DATE: 9:30 a.m., Tuesday, December 11, 1979.

PLACE: Hearing Room "A", Interstate Commerce Commission Building, 12th Street and Constitution Avenue NW., Washington, D.C.

STATUS: Open Special Conference (Cancels Conference scheduled for December 4, 1979).

MATTERS TO BE DISCUSSED:

(1) Division Assignments; and
(2) Rail Rate Bureaus.

The Commission's professional staff will be available to brief news media representatives conference issues at the conclusion of the meeting.

[S–2344–79; Filed 11–30–79; 12:50 pm]

BILLING CODE 7035–01–M

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NATIONAL CREDIT UNION ADMINISTRATION.

TIME AND DATE: 10 a.m., December 6, 1979.

PLACE: 1776 G Street N.W., Washington, D.C., 6th Floor Conference Room.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Review of Central Liquidity Facility Lending Rates.
2. Central Liquidity Facility Repayment Agreements.
3. Final language amending Part 708, "Mergers of Credit Unions."
4. Federal credit union loan interest rate ceiling.
5. Response to Executive Order 12160: "Providing for Enhancement and Coordination of Federal Consumer Programs."
6. Uniform Financial Institutions Rating System.
7. Supervisory policy regarding the purchase and sale of U.S. Government guaranteed loans by financial insitutions.
8. Applications for charters, amendments to charters, bylaw amendments, mergers, conversions and insurance as may be pending at that time.

CONTACT PERSON FOR MORE INFORMATION: Rosemary Brady, Secretary of the Board, telephone (202) 357–1100.

[S–2341–79; Filed 11–30–79; 9:18 am]

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federal register

Tuesday
December 4, 1979

Part II

Department of Health, Education, and Welfare

Food and Drug Administration

External Analgesic Drug Products for Over-the-Counter Human Use; Establishment of a Monograph and Notice of Proposed Rulemaking

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 348

[Docket No. 78N-0301]

External Analgesic Drug Products for Over-the-Counter Human Use; Establishment of a Monograph and Notice of Proposed Rulemaking

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: This proposed rule would establish conditions under which over-the-counter (OTC) external analgesic drug products are generally recognized as safe and effective and not misbranded. The proposed rule, based on the recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products, is part of the ongoing review of OTC drug products conducted by the Food and Drug Administration (FDA).

DATES: Comments by March 6, 1980 and reply comments by April 3, 1980.

ADDRESS: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Bureau of Drugs (HFD-510), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4960.

SUPPLEMENTARY INFORMATION: In accordance with Part 330 (21 CFR Part 330), FDA received on May 23, 1978, a report of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products. Under § 330.10(a)(6) (21 CFR 330.10(a)(6)), the agency issues (1) a proposed regulation containing the monograph recommended by the Panel, which establishes conditions under which OTC external analgesic drugs are generally recognized as safe and effective and not misbranded; (2) a statement of the conditions excluded from the monograph because the Panel determined that they would result in the drugs not being generally recognized as safe and effective or would result in misbranding; (3) a statement of the conditions excluded from the monograph because the Panel determined that the available data are insufficient to classify these conditions under either (1) or (2) above; and (4) the conclusions and recommendations of the Panel.

The unaltered conclusions and recommendations of the Panel are issued to stimulate discussion, evaluation, and comment on the full sweep of the Panel's deliberations. The report has been prepared independently of FDA, and the agency has not yet fully evaluated the report. The Panel's findings appear in this document as a formal proposal to obtain public comment before the agency reaches any decision on the Panel's recommendations. This document represents the best scientific judgment of the Panel members but does not necessarily reflect the agency's position on any particular matter contained in it.

The Panel recommended classification of the ingredient methapyrilene hydrochloride in Category I for topical use as an external analgesic. Subsequent to this recommendation, studies, not available to the Panel, provided data from which the agency concluded that methapyrilene is a potent carcinogen in animal and must be considered a potential human carcinogen. These data are on file in the office of the Hearing Clerk (address given above) under Docket No. 75N-0244. In June 1979, the agency initiated a recall of all oral and topical products containing methapyrilene. Products containing methapyrilene are considered misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act. The Panel's report and proposed monograph, however, have not been changed to reflect these subsequent events.

FDA is aware of the recommendation to make low concentrations of hydrocortisone available for OTC use. Without addressing the merits of this recommendation, the agency merely wishes to point out that no final decision will be made without careful and thorough evaluation of all comments which are submitted in response to the publication of this recommendation. Any persons marketing such an OTC product prior to the publication in the **Federal Register** of a final monograph will do so at their own risk, as detailed in § 330.13 (21 CFR 330.13).

After reviewing all comments submitted in response to this proposal, FDA will issue a tentative final regulation in the **Federal Register** to establish a monograph for OTC external analgesic drug products.

In accordance with § 330.10(a)(2) (21 CFR 330.10(a)(2)), the panel and FDA have held as confidential all data and information concerning OTC external analgesic drug products submitted for consideration by the Advisory Review Panel. All the submitted information will be put on public display at the office of the Hearing Clerk, Food and Drug Administration, after January 3, 1980, except to the extent that the person submitting it demonstrates that it still falls within the confidentiality provisions of 18 U.S.C. 1905 or section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Requests for confidentiality should be submitted to William E. Gilbertson, Bureau of Drugs (HFD-510) (address given above).

Based upon the conclusions and recommendations of the Panel, the agency proposes the following:

1. That the conditions included in the monograph, under which the drug products would be generally recognized as safe and effective and not misbranded (Category I), be effective 30 days after the date of publication of the final monograph in the **Federal Register**.

2. That the conditions excluded from the monograph because they would cause the drug to be not generally recognized as safe and effective or to be misbranded (Category II), be eliminated from OTC drug products effective 6 months after the date of publication of the final monograph in the **Federal Register**, regardless of whether further testing is undertaken to justify their future use.

3. That the conditions excluded from the monograph, because the available data are insufficient (Category III) to classify such conditions either as Category I or Category II will be the subject of a later notice. The status of Category III conditions after publication of a final order is the subject of the recent decision in *Cutler* v. *Kennedy*, No. 77-0734 (D.D.C. July 16, 1979). In that case, the court held that "FDA may not lawfully maintain Category III in any form in which drugs with Category III conditions * * * are exempted from enforcement action." (*Cutler, supra.*, slip op. at 38). The agency is presently studying the effect of this decision on the OTC drug review procedures. Accordingly, although this document retains the concept of Category III in its original form, the agency's response to the court's decision may result in substantial changes in the regulatory treatment of Category III conditions.

In the **Federal Register**, of January 5, 1972 (37 FR 85), FDA announced a proposed review of the safety, effectiveness, and labeling of all OTC drugs by independent advisory review panels. In the **Federal Register**, of May 11, 1972 (37 FR 9464), the agency published the final regulations providing for the OTC drug review under § 330.10

which were made effective immediately. Pursuant to these regulations, FDA issued in the **Federal Register**, of December 12, 1972 (37 FR 26456) a request for data and information on all active ingredients utilized in OTC topical analgesic, including antirheumatic, otic, burn, sunburn treatment and prevention, drug products.

The Commissioner appointed the following Panel to review the data and information submitted and to prepare a report pursuant to § 330.10(a)(1) on the safety, effectiveness, and labeling of those products: Thomas G. Kantor, M.D., chairman; John Adriani, M.D.; Col. William A. Akers, M.D.; Maxine Bennett, M.D.; Minerva S. Buerk, M.D.; Walter L. Dickison, Ph.D.; and Jerry Mark Shuck, M.D.

The Panel was charged to review submitted data information on OTC topical analgesics, including antirheumatic, otic, burn, and sunburn treatment and prevention active ingredients. For purposes of this review, the Panel grouped the active ingredients and labeling into four major pharmacologic groups—external analgesics, skin protectants, topical otics, and sunscreens.

The Panel presents its conclusions and recommendations for external analgesic active ingredients in this document. For discussion purposes, the external analgesic active ingredients have been further divided into four pharmacologic groups—topical anesthetics, topical antipruritics, topical counterirritants, and topical analgesics. The Panel's conclusions for topical otic active ingredients were published in the **Federal Register** of December 16, 1977 (42 FR 63556); the conclusions for sunscreen active ingredients were published in the **Federal Register** of August 25, 1978 (43 FR 38206); and its conclusions for skin protectants were published in the **Federal Register** of August 4, 1978 (43 FR 34628).

The Panel was first convened on March 6, 1973 in an organizational meeting. Working meetings were held on May 8 and 9, July 12 and 13, September 27 and 28, November 3 and 4, November 26 and 27, 1973; January 30 and 31, March 6 and 7, April 10 and 11, May 8 and 9, June 10 and 11, July 17 and 18, September 24 and 25, October 22 and 23, November 26 and 27, 1974; January 21 and 22, March 13 and 14, April 17 and 18, May 21 and 22, July 15 and 16, September 30 and October 1, November 12 and 13, 1975; March 4 and 5, May 19 and 20, June 22 and 23, September 27 and 28, November 18 and 19, 1976; February 23 and 24, May 25 and 26, August 22, 23, and 24, October 25, and December 13, 14, and 15, 1977; February 21, 22, and 23, April 19 and 20, and May 22 and 23, 1978.

The minutes of the Panel meetings are on public display in the office of the Hearing Clerk (HFA–305), Food and Drug Administration (address given above).

Seven nonvoting liaison representatives served on the Panel. Jacqueline Pendleton (at the initial meeting), Valerie Howard, (from May 8, 1973 to September 28, 1973), Lynn Berry (from November 3, 1973 to April 27, 1976), Kathleen A. Blackburn (from July 6, 1976 to August 24, 1977), and Emily Londos (from October 25, 1977) were nominated by an ad hoc group of consumer organizations and served as the consumer liaison. Joseph L. Kanig, Ph.D., nominated by the Proprietary Association, and Ben Marr Lanman, M.D., nominated by the Cosmetic, Toiletry, and Fragrance Association, until February 21, 1977, served as the industry liaisons.

The following FDA employees served: C. Carnot Evans, M.D., served as executive secretary; Lee Geismar served as panel administrator; Lee Quon, R.Ph., served as drug information analyst until July 1973, followed by Thomas H. Gingrich, R.Ph., until July 1975, followed by Timothy T. Clark, R.Ph., until July 1976, followed by Victor H. Lindmark, Pharm.D., until February 1978, followed by Thomas J. McGinnis, R.Ph.

The following individuals were given an opportunity to appear before the Panel, either at their own or at the Panel's request, to express their views on the issues before the Panel: Joseph P. Armellino, M.D.; Robert Blank, Ph.D.; Charles Bluestone, M.D.; Stuart Ericksen, Ph.D.; Carol Farhi, Esq.; Alexander A. Fisher, M.D.; Thomas Fitzpatrick, M.D., Ph. D.; J. M. Glassman, M.D.; Peter Hebborn, Ph.D.; George E. Heinze; Kenneth R. Johannes; Albert M. Kligman, M.D.; Howard Maibach, M.D.; Edward Marlowe, Ph.D.; Kenneth L. Milstead; John Parrish, M.D.; Madhue Pathak, M.D.; Leroy H. Possley; Robert Sayre, Ph.D.; Joseph P. Soyka, M.D.; Garrett Swenson, Esq.; Stephen M. Truitt, Esq.; and Frederick Urbach, M.D.

No person who so requested was denied an opportunity to appear before the Panel.

The Panel has thoroughly reviewed the literature and data submissions, has listened to additional testimony from interested persons, and has considered all pertinent data and information submitted through May 23, 1978, in arriving at its conclusions and recommendations.

In accordance with the OTC drug review regulations (21 CFR 330.10), the Panel's findings on external analgesic drug products are set out in three categories:

Category I. Conditions under which OTC external analgesic drug products are generally recognized as safe and effective and are not misbranded.

Category II. Conditions under which OTC external analgesic drug products are not generally recognized as safe and effective or are misbranded.

Category III. Conditions for which the available data are insufficient to permit final classification at this time.

I. Submission of Data and Information

Pursuant to the notice published in the **Federal Register** of December 12, 1972 (37 FR 26456), the following firms made submissions related to the indicated products:

A. Submissions by Firms

Firms and Marketed Products

Abbott Laboratories, North Chicago, IL 60064: Butesin Picrate Ointment with Metaphen, Tronothane Hydrochloride Cream, Tronothane Hydrochloride Jelly.

Arnar-Stone Laboratories, Inc., Mount Prospect, IL 60056: Americaine Aerosol Spray, Americaine Ointment, Americaine Sunbalm, Americaine-12 Aerosol Spray, Americaine-12 Ointment.

B. F. Ascher and Co., Inc., Kansas City, MO 64030: Mobisyl Creme.

Astra Pharmaceutical Products, Inc. Worcester, MA 01606: Xylocaine Ointment.

Beecham Products, (formerly Calgon Consumer Products Co., Inc.), Rahway, NJ 07065: S. T. 37.

Berry and Withington Co., Cambridge, MA 02140: Analgesic Balm.

Block Drug Co., Inc., Jersey City, NJ 07302: Omega Oil.

Bowman Pharmaceuticals, Inc., Canton, OH 44702: Almophen Ointment, Analgex Ointment, Benz-Pic Ointment, Calamine Compound Paste, Caloxal Lotion, Liquid Analgesic Green, Liquid Analgesic White.

Brown Medicine Co., Knoxville, TN 37917: Brown's N&B Liniment.

Carbisulphoil Co., Dallas, TX 75204: Foille Liquid, Foille Ointment.

Ciba-Geigy Corp., Summit, NJ 07901: Nupercainal Cream, Nupercainal Ointment, Nupercainal Spray, Pyribenzamine Cream, Pyribenzamine Ointment, Vioform Hydrocortisone.

Otis Clapp and Sons, Inc., Cambridge, MA 02139: Obtundia Antiseptic Swab Pads, Obtundia Cream, Obtundia Calamine Cream, Obtundia First Aid Spray, Obtundia Surgical Dressing.

Combe, Inc., White Plains, NY 10604: Johnson's Soak 'N Massage, Lanacane Cream, Lanacane Spray.

Denver Chemical Manufacturing Co., Stamford, CT 06904: Antiphlogistine Poultice, Dencorub, Painaway.

The Dow Chemical Co., Zionsville, IN 46077: Dyclone Cream.

Eneglotaria Medicine Co., Inc., Santurce, PR 00907: Balmaflex, Linimento Daire.

Gebauer Chemical Co., Cleveland, OH 44104: Gebauer's Tannic Spray.
Geriatric Pharmaceutical Corp., Floral Park, NY 11001: Ger-O-Foam.
M. S. Glorius, Washington, D.C. 20021: Glorius Pain Relief.
C. F. Kirk Laboratories, Inc., New York, NY 10021: Exocaine Medicated Rub, Exocaine Plus.
Lilly Research Laboratories, Indianapolis, IN 46206: Surfacaine, Surfadil Cream, Surfadil Lotion.
Medical Supply Co., Rockford, IL 61101: MSCo Burn Compound, MSCo Burn Spray, Medicated Ointment, Telephone Ointment.
The Mentholatum Co., Inc., Buffalo, NY 14213: Mentholatum Deep Heating Lotion, Mentholatum Deep Heating Rub.
Meyer Brothers Drug Co., St. Louis, MO 63132: Bet-U-Lol.
Norwich Pharmacal Co., Norwich, NY 13815: Unguentine Aerosol with Benzocaine, Unguentine Ointment, Unguentine Plus, Unguentine Spray.
Noxell Corp., Baltimore, MD 21203: Noxzema Skin Cream.
Parke, Davis & Co., Detroit, MI 48232: Benadryl Cream, Caladryl Cream, Caladryl Lotion.
Pfizer Pharmaceuticals, New York, NY 10017: Ben Gay Greaseless/Stainless Ointment, Ben Gay Lotion, Ben Gay Ointment, Un-Burn.
Plough, Inc., Memphis, TN 38101: Dermasol Cream, Dermasol Foam, Dermasol Lotion, Dermasol Spray, Medicated Skin Cream, Medicated Skin Lotion, Medicated Skin Ointment, Musterole, Musterole Deep Strength Arthritis Pain Relief Rub, Musterole Extra Strength, Solarcaine Aerosol Spray, Solarcaine Cream, Solarcaine Foam, Solarcaine Lotion.
William P. Poythress & Co., Inc., Richmond, VA 23261: Panalgesic.
Quist Chemical Co., Niagara Falls, NY 14304: "A May's-on" Ointment.
Reed and Carnrick, Kenilworth, NJ 07033: Tarcortin.
Resinol Chemical Co., Baltimore, MD 21201: Resinol Medicated Cream, Resinol Medicated Ointment.
Rexall Drug Co., St. Louis, MO 63115: Thru, Intracel.
The R. Schattner Co., Washington, DC 20016: Chloraderm, Oraderm Lip Lotion.
Smith, Kline & French Laboratories, Philadelphia, PA 19101: Quotane Lotion, Quotane Ointment. C. G. Smith Products Co., Blytheville, AR 72315: Bob's Gypsy Rub Liniment #2.
Sperti Drug Products, Inc., Ft. Mitchell, KY 41017: Aspercreme.
E. R. Squibb & Sons, Inc., New Brunswick, NJ 08903: Counterpain Rub.
Sterling Drug, Inc., New York, NY 10016: Campho-Phenique Liquid, Campho-Phenique Powder, Medi-Quick Spray, Pontocaine Cream, Pontocaine Ointment.
Wade Chemical Corp., Shreveport, LA 71103: Jim Wade Deep Treet Liniment.
Warner-Lambert Research Institute, Morris Plains, NJ 07950: Sloan's Balm Analgesic, Sloan's Liniment.
Warren-Teed Pharmaceuticals Inc., Columbus, OH 43215: Myoflex Creme.
Whitehall Laboratories, Inc., New York, NY 10017: Anbesol, HEET, HEET GEL, HEET Spray, Infrarub, Outgro.
Yager Drug Co., Baltimore MD 21201: Yager's Liniment.
W. F. Young, Inc., Springfield, MA 01101: Absorbine Arthritic Pain Lotion, Absorbine Jr.

In addition, the following firms made related submissions:

Dermik Laboratories, Fort Washington, PA 19034: Hydrocortisone.
Monsanto Industrial Chemicals Co., St. Louis, MO 63166: Methyl Salicylate.
National Program for Dermatology, Washington, DC 20006: Hydrocortisone.
Plough, Inc., Memphis, TN 38101: Hydrocortisone Acetate.
E. R. Squibb and Sons, Inc., New Brunswick, NJ 08907: Lanolor, Lanolin with emulsifiers.
The Upjohn Co., Kalamazoo, MI 49001: Hydrocortisone.

Deferred from the Miscellaneous External Drug Products Review Panel:

Miles Laboratories, Inc., Elkhart, IN 46514: Cort-Dome Cream, Cort-Dome Lotion.

B. Labeled Ingredients Contained in Marketed Products Submitted to the Panel

As stated above, the Panel established four major groups, three of which (otics, sunscreens, and skin protectants) have been discussed in previous issues of the **Federal Register.** Since many currently marketed OTC drug products, which the Panel has classified in this document as external analgesics, also have other labeled ingredients which more appropriately may be classified as skin protectants or pharmaceutical necessities depending upon dosage and claims, the Panel has attempted in the following list to identify primarily those labeled ingredients in submitted products which are properly used and labeled as external analgesics. (See part III. paragraph B.1. below—Category I labeling.)

The Panel has identified the following labeled ingredients in marketed products:

Acetone
Acetone sodium bisulfite
Alcohol
Ammonium oleate
Aqua ammonia
Aspirin
Barbadoes tar
Benzalkonium chloride
Benzethonium chloride
Benzocaine
Benzoic acid
Benzyl alcohol
BHA
BHT
Boric acid
Butesin picrate (butamben picrate)
Calcium silicate
Camphor
Camphorated meta-cresol
Camphorated oil
Capsicum
Capsicum oleoresin
Carbolic acid
Carbomer 934
Carboset
Cellulose gum
Cetyl alcohol
Cetyl palmitate
Cetyl stearyl glycol
Chloral hydrate
Chlorbutanol
Chlorobutanol
Chloroform
Chlorothymol
Chloroxylenol
Citric acid
Clove oil
Coal tar extract
Color
Corn oil
Cyclomethycaine sulfate
Dibucaine
Diglycol stearate
Dimethisoquin hydrochloride
Dimethyl polysiloxane
Diphenhydramine hydrochloride
Dyclonine hydrochloride
Epsom salts
Essential oils and tinctures
Ethyl alcohol
Eucalyptol
Eucalyptus oil
Eugenol
Fragrances
Glycerin
Glycerine
Glycol monosalicylate
Glyceryl monostearate
Glyceryl stearate
Hexylresorcinol
Histamine dihydrochloride
Hydrocortisone
Hydrocortisone acetate
8-Hydroxyquinoline
Ichthammol
Iodine
Iodochlorhydroxyquin
Isopropyl alcohol
Isopropyl myristate
Isopropyl palmitate
Lanolin
Lanolin alcohol
Lanolin anhydrous
Lanolin derivatives
Lanolin oil
Lidocaine
Lidocaine hydrochloride
Lime water
Menthol
Merthiolate
Metaphen
Methapyrilene hydrochloride
Methylcellulose
Methyl nicotinate
Methylparaben
Methyl salicylate
Microcrystalline wax
Mineral oil
Mustard
Oil eucalyptus
Oil of cade
Oil of camphor
Oil of camphor sassafrassy
Oil of cloves

Oil of eucalyptus
Oil of lemon
Oil of peppermint
Oil of pine
Oil of turpentine
Oil of white camphor
Oil of wintergreen
Oil of pine tar
Oil turpentine
Oleoresin capsicum
Oleoresin of capsicum
Oleostearin
Oleth-3-phosphate
Oxyquinoline base
Oxyquinoline sulphate
Parabens
Parachlorometaxylenol
Paraffin
Parahydrecin™ (Norwich brand of anhydropara hydroxy mercuri meta cresol)
PEG 2 stearate
Phenol
Phenylmercuric acetate
Phenylmercuric nitrate
Picric acid
Poloxalkol
Polyoxyethylene sorbitan monostearate
Polyoxyl-40-stearate
Polysorbate 20
Pontocaine base (tetracaine)
Pontocaine hydrochloride (tetracaine hydrochloride)
Potassium oleate
Potassium stearate
Pramoxine hydrochloride
Propellant 46 (80 percent isobutane and 20 percent propane)
Propellant 13/114 (dichlorodifluoromethane/dichlorotetrafluoroethane)
Propylene glycol
Propylene glycol stearate
Propylparaben
Purified water
Quaternium 15
Resorcinol
Salicylamide
Salicylic acid
Sesame oil
Silica
Sodium bisulfite
Sodium borate
Sodium carbomer
Sodium citrate
Sodium lauryl sulfate
Sodium phenolate (phenolate sodium)
Sorbitan monostearate
Sorbitan oleate
Stearic acid
Stearyl alcohol
Synthetic methyl salicylate
Synthetic spermaceti
Talcum power
Thimerosal
Thyme oil
Thymol
4,2',4'-Trichloro-2-hydroxydiphenylether
Triclosan
Triethanolamine
Triethanolamine salicylate
Triethanolamine stearate
Tripelennamine hydrochloride
Tronothane hydrochloride (pramoxine hydrochloride)
Turpentine
Turpentine oil
Volatile oil of mustard
Volatile oils
Water
Wax
White wax
Wormwood oil
Zinc oxide
Zirconium oxide (as the carbonate)

C. Classification of Ingredients

1. *Active ingredients.*

Allyl isothiocyanate (mustard, volatile oil of mustard)
Ammonium water, stronger (aqua ammonia, ammonium oleate)
Aspirin
Benzethonium chloride
Benzocaine
Benzyl alcohol
Butamben picrate (butesin picrate)
Camphor (camphorated oil, oil of camphor, oil of white camphor)
Camphorated metacresol (camphorated metacresol)
Capsicum preparations: Capsaicin, Capsicum, and Capsicum oleoresin (oleoresin capsicum, oleoresin of capsicum)
Chloral hydrate
Chlorobutanol (chlorbutanol)
Cyclomethycaine sulfate
Dibucaine
Dibucaine hydrochloride
Dimethisoquin hydrochloride
Diphenhydramine hydrochloride
Dyclonine hydrochloride
Eucalyptus oil (oil eucalyptus, oil of eucalyptus, eucalyptol)
Eugenol (clove oil, oil of cloves)
Glycol salicylate (glycol monosalicylate)
Hexylresorcinol
Histamine dihydrochloride
Hydrocortisone preparations: Hydrocortisone, and Hydrocortisone acetate
Juniper tar (oil of cade)
Lidocaine
Lidocaine hydrochloride
Menthol
Methapyrilene hydrochloride
Methyl nicotinate
Methylsalicylate (oil of wintergreen, synthetic methyl salicylate)
Phenol (carbolic acid)
Phenolate sodium (sodium phenolate)
Pramoxine hydrochloride (tronothane hydrochloride)
Resorcinol
Salicylamide
Tetracaine (pontocaine base)
Tetracaine hydrochloride (pontocaine hydrochloride)
Thymol
Triethanolamine salicylate
Tripelennamine hydrochloride
Turpentine oil (oil of turpentine, oil turpentine, turpentine)

2. *Inactive ingredients.* The Panel has classified the following as inactive ingredients or pharmaceutical necessities. The list is not intended to be exhaustive. In some cases, when used in concentrations at the level of or above the minimum effective dose, the ingredient(s) are also classified as active and included above in No. 1.

Acetone
Acetone sodium bisulfite
Alcohol
Aluminum acetate
Ammonium oleate (with less than 0.5 percent free ammonia)
Barbadoes tar
Benzalkonium chloride
BHA
BHT
Boric acid
Butyl stearate
Calcium silicate
Carbomer 934
Carboset
Cellulose gum
Cetyl alcohol
Cetyl palmitate
Cetyl stearyl glycol
Chlorothymol
Chloroxylenol
Citric acid
Color
Corn oil
Diglycol stearate
Dimethyl polysiloxane
Epsom salts (magnesium sulfate)
Essential oils and tinctures
Ethyl alcohol
Eucalyptus oil
Fragrances
Glycerin (glycerine)
Glyceryl monostearate
Glyceryl stearate
Isopropyl alcohol
Isopropyl myristate
Isopropyl palmitate
Lanolin
Lanolin alcohol
Lanolin anhydrous
Lanolin derivatives
Lanolin oil
Lime water
Menthol
Merthiolate (thimerosal)
Methylcellulose
Methylparaben
Methyl salicylate
Microcrystalline wax
Mineral oil
Nitromersol chloride (Metaphen)
Oil of lemon
Oil of peppermint
Oil of pine tar
Oleostearin
Oleth-3-phosphate
Parabens
Paraffin
Parahydrecin ™ (Norwich brand of anhydropara hydroxy mercuri meta cresol)
PEG 2 stearate
Phenol (carbolic acid)
Phenylmercuric acetate
Phenylmercuric nitrate
Picric acid
Pine oil
Poloxalkol
Polyoxyethylene sorbitan monolaurate
Polyoxyethylene sorbitan monostearate
Polyoxyl-40-stearate
Polysorbate 20
Potassium oleate
Potassium stearate
Propellant 46 (80 percent isobutane and 20 percent propane)
Propellant 12/114 (dichlorodifluoromethane/dichlorotetrafluoroethane)

Propylene glycol
Propylene glycol stearate
Propylparaben
Purified water
Quaternium 15
Salicylic acid
Sesame oil
Silica
Sodium bisulfite
Sodium borate
Sodium carbomer
Sodium citrate
Sodium lauryl sulfate
Sorbitan monostearate
Sorbitan oleate
Stearic acid
Stearyl alcohol
Synthetic spermaceti
Talcum powder
Thimerosal
Thyme oil
Triclosan (2,4,4'-trichloro-2'-hydroxydiphenyl ether)
Triethanolamine
Triethanolamine stearate
Volatile oils
Water
Wax
White wax
Wormwood oil
Zinc oxide
Zirconium oxide (as the carbonate)

3. *Ingredients deferred to other OTC advisory review panels or other experts.*

Benzethonium chloride
Benzoic acid
Chloroxylenol (parachlorometaxylenol)
Coal tar extract
8–Hydroxyquinoline
Ichthammol
Iodine
Iodochlorhydroxyquin
Magnesium sulfate (epsom salt)
Oxyquinoline base
Oxyquinoline sulfate (oxyquinoline sulphate)
Zirconium oxide (as the carbonate)

4. *Labeled ingredients no longer marketed.*

Chloroform
Oil of camphor sassafrass

D. Referenced OTC Volume Submissions

All OTC Volumes cited throughout this document refer to the submissions made by interested persons pursuant to the call for data notice published in the **Federal Register** of December 12, 1972 (37 FR 26456). The volumes will be put on public display after January 3, 1980, in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

II. General Statements and Recommendations

A. Introduction

The Panel was responsible for evaluating the safety and efficacy of individual active ingredients and combinations of active ingredients which are applied to the skin to relieve the symptoms of pain, itching, or irritation, and which as a group are designated "external analgesics." The Panel identified symptoms, in and under the skin, due to trauma, irritating chemicals, allergic reactions, toxins, physical agents such as infrared or ultraviolet radiation, or systemic disease.

External analgesics, like all other OTC medications, are intended to provide relief for symptoms that are self-limiting. They are not designed to be curative agents.

The Panel recognizes two distinct pharmacologic subgroups of active ingredients within the external analgesic group: ingredients that depress cutaneous sensory receptors and those that stimulate cutaneous sensory receptors. Because this subgroup classification is used throughout the document, it is important to state this distinction as early as possible. The pharmacologic subgroups are discussed at length in the section on pharmacological classification. (See part II. paragraph F. below—Pharmacology of External Analgesic Active Ingredients.)

External analgesic active ingredients which depress cutaneous sensory receptors for pain, itching, and burning act directly to diminish or obliterate these symptoms due to burns, cuts, abrasions, insect bites, and other cutaneous lesions. These ingredients may be further classified into three pharmacologic groups, i.e., topical analgesics, topical anesthetics, and topical antipruritics.

The other group of external analgesic active ingredients stimulates cutaneous sensory receptors to induce sensations such as burning, warmth, coolness, etc. These induced sensations serve as a distraction from the deep-seated pain in areas such as muscles, joints, and tendons which are distant from the skin surface where the ingredient is applied. In this manner, deep-seated pain is indirectly relieved. The ingredients which stimulate cutaneous sensory receptors can be further classified pharmacologically as topical counterirritants.

Some active ingredients, e.g., camphor, menthol, can depress cutaneous sensory receptors at low concentrations and stimulate cutaneous sensory receptors at high ones. These actions are discussed in individual ingredient statements specifying the dosages at which each action occurs. The Panel recognizes that two separate descriptions of an ingredient with a dual action, once as an ingredient which depresses cutaneous sensory receptors and elsewhere as an ingredient which stimulates cutaneous sensory receptors, would be confusing. Therefore, such ingredients are described under one ingredient statement.

The Panel has grouped all external analgesic ingredients together into this document, whether they depress or stimulate cutaneous sensory receptors, because all of these ingredients are applied to the skin to relieve painful sensations of one type or another.

Many products reviewed by the Panel were combinations of ingredients. They had labeling claims associated with the combination, not for each specific ingredient in the combination. Where this was the case, the Panel made a judgment and linked a specific claim with a specific ingredient.

B. Definitions

The following are definitions of terms used in this document:

1. *Addition.* The combined effect of two or more similarly acting therapeutic agents binding at the same receptor site. This is in contrast to "summation," which applies to agents binding at separate receptor sites. The effect of addition is greater than each would produce alone in the particular concentration used, e.g., benzocaine combined with tetracaine.

2. *Base (organic).* An organic base is a nitrogenous compound which is alkaline in an aqueous medium and is capable of forming salts with acids.

3. *Bioactive.* The moiety of a bioavailable substance or an active metabolite that exerts the intended therapeutic effect on a receptor site.

4. *Bioavailability.* The rate and extent to which the active drug ingredient or therapeutic moiety is absorbed from a drug product and becomes available at the site of drug action.

5. *Burns.* The Panel recognizes the following types of burns:

a. *Thermal burns.* Injuries to the skin resulting from exposure to heat or infrared radiant energy.

b. *Sunburn.* An injury to the skin resulting from exposure to ultraviolet (UV) radiant energy.

c. *Chemical burns.* An injury to the skin resulting from exposure to certain chemicals.

6. *External analgesic.* A topically applied substance that may have a topical analgesic, anesthetic, antipruritic, or counterirritant effect as defined below.

7. *Haptene.* An incomplete antigen incapable of causing the production of antibodies but capable of neutralizing specific antibodies in vitro.

8. *Hydrophilic.* A substance with an affinity for water.

9. *In vitro.* A laboratory study on the physical, chemical, or therapeutic properties of an agent. Such a study is not performed on living animals or man. An in vitro study may be done in laboratory equipment with material obtained from a human or animal body.

10. *In vivo.* A study performed on living animals or man.

11. *Lipophilic.* A substance with an affinity for lipids.

12. *Organoleptic.* A property of a substance which makes an impression upon one or more of the organs of special sense, thereby affecting the flavor, odor, or appearance of a drug product.

13. *Partition.* The distribution of a therapeutic agent between two contiguous phases, i.e., a lipid phase and an aqueous phase, or between cells of a cutaneous surface and a medium in which a therapeutic agent is dissolved or dispersed.

14. *Partition coefficient.* The concentration ratio of distribution of any substance between two immiscible liquids. For example, if 26 grams (g) of a drug are dissolved in a unit volume of water and the solution is then shaken with an equal volume of olive oil, and 25 g of this drug pass into the oil phase and 1 g of the drug remains in the water phase, the partition coefficient for oil to water is 25.

15. *Skin conditions*—a. *Intact skin.* This term refers to a cutaneous surface in which the stratum corneum has not been disrupted and has not lost its integrity or continuity.

b. *Damaged skin.* A surface in which the stratum corneum barrier is disrupted.

(1) *Injured intact skin.* Skin or other cutaneous surfaces in which the stratum corneum remains intact but edema, inflammation, or other pathologic processes are present in the lower layers as a result of injury from physical or chemical agents and disease.

(2) *Abraded skin.* A cutaneous surface in which stratum corneum has lost its continuity as a result of trauma and permits access of drugs and other substances to the cells beneath.

(3) *Excoriated skin.* A cutaneous surface that has been disrupted by the trauma of scratching.

16. *Summation.* An effect of the combination of two or more similarly acting therapeutic agents binding at separate receptor sites. The effect results in a response that is greater than each agent produces alone in the particular concentration used, e.g., an antihistamine combined with a topical anesthetic.

17. *Topical analgesic.* An externally applied substance that relieves pain without necessarily abolishing other sensations, or one that causes partial blockade of subcutaneous terminal nerve endings so that a minimal stimulus evokes no painful response, but a greater stimulus does.

18. *Topical anesthetic.* An externally applied substance that completely blocks pain receptors, resulting in a sensation of numbness and abolition of responses to painful stimuli.

19. *Topical antipruritic.* An externally applied substance that relieves itching.

20. *Topical counterirritant.* An externally applied substance that causes irritation or mild inflammation of the skin for the purpose of relieving pain in muscles, joints, or viscera distal to the site of application.

C. The Skin and Skin Penetration

1. *General discussion.* The skin is an organ that protects man from his environment. Both the skin and its underlying structures often undergo pathologic changes that are annoying, uncomfortable, or even incapacitating. These pathologic changes may be manifestations of some systemic disease or local microbial infection in the skin, or they may be induced by trauma, physical agents, and exogenous or endogenous chemical agents. Some of these pathologic processes are self-limiting and disappear or heal spontaneously. Before they heal they are accompanied by annoying symptoms such as pain, burning, or itching. These symptoms are amenable to self-treatment. Other skin conditions, more serious and progressive in nature, are not amenable to self-treatment and should be treated by a physician (Ref. 1).

Since antiquity man has applied to or rubbed into his skin a variety of drugs to relieve symptoms of pain, burning, and itching. Today a considerable number of OTC preparations, which are promoted as providing relief from these symptoms, are available to the American public. To evaluate the safety and efficacy of such preparations, it is necessary to be familiar with certain aspects of the skin's anatomy and physiology and to have some understanding of the mode of action of these drugs and how they penetrate the epithelial and sub-epithelial barriers.

The Panel relied upon standard references and texts and on its own expertise for information on the anatomy and physiology of the skin (Refs. 1 and 2). The conclusions below were drawn from the information at hand.

Adult human skin refers to the skin of humans older than 6 months of age. Although it is possible that penetration of drugs through geriatric skin differs from drug penetration through skin of younger adults and may warrant special consideration, the Panel obtained no information which allowed it to come to a conclusion on this issue.

Skin of those under the age of 6 months may also have different absorptive characteristics. The Panel was concerned with possible differences in percutaneous absorption between infant skin and adult skin. Maibach, a recognized authority, addressed the Panel on the subject.

Maibach (Ref. 3), citing the results of several studies, stated that, depending on the compound being tested, infant skin is relatively similar to adult skin with respect to percutaneous absorption. He noted, however, that the skin of premature infants had a greater degree of drug absorption than either skin of term infants or the skin of adults. Propylene glycol, in an in vitro experiment, was applied to cadaverous skin from infants, premature infants, and adults. The drug penetration of the infant skin and the adult skin was similar, but the penetration through the premature infant skin was tenfold greater than through term infant skin.

A correlation was also made by Maibach between hexachlorophene myelinopathy and premature infant deaths. He described a study in which it was found that there were more deaths attributable to hexachlorophene in the premature infant than in the term infant.

In another study on percutaneous absorption in the newborn, a vasoconstrictor was applied to infant skin and the degree of blanching was observed. There was a definite correlation between the degree of blanching and the gestational age. The premature infant skin permitted greater penetration of the vasoconstrictor than the term infant skin.

To provide an added margin of safety, the ingredients reviewed below are not to be used for children under the age of 2 years except on the advice of a physician. Although the Panel has defined adult skin as skin that is older then 6 months of age, the added margin of safety between 6 months and 2 years of age, is considered important because of the sensitive nature of the problems of medicating infants.

By the age of 2, a child is walking, verbally communicating, and better able to express his or her symptoms and feelings to a parent who would apply a topical medicament. The infant under 2 years of age is more passive and less able to express and localize symptoms.

The effects of occlusion from a diaper, lying on a waterproof mattress, wet clothing, or from body folds touching each other can cause disease and enhance cutaneous penetration of medicaments. Occlusion of adult skin by impervious materials or wet cloth has been demonstrated to cause prickly heat (miliaria) within 48 hours, enable fungi to attack the skin within 72 hours, and permit a 100-fold rise in cutaneous bacteria in 6 hours. The penetration of hydrocortisone is enhanced 10- to 100-fold by occlusion. The Panel is concerned about the effects of a high local concentration of a drug on the integument itself under the occlusive conditions which exist in infants. Ingredients under occlusion may possibly be corrosive to the infant's skin. Biologic systems which metabolize and excrete drugs absorbed through the skin may not be fully developed in children less than 2 years of age.

The Panel concludes that its subsequent considerations of safety and efficacy of OTC drug products are suitable for humans 2 years old and older. Children under 2 should receive these drugs only under the advice and supervision of a physician.

While obvious differences are known to exist between male and female skin, the Panel believes that these differences are not likely to affect the safety or efficacy of the various drugs considered.

2. *Skin penetration.* Three important factors which affect penetration of the skin by drugs are physiological factors, physicochemical factors, and pathological factors.

a. *Physiological factors.* Among the physiological factors affecting the penetration of drugs through the intact skin are the arrangement of the layers of cells in the cutaneous barriers, differences in arrangement of the layers and the types of cells comprising them; differences in thickness or arrangement at various anatomic sites of the body; electrical charges present in the proteins and ions in various layers of the epithelial barriers; the water content of the skin; and the blood flow in a particular area of skin (Refs. 1 and 2). There are three possible portals of entry through the human skin—the epidermal barrier, the hair follicles, and the sweat glands.

For practical purposes, all absorption occurs through the epidermal barrier and hair follicles. The epidermal barrier consists of the stratum corneum which is a keratophospholipid complex that can be as much as 1,500 microns in thickness.

The penetration of drugs occurs more readily through damaged skin because the horny layers of the skin have been disrupted, and the drug readily passes through the undermost layers of the stratum corneum into the dermis. Stripping the epidermis by the application of adhesive tapes, vigorous scrubbing, or brushing alters the barrier and allows drugs that ordinarily do not penetrate to pass into the skin and produce analgesia (Refs. 4 and 5). Active ingredients thus come into direct contact with the receptors for various sensations but particularly those forming the network of nerve endings that sense pain, burning, and itch. Abraded, excoriated, or burned skin permits ready access to these nerve endings and the analgesic effect may be more intense than it is when only superficial layers of the epidermis are removed. In some cases, particularly when the skin is abraded or cut, and the receptors are exposed completely, total blockade results and the subject may experience the sensation of numbness or anesthesia. Other receptors, such as those that carry sensations of touch, pressure, cold, or warmth, may also be blocked. This may not be the case on intact skin (Refs. 4 and 6).

Studies in cadaver skin suggest that absorption is directly related to skin thickness, and that it is greater in areas where large hair follicles are present.

Absorption of medications applied to areas in close apposition to other skin areas, such as the axilla (arm pit) and the groin (crotch), may be different. Less may be absorbed and the remainder may be more irritating than in other locations because of the presence of moisture and constant friction. Specialized glands found in the ear canal produce a waxy, protective secretion that may limit the contact of medication to the skin surface. Mucous membranes in close apposition to the skin, such as in the mouth, the inner aspects of the labia, and the borders of the eyelids absorb medications more readily than the adjacent or junctional skin (Refs. 2 and 7).

Human skin appears to be unique and its characteristics regarding drug absorption are not mimicked exactly by any other species.

b. *Physicochemical factors.* (1) Drug absorption is facilitated by hydrating the skin which is capable of absorbing a considerable amount of water. Complete occlusion by physical means can increase absorption of a drug.

(2) The variations in environmental temperature greatly affect absorption.

(3) As a rule, increasing the concentration of ingredients in a preparation leads to increased absorption by the skin. However, in almost every instance, a plateau effect eventually occurs, which may be followed by a reduced rate of absorption at high concentrations due to an effect on the skin itself or to a high concentration of the drug in the skin, which may inhibit further absorption.

(4) The Panel accepts the concept that lipid-soluble substances diffuse through the lipid portion of the skin barrier and water-soluble substances diffuse through the hydrated component of the proteins found within this barrier (Ref. 8). The partition coefficient of the drug and its vehicle in relation to the skin may be rate limiting. Substances soluble in both water and lipids penetrate the skin barrier more readily than those that are predominately hydrophilic or lipophilic (Refs. 1, 7, and 8).

(5) Generally, smaller molecules penetrate more rapidly than larger molecules. Substances up to the size of 1,000 daltons (molecular weight 1,000) are usually absorbed readily while larger ones are absorbed with greater difficulty. Polar groups are readily absorbed. Molecular configuration unquestionably affects absorption. However, the mechanisms involved are not well understood (Ref. 8).

(6) Vehicles are important in determining the absorption characteristics of the drugs and will be considered below. A drug should not bind with any component of its vehicle in such a manner that its partition with respect to the skin barrier favors retention in the vehicle (Refs. 8 and 9).

Although the original charge to the Panel was to review only active ingredients for safety and effectiveness, the Panel believes that the vehicle in which the ingredient or combination of ingredients is incorporated may influence the effectiveness of the ingredient or ingredients involved and must be considered. Known effects of inactive ingredients, therefore, are considered where pertinent in the discussions of the individual ingredient groups to follow.

The Panel stresses that in most cases continued contact of a film of the active ingredient is essential for efficacy. The medium in which an active ingredient is incorporated must provide not only the necessary solubility and stability, but must also maintain contact of the active ingredient with the lesion of the skin. The medium must not retard the passage of the drug into the skin or into lesions, thereby decreasing its bioavailability (Refs. 8, 9, and 10).

A drug's rate of release from its vehicle and consequently its ability to penetrate the skin barrier depend on the rate of diffusion of the drug within the vehicle. The vehicle may also affect the hydration of the stratum corneum. In general, vehicles which increase or

maintain hydration promote drug absorption, although there are exceptions (Refs. 5, 6, and 9).

Some solvents, such as dimethylsulfoxide and demethylformamide, when used as vehicles, may accelerate absorption of substances through the skin barrier. These solvents are still under investigation for possible use in man. Other compounds may decrease penetration.

Surface active agents (surfactants) may alter surface tension and increase absorption of polar compounds by the water within the skin.

Most vehicles consist of emulsions, i.e., suspensions of droplets of one liquid in another in which it is insoluble. Once an emulsion has separated into its components it is difficult to reconstitute. Large dispersed particles in an emulsion can separate and rise to the surface and cause creaming. A creamed emulsion may generally be reemulsified by shaking.

Emulsions may require stabilization which can be accomplished by the use of surfactants or soaps. Some vehicles discussed by this Panel contain anionic surfactants. These may be incompatible with cationic surfactants. Frequently emulsions support growth of molds and preservatives need to be added (Ref. 11).

Semisolid dermatologic vehicles are classified as ointments, pastes, or creams. In addition to emulsions, semisolid vehicles may be oleaginous vehicles consisting of hydrocarbons, fatty acids, or esters of fatty acids. Fatty acids and their esters may become rancid. Pastes or cerates are less fluid and stiffer than ointments. Absorption bases are composed of ingredients that are hydrophilic and absorb water. Newer formulations may incorporate Carbowaxes ™ and glycols of high molecular weight, approximately 1,500 daltons, which are solid and resemble petrolatum in consistency (Refs. 11 and 12).

Vanishing creams consist of oil-in-water emulsions that generally contain large percentages of water (75 percent or greater) plus stearic acid, stearyl alcohol, and a humectant such as propylene glycol. When applied to the skin with moderate friction, the emulsion breaks, the water is lost by evaporation, and the remaining film of stearic acid or stearyl alcohol is invisible. Thus the cream seems to vanish.

Some ingredients may alter the effectiveness of an active ingredient by shifting the pH of the medium in which the active ingredient is incorporated, thereby changing its ionization and lipophilic qualities. An active ingredient that is effective in the form of a free base may be less effective or ineffective as a salt (Ref. 12).

The concentration of ingredients in a film making contact with the skim is an important factor in assuring effectiveness. A partition or division of the ingredient occurs between the medium in which the ingredient is incorporated and the skin. This partition may vary for skin in different areas of the body (Refs. 4 and 11). Some drugs that are obviously effective when used in areas of the body such as mucous membranes may not be effective on the skin because they are formulated in such a manner that insufficient quantities are delivered to the skin. When a medium retains the ingredient and the partition coefficient is high (25 to 1), for example, 25 for the medium and 1 for the skin, the effectiveness may be reduced considerably so that the preparation is not effective. When a poorly water-soluble ingredient, for example 20 percent benzocaine, is dissolved in a medium such as propylene glycol, a bioactive amount is made available to the skin because the propylene glycol acts as a depot to saturate the water in the skin with the drug. A saturated aqueous solution does not ordinarily provide a bioactive amount. If tetracaine base or a base of a similar type of local anesthetic is dissolved in alcohol and applied as a lotion to the skin, the alcohol evaporates and the drug remains on the skin in powder from and is eneffective (Ref. 4). A vehicle that contains the drug and remains on the skin as a film and readily releases the active ingredient is necessary to formulate an effective final product. An ideal dermatological vehicle should be stable, neutral, nongreasy, nondegreasing, nonirritating, nondehydrating, nondrying, washable, odorless, and stainless. It should act efficiently on all kinds of human skin, should hold at least 50 percent water, and should be easily compounded with known chemicals (Refs. 1 and 11).

Vehicles in common use represent a compromise of advantages against disadvantages, many of which have been noted previously. It is difficult to predict with any degree of accuracy the influence of a vehicle fromulation on the percutaneous absorption of an active ingredient without actual testing of the complete drug. Some authorities believe that medicinals are absorbed more readily from animal or vegetable oils than from petrolatum bases.

Vehicles for topical delivery of active ingredients are complex mixtures of substances designed to impart a certain characteristic to the finished product. Although classified as inactive or inert ingredients, many vehicles interact physically and chemically with the outer layer of human skin (the stratum corneum). The substantivity, penetration, and resistance of the active ingredients to sweating, washing, and other factors often depend upon the vehicle.

The Panel strongly recommends that all inactive ingredients, including those in the vehicle, be listed on the labeling, preferably with a statement of quantity. The consumer or his or her physician may find it necessary to know the identity of all the ingredients in a product for a variety of reasons, including possible adverse patient responses (Refs. 1 and 11).

Therapeutic claims cannot be based on pharmacologic characteristics of inactive ingredients or vehicles. Since these substances are intended for topical application where cosmetic ellegance and cosmetic acceptance are considerations for the consumer, a description of the vehicle may be included in the labeling, e.g., nongreasy, nonstaining, oily, greaseless, velvety, emollient, moisturizer, nonsticky.

c. *Pathological factors.* Skin abnormalities may increase or decrease absorption of substances through the skin. Disease conditions, such as psoriasis and lichen simplex chronicus, decrease absorption through the skin because of the formation of thick plaques. Callous formations also interfere with the absorption of drugs through the skin. On the other hand, conditions such as eczema which cause thinning of the skin or oozing enhance the penetration of drugs through the skin.

References

(1) Criep, L. H., "Dermatologic Allergy," W. B. Saunders Co., Philadelphia, pp. 3–20, 1967.

(2) Andrews, G. C., "Diseases of the Skin," 4th Ed., W. B. Saunders Co., New York, pp. 86, 137, 163, 186, 1955.

(3) Summary Minutes of the OTC Panel on Topical Analgesic Drug Products, 27th Meeting, November 18, 1976.

(4) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics Through Epithelial Barriers," *Anesthesia and Analgesia,* 50:834–841, 1971.

(5) Monash, S., "Topical Anesthesia of the Unbroken Skin," *Archives of Dermatology,* 76:752–756, 1957.

(6) Wolff, H. G. and S. Wolf, "Pain," Charles C. Thomas Publishing Co., Springfield, IL, pp. 3–10, 1958.

(7) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics,* 12:913–919, 1971.

(8) Idson, B., "Percutaneous Absorption," *Journal of Pharmaceutical Sciences, 64:901–924, 1975.*

(9) Steiner, M., V. Gstirner, and R. Elsner, "Percutaneous Absorption of Salicylic Acid from Modern Ointment Bases," *Arzneimittel Forschung*, 14:281–286, 1964.

(10) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, pp. 1523–1529, 1975.

(11) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 900–902, 1977.

(12) Davidson, C. and H. G. Mandel, "Non-narcotic Analgesics and Antipyretics: 1. Salicylates," *in* "Drill's Pharmacology in Medicine," Edited by DiPalma, J. R., McGraw-Hill Book Co., New York, p. 383, 1971.

D. Physiology of Pain

Pain is difficult to define. It is a multidimensional experience which involves both a discriminative capacity and an interpretation of a stimulus in terms of present and past experience (Ref. 1).

Receptors are present in the skin for the perception of pain, itching, cold, warmth, touch, and pressure (Ref. 2). The receptors for pain, cold, warmth, touch, and pressure are discussed in this section. A separate section of this document is devoted to the physiology of itching.

Topical analgesics, anesthetics, antipruritics, and counterirritants act at the site of application of a drug after they penetrate the skin and come into contact with receptors. These receptors are connected to terminal fibers of networks of nerves that are present in the various layers of the skin. Each perceives its own type of sensation.

Receptors are classified as follows: 1. *Receptors for pain.* These consist of bare nerve endings that receive the stimuli incited by pain directly and transmit them to larger nerve trunks to the central receptors in the brain. The nerve fibers carrying the sensation are mostly of the small unmyelinated C type (Ref. 1). Some delta A myelinated fibers may also play a role. Although pain fibers are not uniformly distributed over the body surface, they are estimated to average over 4,000 per square inch of skin. The activity of these receptors is obtunded partially or completely by topical analgesics, anesthetics, and antipruritics. They appear to be affected more easily and readily than the receptors for other sensations listed below, probably because they are small and unmyelinated and thereby easily penetrated by drugs (Ref. 2).

2. *Receptors for cold.* The end bulbs of Krause are oval sense organs in the skin that perceive the sensation of cold. These nerve endings may be blocked simultaneously with the pain receptors by analgesics, anesthetics, or antipruritics. Whether or not they are blocked depends upon the concentration that reaches them and the degree of penetration. They may be stimulated by some ingredients, such as menthol or camphor, and produce a sensation of coolness that masks the sensation of pain. Some counterirritants may act by stimulating these receptors.

3. *Receptors for warmth.* The end organs of Ruffini are cylindrical end organs in the skin that perceive the sensation of warmth. They may also be partially or completely blocked simultaneously by the analgesics, anesthetics, or antipruritics, depending upon the concentration and the duration of contact. They may also be stimulated by counterirritants, thereby exerting a topical analgesic effect.

4. *Receptors for pressure.* Pacinian corpuscles are cylindrical end organs in the skin perceiving the sensation of deep pressure. Analgesics and anesthetics in concentrations exceeding those needed to block pain receptors may block these receptors.

5. *Receptors for touch.* Meissner's corpuscles are end organs in the skin perceiving the sensation of touch. They may also be partially or completely blocked by analgesics, anesthetics, or antipruritics (Ref. 2).

While cutaneous pain is easily localized, deep pain arising below the skin is poorly localized, dull in quality, and spreads or radiates in a distinct pattern. The ability to localize pain is not inborn; it is learned. Deep pain is frequently referred, i.e. felt at locations remote from its source (Refs. 3 and 4).

Referred pain syndromes are numerous. Myocardial (heart) pain is referred to the arm or the jaw, diaphramatic pain to the shoulders, hip pain to the knee, etc. Some pain reference patterns are readily explained as overflows to contiguous spinal cord segments, but this is not always the case (Ref. 4).

Pain originating in bones, joints, and tendons ordinarily induces muscle hypertonus (spasm) and associated pain in supportive skeletal muscles. Much of the pain of degenerative joint disease and rheumatoid disease may arise from tight regional musculature rather than from direct impingement upon a sensory nerve. Such induced hypertonus and chronic muscle injury, with pain, is a part of the involuntary defensive mechanism whereby the human organism attempts reflexively to immobilize a painful joint by increasing the tone of the muscle pairs which serve the skeletal area involved (Ref. 5).

Pain threshold varies little among persons, but the psychological response to pain varies greatly among individuals and in the same individual under different circumstances and in different settings. Time, place, situation, social factors, cultural, and family response patterns, and particularly an individual's interpretation of the meaning of the stimulus, determine whether the experience is regarded as painful (Refs. 1, 3, and 4).

Anxiety is an aspect of pain. There is probably no pain which does not have an anxiety component.

The placebo effect is important not only in OTC self-medication but in all aspects of the healing arts. Frank consideration and acceptance of the psychosomatic contribution of specific OTC products is both desirable and appropriate. Response of an individual's pain perception to a placebo effect is independent of the cause or mechanism of the pain, more likely if pain is intense, not peculiar to neurotic individuals, and not predictable (Refs. 1 and 6).

References

(1) Kabler, J. F., "Neural Mechanisms of Pain," Independent Study Program, University of Wisconsin Medical School, pp. 6–14, September 1975.

(2) Best, C. H. and J. H. Taylor, "The Physiological Basis of Medical Practice," 7th Ed., The Williams and Wilkins Co., Baltimore, pp. 1139–1147, 1961.

(3) Kolodny, A. L. and P. McLoughlin, "Comprehensive Approach to the Theory of Pain," Charles C. Thomas Publishing Co., Springfield, IL, pp. 27–33, 1966.

(4) Wolff, H. G. and J. C Hardy, "On the Nature of Pain," *Physiology Review*, 27:167–199, 1947.

(5) Kabler, J. F. "Muscle Pain," Independent Study Program, University of Wisconsin Medical School, pp. 15–28, April 1973.

(6) Beecher, H. K., "Powerful Placebo," *Journal of the American Medical Association*, 159:1602, 1953.

E. Physiology of Itching

Itching is one of the most common and annoying skin symptoms for which users of OTC external analgesics seek relief. How the stimuli are evoked, how the impulses giving rise to the sensation are conducted, and how the sensation is perceived have been the subject of considerable study and speculation. There appears to be almost complete agreement among physiologists that the anatomic pathways subserving pain and itch are identical and that itching results when cutaneous pain fibers are weakly stimulated. In other words, the difference between stimuli causing pain and itch is one of intensity. Those causing itch are subminimal. Subjectively, weak pain is indistinguishable from itching. Objectively, the motor responses to pain differ from those evoked by itching. When pain is felt, there is a tendency to

withdraw from the pain. When itching is felt, there is a desire to scratch.

From the studies of various investigators (Ref. 1), it appears that impulses which subserve the itch sensation are carried by both the small, nonmyelinated Class C fibers and the large and more rapidly conductina myelinated fibers. the sensation of itch has two subjectively distinguishable components, one pricking and the other burning. The pricking sensation is mediated via the myelinated fibers; the burning sensation is mediated by the nonmyelinated fibers. It has been shown that intractable itching can be eliminated by sectioning of the spinothalamic tracts in the cord. The ability to appreciate the itch sensation may depend on some central mechanism for selective interpretation, however, other investigators have suggested that the sensation of itch results from impulses traveling in circuits in the internuncial neurons in the spinal cord, with a subsequent pattern discharge up along the spinothalamic tracts. It has been noted that itching in the skin can be abolished by stimulation of the skin, by pinprick, at a distance of 30 cm or more from the itch stimulus but apparently in the same dermatome. Following the sensations of pinprick, there is a lag of several minutes before the itch is felt again. Moreover, itch cannot be produced in an area of experimentally induced hyperalgesia. Either pain or no sensation is felt (Ref. 1).

Shelley and Arthur (Ref. 2) showed that itching sensation is limited to itch points in the skin. Between these points there are silent areas which do not respond to stimuli that induce itching. It was further shown histologically that itch points are endowed by rich subepidermal aggregates of fine nerve fibers which are absent in the silent areas. Recently, it has also been suggested that the gate theory is involved in the transmission of impulses of the sensation of itch (Ref. 3). In the studies supporting this concept, no intraepidermal nerve filaments and no encapsulated or organized nerve units were observed at the itch sites. Itching can be induced by chemical agents such as cowhage or itch powder. Shelley and Arthur (Ref. 4) showed that the active pruritogenic principle in cowhage was a proteolytic enzyme. They also found that certain plant and animal endopeptidases which were active at pH 7 produced pruritus. As a result of these studies, it was postulated that proteinases are chemomediators of pruritus and these are released in tissues as a result of trauma. The sources of these chemomediators include the epidermal cathepsin, capillary plasmin infiltrates, and fungal proteases. Histamine likewise has been incriminated in causing itching. These findings have been confirmed by others. Monash and Woessner (Ref. 5) treated proteolytic enzymes with heat and reported that heat destroyed proteolytic but not pruritogenic properties. The enzyme concentrations and their materials were considerably higher than those used by Shelley who felt that the pruritus in these studies was probably the result of nonspecific formed protein rather than proteinase action. Although over the years much has been written concerning mechanisms that cause itch, the subject is far from being fully understood (Ref. 3).

Itching may be local in the skin of a particular area of the body or it may be generalized, depending on its etiology, which is multivaried. Localized itching may be due to stimuli arising in a particular area of the skin. Itching may also be generalized due to some systemic cause, such as jaundice, uremia, an allergic state, or other causes. the treatment of localized areas of itching is amenable to topically applied OTC products. Itching due to systemic causes usually requires the attention of a physician and systemic drug treatments.

External analgesics that relieve itch are called antipruritics. Since the sensation of itch is mediated via pain fibers, local anesthetics and analgesics that block conduction along the axonal membranes, such as the nitrogenous drugs of the "caine" type and of the alcohol type, all have antipruritic activity when used in adequate doses in proper formulation. Drugs that decrease inflammation and remove the stimuli that cause pruritus, such as the steroids, are also used to relieve itching. Since itching can be due to chemomediators, certain drugs that act competitively or combine with chemical agents released by trauma and other factors, such as antihistamines, relieve itching.

References

(1) Wolff, H. G. and S. Wolf, "Pain," *in* "American Lecture Series in Physiology," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 42–43, 1958.

(2) Shelley, W. B. and R. P. Arthur, "The Neurohistology and Neurophysiology of the Itch Sensation in Man," *Archives of Dermatology*, 76:296–323, 1957.

(3) Herndon, J. H., "Itching: The Pathophysiology of Pruritus," *International Journal of Dermatology*, 14:465–484, 1975.

(4) Shelley, W. B. and R. P. Arthur, "Studies on Cowhage (Mucuna Pruriens) and Its Pruritogenic Proteinase, Mucunan," *Archives of Dermatology*, 72:399–406, 1955.

(5) Monash, S. and J. M. Woessner, "Pruritus and Proteolytic Enzymes," *Archives of Dermatology*, 78:214–217, 1958.

F. Pharmacology of External Analgesic Active Ingredients

1. *Topical analgesics.* Topical analgesics are externally applied substances that relieve pain without causing numbness. Some are topical anesthetics that in subanesthetic doses partially depress cutaneous pain receptors and thereby produce analgesia. They may act by penetrating the cutaneous barriers and blocking receptors for the perception of pain. Such ingredients penetrate the nerve endings and cause a temporary reversible charge in the nerve membrane, preventing the development of the electrical current at a given point in a nerve fiber that transmits the impulses along a nerve (Ref. 1).

Some ingredients may, in one concentration, stimulate cutaneous sensory receptors and when they act in this manner are referred to as counterirritants. In lower doses, they depress cutaneous pain receptors and exert an analgesic effect. Menthol is an example of such an ingredient. In concentrations exceeding 1.25 percent in certain vehicles, it causes counteriritation and excites cutaneous senory receptors. In concentrations less than 1.0 percent, it depresses cutaneous pain receptors and acts as a topical analgesic in a manner similar to phenol and other alcohols. Certain esters of salicylic acid which are used as counterirritants, such as methyl salicylate, are claimed to be analgesic when applied topically to the skin at less than the counterirritating dose, due to percutaneous absorption and the release of salicylic acid (Refs. 2 and 3). This action is discussed in more detail below.

Some drugs exert analgesic effects by eliminating a painful stimulus. These agents reduce swelling of the tissues or they neutralize noxious chemical substances that are released by trauma, an infection, or another process (Ref. 4). The three groups of drugs thought to act in this manner are salts and esters of salicylic acid and pharmacologically allied compounds; the adrenocorticosteroid hormones; and the antihistamines.

Inflammation is a pathologic process that occurs in the blood vessels and adjacent tissues (Refs. 5 and 6). It is caused by a physical, chemical, or biologic agent, or a combination of one or more of these agents and is a manifestation of an organism's defense reaction. Inflammation is characterized by heat, redness, swelling, and

tenderness of the affected tissues. The amount of blood in the vessels near the inflamed area increases, and a transudation of fluid and white blood cells from the capillaries into the intercellular spaces occurs. This causes swelling which in turn causes stretching of the tissues, or pressure, and excitation of pain and other receptors (Ref. 7).

Certain drugs overcome or reduce these pathologic changes in tissues, thereby removing the stimulus that causes the pain or itching. Salicylates exert their analgesic effects both centrally and peripherally. Some pharmacologically related drugs, such as phenacetin, produce analygesia systemically but lack anti-inflammatory peripheral effects. The peripheral anti-inflammatory effect of the salicylates appears to be exerted upon tissues derived from endoderm and mesoderm and not on those derived from ectoderm (Ref. 10). Since skin is derived from ectoderm, it is reasonable to assume that pain in the skin is not relieved by salicylates. Salicylates may elicit an analgesic anti-inflammatory response by interference with prostaglandin biosynthesis at the cellular level, which may explain their peripheral effect (Refs. 7 and 9). Percutaneous absorption of salicylates has been demonstrated by detecting salicylates in blood and urine. The Panel regards the effects of percutaneously absorbed salicylates as systemic and considers their action to be the same as internal analgesics. The Panel finds no conclusive evidence that they exert any action in the skin (Ref. 9). There is no evidence that salicylates interfere with nerve impluse conduction and block transmission of painful impluses from the pain receptors in the skin. Evidence that salicylates exert anti-inflammatory action on the skin and relieve pain in the skin itself as do the topical anesthetics, antipruritics, and analgesics is lacking (Ref. 9). Thus, claims that salicylates applied to the skin relieve pain, such as that due to subburn and cuts, is without merit. Relief of deep-seated pain is the result of a systemic effect which may follow percutaneous absorption if the interstitial fluid drug concentration obtained is sufficiently high (Ref. 2).

The adrenocortical hormone, cortisone, and synthetic analogues have the capacity to prevent or suppress the development or cause the regression of the local heat, redness, swelling, and tenderness accompanying inflammation (Ref. 5). These drugs belong to a group called adrenocorticosteroids, also called corticosteroids or steroids. They inhibit the development of the early phenomena of inflammatory processes such as the formation of edema, capillary dilatation, the migration of phagocytes into an inflamed area, and possibly inhibit the release of noxious chemical agents or toxins. One theory is that these anti-inflammatory agents in pharmacologic concentrations stabilize the membranes of lysosomes in the cells and prevent the disruption that occurs from influences such as hypoxia, bacterial and chemical toxins, antigen-antibody complexes, and physical agents such as heat and light. Enzymes in the lysosomes such as proteases, peptides, or other chemicals cause inflammation if they leak outside the cells. All that is known for certain about the mode of action of adrenocorticosteroids is that they obviously inhibit the inflammatory responses of mechanical, chemical, or immunological origin (Ref. 11).

Adrenocorticosteroids relieve pain by reducing inflammation and thereby removing the pain stimulus. Steroids have been especially useful in the symptomatic relief of cutaneous lesions of allergic origin. But the use of anti-inflammatory agents, such as steroid hormones or salicylates, is strictly palliative. After their use, the underlying disease process may remain and the symptoms may recur. For this reason the Panel emphasizes that preparations containing steroids for topical use should be used for short-term therapy only, and should not be used if symptoms recur unless so advised by a physician. The development of corticosteroid preparations suitable for topical administration has revolutionized the therapy of more common varieties of skin disease. Steroids have replaced many of the traditional remedies used in the treatment of various eczematous lesions, such as atopic dermatitis, contact dermatitis, etc., and have been of great value in the treatment of such disorders accompanied by pruritus (Ref. 5).

Drugs that act antagonistically to histamines are called antihistamines (Refs. 8, 12, and 13). The antihistamines are nitrogen-containing compounds. They resemble the nitrogen-containing local anesthetics in some respects, depending upon their structural configuration. They possess one or more amine groups, are bases, and form salts with acids. Some are derived from ethylenediamine, such as tripelennamine, and others from ethanolamine, such as diphendydramine. The salts are highly ionized, highly water soluble, and hydrophilic. The bases are poorly ionized, poorly water soluble, lipophilic, and their absorption through the intact skin is similar to the "caine" type of topical anesthetics. The structure of antihistamines, in some respects, resembles the general configuration characteristic of the "caine" drugs. However, there is sufficient modification so that they do not cause systemic effects similar to the "caine" drugs. When they pass into the circulation, the actions of antihistamines overlap the actions of other drugs (anticholinergic, antinauseant, etc.) (Ref. 1).

2. *Topical anesthetics.* Topical anesthetics are externally applied substances that completely block pain receptors, resulting in a sensation of numbness and abolition of responses to painful stimuli (Refs. 14 and 15). These anesthetics may also block receptors of cold, warmth, pressure, and touch, resulting in the subjective sensation of numbness (Ref. 1).

There are two types of topical anesthetics, the nitrogen-containing amino type and the hydroxy or alcohol type (Ref. 16). The nitrogen-containing topical anesthetics consist of diverse chemical types described below. A certain particular chemical configuration appears in the majority of the most potent and serviceable topical anesthetics. This configuration is composed of a hydrocarbon nucleus (benzene ring) and a two-carbon chain bearing the nitrogen atom in the form of a tertiary amine. The hydrocarbon nucleus forms an acid in some compounds; this acid is combined with an alcohol which carries the amino group to form an ester. The ester types of topical anesthetics are the most widely used in OTC products; examples are benzocaine, butamben, and tetracaine.

A second kind used in OTC products, known as the amides, consists of a benzene ring linked to the two-carbon chain by an amide group. The two-carbon chain carries the tertiary amino group. Lidocaine and dibucaine are amides used in OTC preparations (Ref. 16).

The benzene ring, the aromatic portion, is called the lipophilic pole since it is oriented toward fatty materials in cells and toward the nerve membranes which contain large quantities of fatty materials. The water-soluble or hydrophilic amino pole is opposite the aromatic pole, separated by the carbon chain. It becomes oriented into the water phase of a medium or a cell or cell membrane.

The generic names of most topical anesthetics end in the suffix "caine." The "caine" type of compounds are categorized as the water-soluble (tetracaine, lidocaine) and as the relatively insoluble derivatives

(benzocaine, butamben). The so-called insoluble anesthetics are poorly soluble but not totally insoluble, otherwise they would not be effective (Refs. 1 and 16). However, the amount dissolved in water is low. Soluble compounds are readily absorbed from the damaged skin. When applied to large areas, for example 50 percent of the body surface of abraded, excoriated, or otherwise damaged skin, they may be rapidly absorbed in quantities great enough to cause the development of toxic plasma levels that result in life-threatening or even fatal reactions. Toxic reactions are characterized by initial stimulation of the nervous system, manifested by convulsions, followed by depression, paralysis, and cessation of respiration. In addition, these drugs also depress the cardiovascular system, affecting the heart, reducing its output, and relaxing the blood vesseles so that a decrease in blood pressure occurs.

The systemic reactions are referred to as the central nervous system type or the cardiovascular type. Both types may occur simultaneously, but generally the central nervous system type of reaction is the most prominent and occurs first (Ref. 17). When applied to small lesions, the quantities absorbed from the intact or damaged skin are not sufficient to cause reactions. As long as these drugs are in the area of the nerve endings and pass slowly from the tissue fluids into the blood stream, the amount circulating in the blood is insignificant and causes no systemic reaction (Ref. 17). These types of systemic reactions have occurred so rarely following the wide use of these ingredients in OTC products when applied on the skin that the Panel does not consider them to be a serious hazard.

Some nitrogen-containing topical anesthetics have structures that are modifications of the classical type of "caine" drugs with an aromatic nucleus attached to the remainder of the molecule by a ketone, ether, or other type of linkage instead of the ester and amide type (Ref. 16). The names in this group of topical anesthetics usually bear the suffix "ine" instead of "caine." Pramoxine and dyclonine are nitrogen-containing compounds that are examples of non-"caine" type drugs. Their molecules are modified sufficiently so that they are effective topically, but if absorbed do not produce the systemic response of the severity cahracteristic of the "caines." If injected, they are irritating or not effective. They do not cause convulsions, but may cause cardiac depression. These drugs are not as effective as the "caine" type drugs. Some antihistamines have structures that are modifications of the "caine" type of topical anesthetics. They possess, in addition to the antihistamine effect, a topical anesthetic effect (Refs. 1 and 16). Their names also bear the suffix "ine." These are described elsewhere in this document. (See part II. paragraph F.1. above—Topical Analgesics.

The second type of topical anesthetic mentioned above, the alcohol type, is nonnitrogenous. The alcohol type drugs, such as phenol, benzyhl alcohol, etc., do not cause central nervous system or cardivascular effects characteristic of the "caine" type drugs. Systemic effects, if they occur at all, vary with the individual alcohol type drug.

The water-insoluble esters such as benzocaine and butamben are not absorbed in sufficient quantities to produce plasm levels that cause systemic reactions and, therefore, are relatively safe. Convulsions and cardiac depression do not occur from the use of this type of compound. These have been used in oral preparations without any serious toxic effects. They are effective on the mucous membranes as well as on the skin, poor water solubility notwithstanding, because they are soluble in glycols and other similar types of water soluble bases. When solutions prepared with these solvents are applied to a surface, sufficient quantities are delivered to pain receptors to produce analgesia and anesthesia. Benzocaine is one of the safest and most widely used of the OTC topical anesthetics (Refs. 18 and 19).

Salts of bases of topical anesthetics, antihistamines, and alkaloids are usually very water soluble and highly ionized. They are not highly lipophilic and do not readily penetrate lipid barriers of cell membranes. Such salts do not penetrate the intact skin, or, if they penetrate, they do so slowly and in insignificant quantities.When the salt is neutralized with an acid, the free base is released. The free base is poorly soluble in water, but soluble in lipids and readily penetrates the intact skin. These salts are described in the individual ingredient statements. Where claims are made that a preparation of a salt is effective on the intact skin, the Panel recommends testing for effectiveness as described elsewhere in this document. (See part III. paragraph C.5.d. below—Methods of studying salts of bases.)

3. *Topical antipruritics.* Sensations of pain and itch are carried by the same type receptors and nerve filaments; the intesity of the stimulus varies (Ref. 26). (See part II. paragraph E. above—Physiology of Itching.)

Some antihistamines relieve the discomfort of itching due to histamine release in allergic states when applied to the skin, not only by competing with histamine, at the H_1 receptors (one of 2 broad classes of histamine receptors), but also by their topical anesthetic effect. The antihistamines are more effective orally than topically as antipruritics, particularly when itching is generalized. They may be effective in localized areas if the itching is due to histamine release. Since not all itching is due to histamine release, the antihistamines may not always produce the effect claimed in the labeling (Ref. 13). The Panel finds no evidence to support claims that imply that antihistamines stop itching caused by the release of serotonin, various kinins, and other chemical mediators. The antihistamines, formulated as salts, do not readily penetrate the intact skin. The base, however, does penetrate. When the stratum corneum has been disrupted, penetration by the salt readily occurs and the claimed effect is obtained if the discomfort is due to histamine. Thus, the absorption of antihistamines through the skin is similar to the absorption of the "caine" type of drugs and associated compounds.

Other drugs that relieve itching are the steriods and local anesthetics. These have been mentioned above. Evidence that salicylates exert a topical antipruritic effect is lacking.

4. *Topical counterirritants.* Topical counterirritants are included among the external analgesics because they are applied to the intact skin for the relief of pain. They differ from the anesthetics, analgesics, and antipruritic agents, however, in that the pain relief they produce results from stimulation—rather than depression—of cutaneous sensory receptors and occurs in structures of the body other than the skin areas to which they are applied as, for example, in joints, muscles, tendons, and certain viscera (Ref. 21). The use of these products dates from antiquity. Counterirritants act by producing a transient, reversible, and mild inflamation or irritation of the skin (Refs. 21 and 22).

Drugs used to induce counterirritation do not belong to any particular chemcial class as do the topical anesthetics, the antihistamines, and antipruritic agents. The chemical structures are quite diverse. Some are phenolic in nature; others are aromatic oils derived by distillation from various types of wood. Others are obtained from vegetable sources, such as capsicum and mustard. A number may exert a placebo effect through pleasant aromatic odors or a sensation of warmth or coolness which they produce on the skin. Some are not

single entity products but rather mixtures of closely allied compounds or isomers.

Although some neurophysiologists have at times directed their attention to counterirritants, precisely how these drugs act to relieve pain is still far from understood. It is well recognized that pain may be referred to a segment of normal skin subserved by the same spinal nerve that subserves a diseased or injured muscle, bone, joint, or viscus. Presumably, from evidence at hand, counterirritants stimulate the receptors in the skin and produce a milder pain, such as itching or burning, or some other less unpleasant sensation, such as warmth or coolness, which obscures a more severe pain in a structure other than the skin to which they are applied. Thus, counterirritation may be considered to be reverse of referred pain which is felt in an area of the skin when a disease process or injury exists in a structure and the same nerves serve them both (Ref. 21). The practice of voluntarily producing a counter milder pain to relieve a more intense pain is instinctive. Crossland (Ref. 23) introduces the subject of counterirritation as follows: "In order to make intense pain more tolerable the sufferer will bite his lips or clench his fists, digging the nails into the palm of the hand. The voluntary pain this produces reduces the preception of the other."

The gate theory of Melzack and Wall (Ref. 24) has considerable appeal among those interested in studies of pain mechanisms. In brief, this theory holds that exciting certain nerve fibers through sensations of warmth, mild burning, and mildly painful sensations causes a neurophysiological structure in the spinal cord, known as the gate, to close partially so that sensations from other nerve fibers are not transmitted in their entirety. Whether this mechanism is involved in pain relief induced by counterirritants has not been fully established. If the gate is involved, it may not be the only neurophysiological mechanism involved. Other mechanisms that have not been studied may also play a role.

The Panel mentions this concept of the gate mechanism to emphasize the fact that pain relief is accomplished by the substitution of one sensation by another. The phenomenon whereby the threshold of one type of sensory stimulus is modified by the concomitant application of another stimulus is called extinction. Extinction is believed to be a manifestation of the brain's inability to receive and interpret all of the impulses that are transmitted to it coupled with the subject's efforts to concentrate upon the inflow of voluntarily induced pain stimuli or stimuli from application of agents that produce counterirritation. There is no doubt that the action of counterirritants has a psychic component as well as a drug-induced therapeutic component. Whatever relief is obtained from the use of counterirritants is temporary, transient, and symptomatic. The Panel finds no convincing evidence that counterirritants exert any curative effect.

Besides using topical medicaments, counterirritation may be accomplished by physical means, such as using heat lamps and pads, infrared rays, diathermy, microwaves, ultrasound, hot packs, etc. Most medical practitioners use counterirritation as adjuncts to other forms of therapy and rely principally on physcial methods for counterirritation. The number who prescribes drugs for this purpose is very limited indeed. Marketing experience of counterirritants for OTC use is indicative of widespread popularity, but the Panel does not regard this popularity as proof of effectiveness of these products.

Counterirritants exert their effects in various ways. Some counterirritants induce a sensation of warmth. The intensity of the response of the skin depends not only upon the chemical nature of the irritant employed but also upon its concentration, the solvent in which it is dissolved, and the period of contact. At low concentrations, some counterirritants act as rubefacients, i.e., they cause redness but not inflammation of the skin. At higher concentrations, they may induce varying degrees of inflammation and have a vesicant or blistering action. The less the inflammatory response, the safer the drug (Ref. 21). When inflammation is induced, plasma escapes from the capillaries, which in turn causes blisters. Some counterirritants, such as menthol or camphor, at low concentration induce a sensation of coolness rather than warmth and produce analgesics. (See part II. paragraph F.1. Above—Topical analgesics.)

The Panel does not accept claims that counterirritants relieve pain by penetrating the skin and passing into muscles, joints, and other structures.

Some counterirritants with rubefacient activity produce an increase in the temperature and local blood flow at and near the site of application (Ref. 25). Likewise, dillation of the blood vessels at and near the site of application can be demonstrated following topical administration of rubefacients (Ref. 26). Evidence that there is an increase in conduction velocity in peripheral nerves following the percutaneous application of counterirritants to the intact skin may be of considerable significance (Ref. 27) since this observation is consistent with, and lends support to, the gate theory of Melzack and Wall (Ref. 24) mentioned above.

The theoretical mechanisms of pain relief by medication-induced counterirritation are described in numerous authoritative publications (Refs. 23, 26 and 28 through 31).

The types of vehicles used to formulate the finished product containing counterirritants are important.

Percutaneous absorption of counterirritant drugs is generally undersirable. Therefore, the finished product should consist of ingredients and vehicles that keep penetration through the skin at or as near a zero level as possible.

Self-medication with OTC counterirritant preparations may result in harm if directions are not exactly followed. Some individuals overreact to the irritant properties of counterirritants and develop rashes and blisters. The Panel therefore strongly urges that the following warning appear in the labeling of these products: "Discontinue use if condition worsens or if symptoms persist for more than 7 days and consult a physician." The Panel also recommends that the following additional warnings appear on the labeling to alert the consumer to avoid improper use of the OTC counterirritants: "Do not apply to wounds or damaged skin" and "Do not bandage."

5. *Summary.* Most external analgesic ingredients provide temporary symptomatic relief and are not curative. The steroids and possibly the antihistamines may ameliorate the disease process. Relief of symptoms beyond the time the medicament exerts its analgesic, antipruritic, anesthetic, or counteriritant effect sometimes occurs from the use of agents that directly or indirectly decrese or overcome muscle spasm, reduce edema, or alter the degree of blood flow in an affected area of the skin. A sequence sometimes facetiously referred to as the "vicious cycle" may be disrupted by one application of a topical analgesic, anesthetic, or antipruritic agent. Exactly how this comes about is not known. Possibly nociceptors in an injured area that send impulses centrally along special paincarrying fibers, called delta A and C fibers, are blocked when subjected to continuous stimulation by noxious stimuli. The threshold for stimulation is lowered and very light

stimuli induce pain. Such pain may be referred to adjacent spinal segments. Blocking the receptor may cause a restoration to its normal threshold level when the block is terminated. Whatever the mechanism may be, the vicious cycle phenomenon is occasionally observed in the management of pain problems (Ref. 32).

G. Safety of External Analgescis

All analgesic ingredients are capable of producing adverse reactions either topically or systemically. The systemic reactions are described in part II. F. above or in the ingredient statements when a reaction is peculiar to an ingredient. The reactions include side effects due to overdosing, intolerance, and idiosyncracy.

Some ingredients can irritate both intact and damaged skin when applied topically (Refs. 33 and 34). A rash may appear after one or more applications of such an ingredient when no rash existed prior to its use. This type of response occurs when the ingredient has a direct irritating effect on the cells and is termed primary irritant contact dermatitis. No immunological phenomena are involved. This type of response may be detected by using patch and other tests. (See part III. paragraph C, below—Data Required for Evaluation.) Irritation of the skin is deliberately induced by counterirritation with certain select ingredients whose action can be controlled. However, certain patients may overreact and a greater degree of irritation than is ordinarily expected may result after one or two applications.

In addition to irritation, counterirritants may also produce sensitization, in which case immunological phenomena are involved. The manifestations of sensitization may be topical or systemic. Topical sensitization in certain individuals may result from prolonged or repeated contact of an ingredient with the skin (Refs. 8, 33, and 35). Under these circumstances an ingredient may serve as a contact allergen by acting as a haptene and becoming bound to proteins of the skin. Stimulation of the T cell division of the lymphoid system occurs, and lymphoid cells that are sensitive to the contact allergen or the haptene accumulate in the skin. Contact with the ingredient at a later date provokes a cell-mediated sensitivity kind of reaction, termed allergic contact dermatitis. This is characterized by inflammation, pruritus, burning, erythematous macules, papules, exudation, crusting, etc. at the site of application. Immune globulins are not involved in this type of response (Refs. 36 and 37). Topical sensitization may, at times, be difficult to distinguish from direct topical irritation. The resulting contact sensitivity in a particular individual manifests immunological specificity for the particular ingredient (haptene). Patch testing may be used to detect this type of sensitization. (See part III. paragraph C. below—Data Required for Evaluation.) Coombs and Gell (Ref. 36) have classified immune responses into four distinct types. They designate this type of immune response (i.e., topical sensitization) as Type IV (Cytotoxic), in which the allergen or the haptene interacts with the sensitized lymphocytes.

A haptene can be inhaled, injected, or taken orally; it can come in contact with a mucous membrane, or pass through damaged skin and bind with proteins in blood and other tissue fluids to produce a systemic type of sensitization. This type of sensitization is due to immune globulin E (IgE) of the blood protein fraction. Coombs and Gell (Ref. 36) designate this as the Type I response. It occurs in the allergic individual and is associated with a hereditary tendency toward sensitization which is called atopy. Such individuals are sometimes referred to as atopic. Drugs combine with proteins and act as allergens that cause systemic type of sensitization stimulating the production of circulating antibodies (immune bodies).

Antibodies are found in the globulin fraction of blood proteins. Ordinarily immune bodies are protective and neutralize an antigen or a haptene, forming an antibody-antigen complex on contact, and no allergic reactions occur. In susceptible individuals, the antibody-antigen complex acts in an adverse (pathologic) manner and sensitizes certain target cells. IgE antibodies, which are increased in atopic individuals, have a cytophilic affinity for the membranes of mast cells, blood neutrophils, and basophils in susceptible individuals (Ref. 36). These antibody-sensitized cells rupture on subsequent contact with an allergen-haptene (drug) antibody complex and release vasoactive substances that dilate or constrict blood vessels. Other mediators of inflammation are also released. At least one or more exposures and an incubation period of a week are necessary for immune bodies and sensitization to develop.

The B cell division of the lymphoid system is involved in the systemic type of immune response (Ref. 36). The presence of antibodies that sensitize cells is necessary for sensitivity reactions to occur. This type of sensitization may be manifested by anaphylaxis, extrinsic asthma (systemic), rhinitis (systemic), subcutaneous edema, laryngeal and pharyngeal edema (systemic), urticaria, or atopic dermatitis (Ref. 37).

The initiation of antibody formation requires that antigen binds on the surface of a lymphocyte. The binding sites on a lymphocyte are called antigenic receptors. Only select sites on an antigen molecule are involved in binding at the antibody receptor site. These sites on an antigenic molecule are called antigenic determinants and account for a particular antigen having a specificity for a particular antibody.

Only restricted portions of antigenic molecules are involved in actual binding with antibody-combining sites (Refs. 36 and 38). Haptenes are low molecular weight, well-defined chemical substances. They are not immunogenic, but they do react with antihaptene antibodies. Haptenes conjugate with aminoacid or aminoacid complexes on proteins and induce the formation of antihaptene antibodies. The conjugated haptene behaves as a complete antigenic determinant of the protein with which it is conjugated. A protein carrier can therefore have its own set of native antigenic determinants, plus the new determinant of the conjugated haptene. Antigenic determinants have an overall three-dimensional shape. The antigenic determinants and the antibody sites with which they combine possess a structural complement similar to a lock and key arrangement. A haptene can react with an antibody without being bound to a protein if it fits into the receptor. Drugs that are in the same chemical family and are accommodated by the same receptors of an antibody may cross-react. However, even a slight modification of chemical structure between two closely, chemically allied drugs may negate this type of reaction if the haptene does not fit into the antibody receptor. Aminobenzoic acid, for example, is closely allied chemically to its ester, ethyl aminobenzoic acid (benzocaine). Yet it does not necessarily follow that both of these compounds will be accommodated by the same antibody receptor and cross-react even if they bind with the same complex of a protein (Refs. 36 and 38). In some cases the fit of the haptene is poor, resulting in a slight degree of cross-reactivity and a mild allergic response. Once a patient is sensitized to a haptene and carries the antihaptene antibody in the blood and tissues, contact with a haptene causes an adverse response without binding to a protein. The Panel finds that the incidence of cross-reactivity and cross-sensitization of analgesic ingredients is

low and does not consider this to be a problem (Ref. 36).

Human IgE antibodies will also fix to the plasma membranes of mast cells in the skin and cause sensitivity reactions when the appropriate antigen (or haptene) circulates in blood or comes into contact with these cells following percutaneous absorption. The response is cutaneous and can be local or generalized. The systemic type of sensitization differs from the topical, which is due to a contact allergen, causing a cell-mediated type of reaction rather than an adverse response to an antigen-antibody complex acting on sensitized target cells (Ref. 36).

The anaphylactic type of reaction to an analgesic agent is the most serious. This reaction may occur suddenly, with little or no warning, and may be fatal. A trace of the ingredient penetrating the damaged skin of a sensitized person may precipitate the sudden release of mediators, such as massive quantities of histamine, serotonin, slow release substance (SRS–A), or various kinins, etc. These mediators acting on the blood vessels cause them to dilate and may cause syncope, shock, and death in a matter of minutes. Marketing experience of topical analygesic ingredients indicates that the frequency of anaphylaxis from topical application on the skin has been rare.

In the absence of immune bodies, the drug itself may act directly on mast and other cells and cause histamine or other mediator release. This type of reaction is called anaphylactoid and resembles anaphylaxis, but the causative mechanism is different (Ref. 36). Fortunately, this type of reaction also is rare. Testing for sensitivity in this type of patient may be dangerous because the quantity used for testing may be fatal in susceptible individuals. An anaphylactic or anaphylactoid reaction may occur in the first time a drug is applied to the skin. The anaphylactic and anaphylactoid types of reactions may be delayed, but the manifestations, when fully developed, are similar to the instantaneous type.

Other manifestations of systemic sensitization that may occur are relatively benign and disappear with proper treatment or discontinuing use of the drug. Among these manifestations are rhinitis, asthmatic attack, urticaria (hives), and atopic dermatitis. Generally, histamine is the most common offender in causing these responses, but other mediators may also be responsible (Ref. 36).

All drugs can act as haptenes and cause sensitization. Antihistamines, desite their being used systemically for treating allergies, can act as haptenes and be sensitizers when applied topically. The "caine" types of local anesthetics and modifications of the "caine" type cause sensitization to a greater extent than the alcohol type of ingredients, although the alcohols also may produce irritation and sensitization. The salicylic acid derivatives can also act as haptenes and be sensitizers when applied topically.

The Panel believes that the long-term use and wide marketing experience of the majority of the ingredients it reviewed justifies their continued use and that hazards due to sensitization are minimal. However, subjects who are allergic to foods, inhalants, and other substances are high risks and are more apt to become sensitized to drugs (Ref. 34). Also, reactions to topically applied analgesic medications occur with greater frequency than from systemic use of these ingredients. Therefore, the labeling of external analgesic ingredients must indicate prompt discontinuation of a drug when sensitization occurs after one or more applications, or after repeated use, and advise the individual to consult a physician. The Panel recommends the following warning in the labeling: "Discontinue use if condition worsens or if symptoms persist for more than 7 days and consult a physician."

References

(1) Adriani, J. and M. Naraghi, "Pharmacologic Principles of Regional Pain Relief," *Annual Review of Pharmacology and Toxicology*, 17:223–242, 1977.

(2) Beautner, R., B. Calesnick, E. Powell, and L. Bortin, "On the Absorption and Excretion of Methylsalicylate Administered by Inunction," *Journal of Laboratory and Clinical Medicine*, 28:1655–1662, 1943.

(3) Steiner, M., V. Gstirner, and R. Elsner, "Percutaneous Absorption of Salicylic Acid from Modern Ointment Bases," *Arzneimittel Forschung*, 14:281–286, 1964.

(4) Modell, W., H. Schild, and A. Wilson, "Applied Pharmacology," W. B. Saunders Co., Philadelphia, pp. 394–396, 1976.

(5) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 1487–1488, 1975.

(6) "Dorland's Illustrated Medical Dictionary," 25th Ed., W. B. Saunders Co., Philadelphia, pp. 779–780, 1974.

(7) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 92, 161–164, 977–979, 1973.

(8) Modell, W., H. Schild, and A. Wilson, "Applied Pharmacology," W. B. Saunders Co., Philadelphia, pp. 41–44, 145–154, 1976.

(9) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 325–358, 1975.

(10) Lim, R. S., F. Guzman, D. W. Rodgers, K. Goto, C. Braun, G. D. Dickerson, and R. J. Engle, "Site of Action of Narcotic and Non-narcotic Analgesics Determined by Blocking Bradykinin-Evoked Visceral Pain," *Archives Internationales de Pharmacodynamice et de Therapie*, 152:25–58, 1964.

(11) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 29–36, 1973.

(12) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 603–612, 1975.

(13) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 146–149, 1973.

(14) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 263, 1977.

(15) deJong, R. H., "Physiology and Pharmacology of Local Anesthesia," 1st Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 3–7, 1970.

(16) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d. Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(17) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Practitioner*, 25:82–86, 1962.

(18) Adriani, J. and D. Campbell, "Fatalities Following Topical Application of Local Anesthetics to Mucous Membranes," *Journal of the American Medical Association*, 162:527–530, 1956.

(19) Adriani, J. and R. Zepernick, "Clinical Effectiveness of Drugs Used for Topical Anesthesia," *Journal of the American Medical Association*, 188:711–716, 1964.

(20) Wolff, H. G. and S. Wolf, "Pain," Charles C. Thomas Publishing Co., Springfield, IL, pp. 3–10, 1958.

(21) Sollman, T., "A Manual of Pharmacology and Its Applications to Therapeutics and Toxicology," 7th Ed., W. B. Saunders Co., Philadelphia, pp. 118–121, 1948.

(22) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 951–952, 1975.

(23) Crossland, J., "Lewis's Pharmacology," 4th Ed., E. and S. Livingstone, London, pp. 560–563, 1970.

(24) Melzack, R. and P. D. Wall, "Pain Mechanisms: A New Theory," *Science*, 150:971–979, 1965.

(25) Lange, K. and D. Weiner, "The Effect of Certain Hyperkinemics of the Blood Flow Through the Skin," *Journal of Investigative Dermatology*, 12:263–269, 1949.

(26) Fulton, G. P., E. M. Farlier, and A. P. Moreci, "The Mechanism of Action of Rubefacients," *The Journal of Investigative Dermatology*, 33:317–325, 1959.

(27) Post, B. S., S. F. Benton, and J. G. Benton, "The Effect of Percutaneous Medication on Motor Nerve Conduction Velocity," *Archives of Physical Medicine and Rehabilitation*, 45:460–465, 1964.

(28) Krantz, J. C., Jr. and C. J. Carr, "Pharmacological Principles of Medical Practice," 7th Ed., The Williams and Wilkins Co., Baltimore, pp. 765–767, 1968.

(29) Ferguson, F.C., "Drug Therapy," Lea and Febiger, Philadelphia, pp. 312–324, 1962.

(30) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, pp. 719–720, 1975.

(31) Cushny, A. R., "A Textbook of Pharmacology and Therapeutics," 7th Ed., Lea and Febiger, Philadelphia, pp. 197–203, 1918.

(32) Kitihata, L. M., R. G., McAlister, and A. Taub, "Identification of Trigeminal Nociceptors," *International Symposium of Pain, Advances in Neurology*, 4:83–89, 1974.

(33) Criep, L. H., "Dermatologic Allergy," W. B. Saunders Co., Philadelphia, pp. 3–20, 1967.

(34) North American Contact Dermatitis Group, "Epidemiology of Contact Dermatitis in North America 1972," *Archives of Dermatology*, 108:537–540, 1973.

(35) Gordon, B. L., "Essentials of Immunology," 2d Ed., F. A. Davis and Co., Philadelphia, pp. 110–112, 126, 1974.

(36) Coombs, R. R. A. and P. G. H. Gell, "Classification of Allergic Prescriptions Responsible for Clinical Hypersensitivity and Disease," *in* "Clinical Aspects of Immunology," 3d Ed., Blackwell Scientific Publications, London, pp. 761–781, 1975.

(37) Lane, C. G. and R. Luikart, "Dermatitis from Local Anesthetics with a Review of One Hundred and Seven Cases from the Literature," *Journal of the American Medical Association*, 146:717–720, 1951.

(38) Harper, H. A., V. W. Rodwell, and P. A. Mayes, "Review of Physiological Chemistry," 16th Ed., Lange Medical Publications, Los Altos, CA, pp. 602–608, 1977.

H. Effectiveness of External Analgesic Products

1. *Formulation effects.* Reliable objective methods for determining the efficacy of externally applied ingredients are not available. Therefore, the conclusions of the Panel are drawn from data from both controlled and uncontrolled subjective studies. Many of these studies were performed by private agenices and investigators under contract to industry and are unpublished. They were provided in submissions fo FDA by industry. Studies of independent investigators whose reports have been published in the medical literature have also been used to make evaluations. The Panel has also given consideration to reports of long-term, widespread satisfactory clinical use and marketing experience in evaluation of ingredients.

The majority of externally applied preparations submitted to the Panel for review consist of combinations of active ingredients used with pharmaceutical necessities, which are listed as inactive ingredients. The remainder are single entity active ingredients used with pharmaceutical necessities. The Panel recognizes that to be effective, the final product must be formulated properly and conform to accepted pharmaceutical manufacturing standards. Otherwise the active ingredient or ingredients are not bioavailable, or, if they are bioavailable, they are present in less than the effectve minimum dose or not in the forms that exert the intended therapeutic effects.

Important factors which the Panel considered in making its evaluations include the concentration of the active ingredients in the medium in which they are incorporated; viscosity and volatility of the medium; method of maintaining contact of the active ingredient with the skin for the necessary length of time to assure penetration and maximal therapeutic effect; acidity or alkalinity of the medium; and stability of the final product. Another important consideration to which the Panel gave weight was whether the inert ingredients or active ingredients in a preparation interact and nullify the action of the principal active ingredients (Ref. 1). The designation of pharmaceutical necessity as inactive or inert does not necessarily indicate that such an ingredient is chemically or pharmacologically inactive. An ingredient in a formulation containing more than one active ingredient could diminish the efficacy of another ingredient by retarding its absoprtion into the skin or the cutaneous lesion to which it is applied, by altering the alkalinity or acidity of the medium and thereby changing the degree of ionization and its ability to penetrate epithelial barriers, or by binding it in such a manner that it is not released or absorbed (Refs. 1, 2, and 3). On the other hand, when two analgesics, anesthetics, antipruritics, or counterirritants are combined, addition or summation may occur (Ref. 4).

The medium in which an active ingredient is incorporated must provide not only the necessary solubility and stability, but also must maintain contact of the active ingredient with the lesion of the skin. Such a medium must not retard the passage of the drug into the skin or into the lesions, thereby decreasing the bioavailability of the drug (Refs. 1, 2, 5, 6, and 7).

The Panel recognizes that drugs that are effective on the mucous membranes may not be effective on the intact skin. In some cases, concentrations that are safe and effective and recommended for use on the mucous membranes may be inadequate on the intact skin, and the concentration must be increased to be effective (Refs. 1, and 2), but then they may not be safe. However, it is the concensus of the Panel that no safety or efficacy testing is necessay for Category I ingredients or Category I combinations except as required for compliance with current good manufacturing practices.

References

(1) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics Through Epithelial Barriers," *Anesthesia and Analgesia*, 50: 834–841, 1971.

(2) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics*, 12: 913–919, 1971.

(3) Steiner, M., V. Gstirner, and R. Elsner, "Percutaneous Absorption of Salicylic Acid from Modern Ointment Bases," *Arzneimittel Forschung, 14: 281–286, 1964.*

(4) Adriani, J., et al, "The Comparative Potency and Effectiveness of Topical Anesthetics in Man," *Clinical Pharmacology and Therapeutics*, 5:49–62, 1964.

(5) Monash, S., "Topical Anesthesia of the Unbroken Skin," *Archives of Dermatology*, 76:752–756, 1957.

(6) Hardy, J. D., C. B. Potelunas, and M. D. Meixner, "Pain Threshold Measurements on Human Skin Following Application of Topical Analgesics," *Journal of Investigational Dermatology*, 16:369–377, 1951.

(7) OTC Volume 060132.

2. *Techniques of application and their relation to effectiveness.* All of the ingredients reviewed by the Panel are applied to the skin surface to achieve their therapeutic effects. Some ingredients must be applied as a continuous film and must maintain their integrity in order to be effective. Other ingredients must be rubbed gently into the skin without inflicting trauma to facilitate absorption (Ref. 1). Vigorous rubbing or massage is recommended with still other ingredients for effectiveness.

Because the Panel recognizes it is possible that the beneficial effects of some topical medications, particularly when treating musculoskeletal disorders, may be due entirely to the rubbing and massage rather than to the pharmacologic action of the applied preparation, particular attention was given to this technique. Massage causes an increase in flow of blood and lymph in the skin and underlying structures (Refs. 2 and 3).

Massage has been used as a form of therapy for centuries. The concept of rubbing an irritated part is ancient. The term is believed to be Hebrew in origin, being derived from the word "mashesh" in the original text of the Old Testament. The first use of the word in its present connotation appears in a French textbook of medicine published in 1779.

If one examines the older reports of physicians who were strong advocates of massage, one finds little scientific data on massage techniques that prove or disprove their effectiveness. Despite this, the art was and still is widely practiced.

In the 18th century massage therapy fell into disrepute. It was resurrected during the middle and late 19th century by physicians, both in Europe and the United States, who agreed that massage was a useful tool and conducted physiologic and biochemical studies to obtain data that might explain its effectiveness. Investigators examined the effect of massage on absorption of fluid from joints and the abdominal cavity, and measured changes in venous blood flow and skin temperatures induced by massage. They found increases in all these parameters. Some reported that massage had a diuretic effect. In 1890 a study conducted in Italy indicated that massage delayed the onset of fatigue inactively contracting muscles. In addition, histological studies were performed on experimental animals demonstrating that changes were induced in muscle by massage. The healing of fractures in dogs allegedly was influenced in a salutary manner by massage. At the turn of the century, physicians and therapists began to use mechanical devices, such as vibrators, instead of manual techniques to perform massage.

Two divergent schools of thought evolved concerning massage. One was the so-called reflex massage concept, also known as connective tissue massage. This concept was based upon the premise that tenderness was present at the actual site of a disease process, and that rubbing the tender areas utilizing a variety of graded but increasingly complicated techniques of massage produced beneficial effects. The opposing view championed that concept of deep massage, which was based upon the premise that there is no direct relationship between the area of tenderness and the site of actual tissue damage. The tenderness is a referred superficial response mediated by the actual injured part. The injured part may be deep or distal to the site of the actually perceived tenderness.

In present-day therapeutics, massage is used primarily in physical and rehabilitation medicine. Orthopedists also give considerable attention to the technique. The application and rubbing in of medicaments is deemphasized or completely ignored in many descriptions of massage techniques. The consensus is that the massage itself causes the beneficial response. Studies comparing massage with other modalities are virtually nonexistent because it is difficult to prepare protocols for conducting controlled objective clinical studies on the therapeutic effectiveness of massage techniques. Many clinicians have found that massage is therapeutically beneficial in select situations and utilize it extensively.

The Panel has considered the various modes of application of topical products and has used the general term "apply" in the sections on proposed dosage to denote all methods of application that are commensurate with the active ingredients, the dosage form, and the type of vehicle employed, e.g., emulsion, vanishing cream, lotion, aerosol, ointment. Some examples of modifications of "apply" include: "apply freely," "flow on freely," "rub," "rub in well," "rub in gently," "rub on well," "rub in until it vanishes," "massage," "massage in," "spray," or "spray on."

I. Labeling of External Analgesic Products

The Panel concurs with the general labeling requirements adopted by FDA for OTC drug products. The labeling should indicate the concentration, the manner of usage, and the frequency of applications. In addition, the labeling should emphasize the necessary steps that must be taken to insure that the proper amount is present on the affected area to produce the claimed therapeutic effect.

After reviewing the submitted labeling for external analgesic products, the Panel recommends the following additional labeling requirements:

1. *Ingredients.* The Panel concludes that these products should contain only active ingredients plus inactive ingredients that are necessary for product formulation or that provide a distinctive product characteristic which is beneficial to the consumer. The Panel recommends that all such drug products identify in the labeling both active and inactive ingredients. The concentrations of the active ingredients present in the preparation should be listed and the officially recognized established name of the ingredients should be used.

2. *Indications.* The indications for use should be simply and clearly stated. For external analgesic pharmacologic groups, i.e., analgesic, anesthetic, and antipruritic drugs, the Panel concludes that the indication statement should be "for the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bites, and minor skin irritations." For counterirritant drugs the statement should be "for the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains." (See part III. paragraph B.1. below—Category I Labeling.) The Panel used the terms in the above list of indications because it believes these terms would be understood by the general population. These are not necessarily terms which physicians would use in specific diagnoses. These general statements encompass the many slightly different claims, with the same connotation, in the labeling of currently marketed OTC external analgesic preparations.

For hydrocortisone and hydrocortisone acetate, the Panel concludes that the indication statement should be "for the temporary relief of minor skin irritations, itching, and rashes due to eczema, dermatitis, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, and jewelry, and for itchy genital and anal areas."

3. *Warnings.* The Panel recommends that the labeling of OTC products containing the ingredients reviewed in this document includes the following warnings:

a. "For external use only." This warning is reasonable and prudent.

b. "Avoid contact with the eyes." The eye is not protected by an epidermal keratinized layer as is the skin. Ingredients safe on the skin may not be safe in the eye.

c. "If condition worsens, or if symptoms persist for more than 7 days, discontinue use of this product and consult a physician."

d. "Do not use on children under 2 years of age except under the advice and supervision of a physician."

e. For products containing topical counterirritant active ingredients: "Do not apply to wounds or damaged skin," and "Do not bandage."

There may be additional or modified warnings which are specifically considered in the discussions of the individual active ingredients described elsewhere in this document.

4. *Labeling descriptive of product attributes.* The Panel accepts the use of terms describing certain physical and chemical qualities of OTC external analgesic drug products, as long as these terms do not imply that any therapeutic effect occurs. These terms pertain to product attributes or to the pharmaceutical elegance of the formulation. These properties are usually due to specific inactive (in some cases, active) ingredients included in the final product formulation. Such product characteristics appear in the labeling to inform the consumer of them or to make the product appealing to the consumer, but the terms must be carefully chosen so that they do not imply any therapeutic effect.

The use of colors in pharmaceutical preparations has a long history (Ref. 4). The symbolism of color may date back to the days of the Chinese physician-

priests who noted that the color of the tongue as an indicator of disease. The Egyptians associated the vital properties of blood with its red color. Thirteenth century apothecaries used colored medicine bottles as displays. Even today rosy cheeks are associated with health. Such phrases as "creamy white," "golden lotion," "lustrous," and even "colorless" have been used to describe the coloration or lack of coloration of OTC topical drug products. Many standard coloring agents are officially recognized in the compendia, attesting to the acceptability of the practice by the medical and pharmaceutical communities.

The use of medicinal odors has been associated with the practice of medicine and pharmacy since the beginnings of recorded history (Ref. 4). The burning of leaves, sulfur, hair, feathers, and the wearing of odorous amulets were believed to drive out evil spirits which cause disease. The odor of a patient's breath has been and is still used as a diagnostic tool.

Although many chemical and instrumental methods are used to assess and measure odor, the cosmetic and pharmaceutical industries often rely on the personal reactions of human subjects in making such assessments and measurements (Ref. 4). Individuals can be trained to recognize standard reference odors and their intensity. They are then given various test formulations to evaluate and to describe in standard reference terms. Good reproducibility indicates well-trained experts. In this way, medicinal essences are blended like fine perfumes. In describing odors, such words as "aromatic," "etherlike," "camphoraceous," "acrid," and "chocolate-like" have been used by the official compendia. Some pharmaceutical companies use such phrases as "mild lemon-grass fragrance," "pleasantly scented," and "no tell-tale odor" to describe the odor or lack of odor of their particular drug products. The presence of medicinal essences in the official compendia attests to the acceptability of the practice by the medical and pharmaceutical communities.

By far the most abundant and diverse claims, with respect to the sensual attribute of an OTC external analgesic drug product, pertain to the sense of touch. Many times these attributes are associated with the physical characteristics of the vehicle. If a vehicle is soluble in water, phrases such as "greaseless," "water washable," and "not oily or sticky" are used to inform the consumer that the product is not messy. Light creams and lotions that are applied with a minimum of rubbing are ideal for application to skin lesions where inunction would result in further irritation or pain, e.g., sunburns. Phrases such as "vanishing cream base," "spreads on evenly," and "easy to apply" have been used to describe the ease of application of OTC external analgesic drug products.

In addition to the physical properties of the vehicle, there are sensations, resulting from the inclusion of certain ingredients in topical drug formulations, that provide a beneficial effect. The application of certain aromatic substances and volatile bases provide what can best be called a cooling and soothing sensation. Because of a strong psychological and emotional component, these effects are difficult to define and describe. It is the Panel's opinion that by using these sensations to distract from the patient's sensation of pain, the patient's subjective response can be favorably modified.

The Panel concludes that certain labeling claims are reasonable and informative to the consumer when they accurately reflect inherent characteristics of the marketed product. Terms such as "nongreasy," "does not stain," "soothing," "does not burn or stain," "soothing ingredients," "cooling action," "soothing or cooling relief," "penetrating relief," "provides warming relief," "for cool comforting relief," "warm comforting relief," "penetrating cooling action," "warmth that penetrates to soothe," and "soothes itching and burning" are considered acceptable in labeling. However, the Panel emphasizes that these terms should not be identified as indications for use. They are merely factual statements related to product performance. Other terms, such as "warm relief" or "soothing relief," not associated with the indications may also be included on the principal display panel.

5. *Labeling descriptive of product performance.* The Panel finds it unacceptable to use any claims related to product performance unless they can be substantiated by scientific data. Any claims, i.e., "fast," "quick," "long acting," "remarkable," etc. are considered to be misleading and may be confusing to the consumer unless they can be supported by adequate scientific data.

6. *Claims deferred to other Panels.* The following labeling claims have been deferred to other Panels since these claims are not within the scope of this Panel: "discourages infection," "helps prevent infection," "first aid," "kills germs," "chest cold discomfort," and "eases inflammation accompanying ingrown toenail."

References

(1) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 895–896, 1977.

(2) Wale, J. P., "Tidy's Massage and Remedial Exercises in Medical and Surgical Conditions," The Williams and Wilkens Co., Baltimore, pp. 18, 1961.

(3) Licht, S., "Manipulation and Traction," Waverly Press, Baltimore, 1960.

(4) Burlage, H. M., C. O. Lee, and L. W. Rising, "Other Pharamaceutical Adjuncts," *in* "Physical and Technical Pharmacy," McGraw-Hill Book Co., New York, pp. 645–686, 1963.

J. Principles Applicable to Combination Products

The Panel disagreed on principles applicable to combination products. Accordingly, this section consists of a majority report and a minority report. The minority report reflects the opinion of two Panel members.

1. *Majority report on principles applicable to combination products*—a. *General comments.* In reviewing OTC external analgesic drug combinations in the marketplace, the Panel applied the OTC Drug Review regulation (21 CFR 330.10(a)(4)(iv)) which states:

An OTC drug may combine two or more safe and effective active ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

The Panel not only concurs with, but strongly supports this regulation, and believes that each active ingredient in a combination product must contribute to the claimed effect, and that the combination must provide rational concurrent therapy. It is the view of the Panel that it is irrational to use a combination product unless each of its active ingredients contributes to the effective treatment of at least one of the labeled symptoms for which the combination of ingredients is recommended. The specific combination should be at least as safe and effective as therapeutic doses of the individual active ingredients when used alone.

The Panel considered two major groups of combination products, i.e., combinations of ingredients that depress cutaneous sensory receptors (anesthetics, analgesics, and antipruritics), and combinations of

ingredients that stimulate cutaneous sensory receptors (counterirritants).

Below are proposed standards for combinations for all the ingredients reviewed, together with certain elaborations and reasons upon which the proposed standards are based.

OTC products containing safe and effective single active ingredients are preferred to those having multiple active ingredients. Products containing a single active ingredient reduce the possibility for occurrence of toxic, allergic, and idiosyncratic reactions, and possible unrecognized and undesirable drug interactions. It is the consensus of the Panel, therefore, that OTC external analgesic products ideally should contain only one active Category I ingredient of a particular pharmacologic class and such inactive ingredients as are necessary for pharmaceutical formulation.

Despite the idealistic situation stated above, the Panel is strongly convinced that there is a need for combination products. This conclusion is based on the premises that there is a target population for whom combination products are rational therapy, that few ingredients act exactly the same, and that external analgesic combination products have an extensive marketing history.

The Panel is aware of the lack of controlled studies in the area of use of external analgesics. Controlled clinical studies are difficult to perform for symptoms that are frequently fleeting and usually self-limiting, and the Panel is especially aware that it would be almost impossible to interest investigators in such studies. On the basis of its expertise in this area, the Panel concludes that the combinations described below are acceptable.

The Panel concludes that in the groups of combinations described below, a contribution is made by every ingredient and that the attributes added to the combination by the various ingredients enhance the product's effectiveness and convey a noticeable benefit to the consumer.

The Panel considered a highly diversified group of ingredients. Even though many are qualitatively similar in pharmacologic action, they are, in most instances, quantitatively different. The Panel has made four subdivisions of each of the two major groups (stimulate skin receptors (I), depress skin receptors (II)). Their unique characteristics are described.

The breakdown into chemical and pharmacological subclasses allows a selection of ingredients working presumably on different receptor sites to provide a variegated response not possible with a single ingredient. Combining two drugs that act at different receptor sites, as for example a "caine" type drug and an alcohol type of topical anesthetic, may result in summation (of the mixture combination) instead of addition, and the effect might be greater than that produced if each ingredient were used alone. In other words, instead of a $1 + 1 = 2$ effect, a $1 + 1 = 3$ or 4 effect could result.

Combining two topical anesthetics that act by stabilization of the nerve membrane, such as the "caine" type drugs and their pharmacological counterparts (dyclonine, pramoxine, etc.), results in an additive effect. Adriani and Zepernick (Ref. 1) showed that if half of a dose of lidocaine that causes central nervous system excitation manifested by seizures is combined with half of the dose of tetracaine that does the same intravenously, the two act additively and cause seizures. They also showed that when equal volumes of aqueous solutions of lidocaine and tetracaine are combined in concentrations that produce the maximal topical effect on the mucous membranes beyond which no further benefit is gained by increasing the concentration, the duration of action of the combination is that of the longer lasting drug. Combining the two does not further increase the duration of anesthesia.

b. *Groups and subgroups of external analgesics.* The Panel has identified four separate chemical and/or pharmacologic groups of counterirritants which provide four qualitatively different types of irritation. The Panel believes it is rational and appropriate to provide the opportunity to utilize at least two different such effects to operate when greater potency is required. The more potent counterirritants are grouped together (IA). IB is made up of drugs that provide cooling, warmth, and tingling sensations which stimulate the skin and provide organoleptic properties. Two drugs which cause vasodilatation are grouped as IC; and the capsaicin derivatives (ID) provide counterirritation probably close in potency to IA but without rubefacient properties.

The nitrogen-containing local anesthetics (IIA) that block the nerve conduction are chemically similar; they are amines. The "caine" type drugs, also IIA, tend to resemble each other chemically and are generally more effective pharmacologically but also more toxic than those drugs resembling them in structure. The hydroxy compounds (IIB) behave in the same pharmacologic manner as the nitrogen-containing drugs, yet their effectiveness and toxicities are different.

The antihistamines (IIC) not only block one of the mediators of inflammation (histamine) but also are mildly anesthetic. The salicylates (IID), whose action is not known, are grouped together as a natural chemical group.

The Panel recognizes that ingredients within the same pharmacologic group may not necessarily have the same potency or produce the same sensation (i.e., soothing, cooling, or warming effect). Because the sensations and potencies may differ, each ingredient may be characterized by its own effect or clinical impression and thus be placed into certain subgroups, or types, summarized in the following table:

Groups and Subgroups of External Analgesics

Groups and subgroups	Characteristics of subgroups
I. Counterirritants (Stimulate cutaneous sensory receptors).	....
A. Allyl isothiocyanate, Ammonia water, Methyl salicylate, Turpentine oil.	Cause redness, irritation, and are relatively more potent than other commonly used counter-irritants.
B. Camphor, Eucalyptus oil, [1] Menthol.	Produce cooling sensation and have organoleptic properties.
C. Histamine dihydrochloride, Methyl nicotinate.	Vasoactive substances, vasodilators.
D. Capsaicin, Capsicum, Capsicum oleoresin.	Produce irritation without rubefaction, although approximately equal in potency to Group A ingredients.
II. Analgesics, anesthetics, antipruritics (Depress cutaneous sensory receptors).	....
A. Benzocaine, Butamben picrate, Cyclomethycaine sulfate, [1] Dibucaine, Dibucaine hydrochloride, Dimethisoquin hydrochloride Dyclonine hydrochloride, Lidocaine, Lidocaine hydrochloride, Pramoxine hydrochloride, Tetracaine, Tetracaine hydrochloride.	All have similar chemical structure, pharmacologic action, and common precursors.
B. Benzyl alcohol, Camphor, Camphorated metacresol, [1] Chlorobutanol, [1] Eugenol, [1] Hexylresorcinol, [1] Juniper tar, Menthol, Phenol, Resorcinol, Sodium phenoxide, Thymol [1].	Alcohols (hydroxyl-group), and ketones.
C. Diphenhydramine hydrochloride Methapyrilene hydrochloride Tripelennamine hydrochloride.	Antihistamines
D. Aspirin, [1] Glycol salicylate, [1] Salicylamide, [1] Triethanolamine salicylate.	Salicylic acid derivatives

[1] Indicates ingredient is classified in Category III. All other ingredients are classified in Category I.

c. *Permitted combinations of Category I ingredients*—(1) *Permitted combinations of active ingredients that stimulate cutaneous sensory receptors (counterirritants)*—(i) One Category I active ingredient from any subgroup of the active ingredients that stimulate

cutaneous sensory receptors (counterirritants) may combined with one, two, or three other active ingredients that stimulate cutaneous sensory receptors, provided that each active ingredient is from a different subgroup.

(ii) Camphor and menthol together (subgroup B) may be combined with one, two, or three active ingredients, provided that each other active ingredient is from a different subgroup.

(2) *Permitted combinations of active ingredients that depress cutaneous sensory receptors (analgesics, anesthetics, antipruritics)*—(i) One Category I active ingredient from subgroup A may be combined with any one Category I active ingredient from subgroup B.

(ii) One Category I active ingredient from subgroup B may be combined with any one Category I active ingredient from subgroup C.

(iii) Any three Category I active ingredients from subgroup B may be combined, as long as two of the three are camphor and menthol.

(iv) Any one active ingredient from subgroup D that is classified as Category I may be combined with one Category I ingredient from subgroup A or subgroup B.

(3) *Permitted combinations of external analgesic active ingredients with other externally applied ingredients.* One Category I external analgesic active ingredient that depresses cutaneous sensory receptors or a Category I combination of such ingredients may be combined with a Category I skin protectant active ingredient, or with a Category I skin protectant combination, and/or a Category I antimicrobial active ingredient or with a Category I antimicrobial combination.

d. *Standards for Category II combination products*—(1) Combinations containing a Category II external analgesic ingredient are classified as Category II.

(2) Any combination product containing hydrocortisone or hydrocortisone acetate and other active external analgesic ingredients is classified as Category II.

(3) Combinations containing Category I external analgesic active ingredients combined with any active ingredient not reviewed by this or other OTC Advisory Review Panels, or having been reviewed by another OTC Advisory Review Panel and found to be either unsafe or ineffective or considered to be an irrational combination, are classified as Category II.

(4) Combinations containing any external analgesic active ingredient and a sunscreen active ingredient are classified in Category II. Such combinations are considered to be unsafe because the external analgesic active ingredient may mask the symptoms of overexposure to the sun.

(5) Combinations containing Category I external analgesic active ingredients which depress cutaneous sensory receptors (topical analgesics, anesthetics, and antipruritics) combined with any Category I external analgesic which stimulates cutaneous sensory receptors (counterirritant) are classified in Category II. It is irrational to combine such ingredients because they act in opposition to each other.

(6) Combinations containing any Category I counterirritant combined with a skin protectant as an active ingredient are classified in category II. Protectants act in opposition to counterirritant ingredients and may nullify their analgesic effect.

e. *Standards for Category III combination products*—(1) Combinations containing a Category III external analgesic active ingredient are classified in Category III.

(2) Any Category I combination listed above containing external analgesic active ingredients at less than the minimal effective dose is classified in Category III for effectiveness.

(3) Combinations containing a Category I external analgesic from subgroup A of the external analgesics that depress cutaneous sensory receptors and a Category I ingredient from subgroup C of that same group are classified as Category III for effectiveness.

2. *Minority report on principles applicable to combination products*—a. *General comments.* The minority of the Panel disagrees with the standards for combination products containing external analgesic active ingredients recommended by the majority of the Panel. The minority presents its standards for Category I, Category II, and Category III combination products below including general comments on the justification for these standards.

In reviewing OTC external analgesic drug combinations in the marketplace, the Panel bore in mind the OTC Drug Review regulation (21 CFR 330.10(a)(4)(iv)) which states:

An OTC drug may combine two or more safe and effective ingredients and may be generally recognized as safe and effective when each active ingredient makes a contribution to the claimed effect(s); when combining of the active ingredients does not decrease the safety or effectiveness of any of the individual active ingredients; and when the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent therapy for a significant proportion of the target population.

Members of the minority concur with the basic concepts embodied in this regulation, that each active ingredient in a combination product must contribute to the claimed effects and that the combination must provide rational concurrent therapy. They believe that it is irrational to use a combination product unless each active ingredient contributes to the effective treatment of at least one of the labeled symptons for which the combination of ingredients is recommended.

The Panel considered two major groups of combination products, i.e., combinations of ingredients that depress cutaneous sensory receptors (anesthetics, analgesics, and antipruritics), and combinations of ingredients that stimulate cutaneous sensory receptors (counterirritants).

The minority has outlined below the proposed standards for combinations for all the ingredients reviewed. Also included are their elaborations and reasons for disagreeing with the majority on the proposed standards for the combination of analgesics, anesthetics, antipruritics, and counterirritants with each other and with other classes of ingredients.

It is accepted medical practice to use only drugs that are necessary to safely and effectively treat a patient. In most cases, single entity ingredients suffice to treat a particular sympton or disease entity. The minority of the Panel sees no reason why this concept is not equally applicable to self-medication with OTC products. In fact, the consumer is at a disadvantage because he or she is self-treating symptoms with OTC products without a physician's advice.

OTC products containing single safe and effective active ingredients are therefore preferred to those having multiple active ingredients. Products containing a single active ingredient reduce the possibility of the occurrence of toxic, allergic, and idiosyncratic reactions, and possible unrecognized and undesirable drug interactions. This is the case when a drug is prescribed by a physician and should also be the case when a drug is used by a layman for self-treatment. Therefore the Panel minority believes that OTC external analgesic products should contain only one active Category I ingredient of a particular pharmacologic class to treat a particular indication and such inactive ingredients as are necessary for pharmaceutical formulation.

The minority of the Panel is familiar with the concept that is sometimes

proposed, that subtherapeutic doses of active ingredients of the same pharmacologic class may be combined for treating a particular indication provided that the resulting combination is as safe and effective as each individual ingredient would be when used alone in full therapeutic doses. For example, if drug A and drug B, each of which has a similar pharmacologic activity, are combined at half of their usual therapeutic doses, the combination AB must be as safe and effective as drug A or drug B used alone in full therapeutic doses. Neither safety nor effectiveness is compromised by allowing this combination.

This concept appears plausible and has considerable appeal, at least theoretically. The concept may be applicable to some ingredients reviewed by some OTC Panels. However, there is a paucity of data supporting the application of this concept to external analgesics. Actually, there is considerable evidence that the contrary is true. Although the pharmacologic responses of all the topical anesthetics and analgesics reviewed by the Panel are qualitatively similar, each drug is quantitatively different. Whether the hydroxy type of topical analgesics act in consort when combined with the nitrogenous type of anesthetics and to what degree they may do so is not known. Valid data from controlled studies are not available. The pharmacologic activities of anesthetics, such as periods of latency, duration of action, and degree of blockade vary widely since they are dependent on their oil-water partition coefficients, protein-binding power, erythrocyte plasma distribution ratio, surface tension lowering effects, pKa, biologic stability in vivo, and other physical and chemical factors. These factors all vary widely with each ingredient. Reducing the concentration of a topical anesthetic in a solution that is applied to a nerve reduces the amount of the anesthetic that passes into a nerve fiber, prolongs the latent period, and shortens the duration of action. The blockade may only be partial because the fibers in a nerve differ in size. Each fiber is not blocked simultaneously, and some fibers are not blocked at all if the concentration of the anesthetic is below the minimum effective concentration (Cm) for that fiber size.

Longer lasting drugs have longer latent periods than those whose durations of action are short. It is known that if half of a minimum effective dose of a long-lasting topical anesthetic of the "caine" type is combined with half of a minimum effective dose of a short-acting topical anesthetic of the same type, no blockade occurs, or if it occurs, it is incomplete. The minimum effective concentration of each ingredient must be combined to obtain an effective blockade. Thus, combining two "caine" type topical anesthetics at half the therapeutic concentrations does not follow the A+B concept mentioned above. Combining two topical anesthetics at their minimum effective concentrations usually results in a duration of action equal to that of the longer-lasting drug when that drug is used alone. The period of latency will be the same as that of the shorter acting drug if that drug were used alone. Nothing of significance is gained from a therapeutic standpoint by combining the two topical anesthetics. In addition, safety is compromised because the potential for toxicity is increased by combining the two drugs at full therapeutic doses. This is not in conformity with the principles as mandated in OTC Drug Review regulations 21 CFR 330.10(a)(4)(iv).

These facts have been verified by testing these drugs on mucous membranes. However, since topical anesthetics behave similarly at different sites of the body, there is little reason to believe that they do not behave in the same manner on the skin. There is a paucity of data derived from controlled studies concerning periods of latency or duration of action of topical anesthetics on the skin. Such data are not available for single entity ingredients, let alone combinations of two or more ingredients. The minority of the Panel finds no valid reason for combining two effective topical anesthetics or analgesics. Since the actions of topical anesthetic ingredients are diverse, and they differ from each other quantitatively in their responses, single ingredients can be selected to meet the desired therapeutic need, i.e., a short-acting drug may be selected when a short action is desired and a long-acting drug may be selected when long duration is desired.

More strenuous objections can be raised for combining two or more counterirritants (analgesics) than for combining two or more topical anesthetics. Although effectiveness is an important consideration, these objections are based largely on safety considerations. The counterirritants are a heterogenous group of chemicals that are irritating to the skin. They do not fall into well-delineated chemical families, as do the analgesics and anesthetics. Counterirritants act by inducing a temporary reversible inflammatory response on the skin and by inciting sensory cutaneous receptors to exert their claimed effect. The minority of the Panel cannot concur with the statement of the majority that "The Panel has identified four separate chemical and/or pharmacologic groups of counterirritants which provide four qualitatively different types of irritation." No valid data are available to support this concept. Irritation is irritation and the apparent different types assumed to exist by the majority are the result of variations in response of the skin that depend upon such factors as dosage, sensitivity, or responsiveness of the skin of an individual to a drug, duration of contact, and various other factors. The minority, therefore, believes that the majority cannot justify delineating four types of irritation (Ref. 2).

In both its introductory statement and in the ingredient evaluation statements elsewhere in this document, the majority has emphasized that these drugs are hazardous, and unless used cautiously and according to directions, cause damage to the intact skin. It has also emphasized, in its introductory statement on counterirritants, that counterirritant ingredients that are the least readily absorbed from the skin are most desirable for clinical use. (See part II. paragraph F.4. above—Topical counterirritants.) The majority of the Panel has proposed special warnings in the labeling for the use of counterirritants. There are no data from controlled studies indicating that the A+B concept described above can be applied to counterirritants, and there are no data from controlled studies on the additive effects or possible synergistic effects when counterirritants are combined. Such additive effects may enhance toxicity more than efficacy and impair safety. Furthermore, some counterirritant ingredients are not single chemical entities but are unrefined mixtures of organic substances, such as oleoresins, terpins, resins, and other chemicals. Some counterirritants are distillates of wood and other raw materials of botanical origin. Thus, a combination supposedly composed of two or more single entity counterirritant ingredients could consist of many ingredients. The minority of the Panel finds no well-documented scientific justification for combining two or more effective counterirritants. Counterirritant ingredients have received little attention from clinical investigators in recent years. In fact, these ingredients are not mentioned in the majority of present-day textbooks on pharmacology and therapeutics.

The Panel recognizes that many combinations of external analgesics,

particularly the counterirritants, have been on the market for many years. The counterirritants continue to be used by the laity for the symptomatic relief of pain of muscle and joints; however, their use for these conditions has been supplanted mostly by other methods of treatment by the medical profession.

The minority of the Panel feels that neither the OTC drug review regulations nor the historical evidence for the use of these combination products support the concept that the long-time use of an OTC product, with apparent beneficial results based on clinical observations by consumers, or without complaints of adverse reactions, attests to their safety and effectiveness. The minority of the Panel is not impressed by statements appearing in manufacturer submissions, such as "marketing experience has been favorable" or "no complaints have been reported," etc. Although the Panel minority considers marketing experience data and frequency of customer complaints to be of interest, it does not consider such data to be the type of proof that is valid for establishing safety and efficacy in a scientific review of standards of existing OTC products. The paucity or lack of reports of adverse reactions are merely negative findings, and negative findings obtained from marketing data do not constitute a sound basis for establishing a product's safety and efficacy. Furthermore, none of the submissions describe the manner in which the data were collected from the users of these products, the instructions provided to the users to facilitate and assure that all the necessary and meaningful data would be forthcoming in reporting adverse reactions, and the manner in which collection of such data was monitored. None of the submissions describe by whom the data were interpreted, or otherwise explain pertinent, significant details concerning their methods of adverse reaction reporting. The minority of the Panel, therefore, does not concur with the opinion of the majority of the Panel that the use of analgesic combinations is justified because such combinations have an extensive marketing history.

The minority of the Panel recognizes that it may have overlooked or may otherwise be unaware of data concerning combinations of external analgesic ingredients on the marketplace that provide therapeutic advantages not possessed by single entity Category I ingredients. It is not the intent of the Panel minority to deprive the public of the benefits of the use of such combinations if they do, indeed, exist and provide effective rational therapy. The minority of the Panel, therefore, recommends that a combination of two Category I active ingredients with the same pharmacologic activity be allowed if it is known, or has been shown, that the combination is as safe and effective as doses of the individual active ingredients alone and that the combination provides some well defined therapeutic advantage that neither ingredient provides when used alone and not in combination.

The term "therapeutic advantage" does not indicate that the combination is expected to be pharmacologically superior to each ingredient. It does indicate, however, that combining the ingredients provides a therapeutic effect that is beneficial for treating the claimed symptoms not provided for by using the individual ingredients alone. Combinations of ingredients meeting these stipulations should be classified as Category I. If it is not known or it has not been shown that the foregoing stipulations concerning safety, effectiveness, and therapeutic advantage have been met, the minority of the Panel recommends classification of such a combination as Category III. It is the opinion of the minority of the Panel that if no therapeutic advantage is gained by combining two ingredients of the same pharmacologic activity, the possibility of toxic, allergic, and idiosyncratic reactions is increased, as mentioned above, and safety is compromised.

The minority of the Panel is puzzled by the comment of the majority of the Panel when it states that:

> It is the consensus of the Panel, therefore, that OTC external analgesic products ideally should contain only one active Category I ingredient of a particular pharmacologic class and such inactive ingredients as are necessary for pharmaceutical formulation.
>
> Despite the idealistic situation stated above, the Panel is strongly convinced that there is a need for combination products. This conclusion is based on the premises that there is a target population for whom combination products are rational therapy, that few ingredients act exactly the same, and that external analgesic combination products have an extensive marketing history.

The majority of the Panel agrees with the minority that only one Category I active ingredient of a pharmacologic class is necessary; yet the majority of the Panel contradicts this established medical principle by stating that it is strongly convinced that "there is a need for combination products." There is no data from controlled studies to substantiate that there is such a need upon which the Panel can base its conclusions. The minority of the Panel finds no supporting data in the entire OTC review of topical external analgesics that identify the target population mentioned for whom such a need exists.

The majority of the Panel states, "The Panel is aware of the lack of controlled studies in the area of use of external analgesics. Controlled clinical studies are difficult to perform for symptoms that are frequently fleeting and usually self-limiting, and the Panel is especially aware that it would be almost impossible to interest investigators in such studies. On the basis of its expertise in this area, the Panel concludes that the combinations described below are acceptable."

On the one hand, the majority of the Panel admits that there is a lack of meaningful data from controlled studies on the use of external analgesics. On the other hand, the majority of the Panel concludes on the basis of its expertise, but without supporting data, that the combinations it describes in its combination principles are acceptable. The minority of the Panel is unable to reconcile these opposing and contradictory views expressed by the majority of the Panel.

The minority of the Panel agrees with the following conclusions of the Commissioner, published in the **Federal Register** of November 12, 1973 (38 FR 31261), concerning difficulties in performing controlled clinical studies to determine the safety and effectiveness of OTC drug products:

> The Food and Drug Administration recognizes that OTC drug studies are often more difficult to undertake than those involving prescription drugs. OTC drug studies are principally concerned with measuring symptomatic relief, requiring methods that are more subjective than those used to measure the resolution of a disease condition. In all cases, however, such tests are entirely feasible and, indeed, have in many cases been conducted in the past. Nor is difficulty in performing studies sufficient justification for retaining on the market drugs the safety and effectiveness of which are inadequately documented.

The minority of the Panel also disagrees with the assumptions made by the majority in its conclusion that "in the groups of combinations described * * * a contribution is made by every ingredient and that the attributes added to the combination by the various ingredients enhance the product's effectiveness and convey a noticeable benefit to the consumer." The minority cannot support these contentions. There is no scientific data in the literature or in the submissions upon which to base such generalizations regarding either the

contribution made by every ingredient in a combination or the "attributes" added to a combination to enhance a product's effectiveness.

On the basis of its evaluation of the majority's combination principles, the minority of the Panel concludes that two active ingredients with the same pharmacologic activity, i.e., two active ingredients that stimulate cutaneous sensory receptors, e.g., two topical counterirritants, may be combined when the conditions concerning safety, efficacy, and therapeutic advantage are met as discussed above.

b. *Standards for Category I combination products*—(1). Each active ingredient and its labeling in a combination product must be generally recognized as safe and effective (Category I).

(2) One Category I external analgesic active ingredient that depresses cutaneous sensory receptors may be combined with one external nonanalgesic Category I active ingredient, e.g., skin protectant, at a dosage range between its minimum effective dosage and maximum allowable dosage, provided the product is labeled for the concurrent symptoms involved, e.g., "For the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bites, and minor skin irritations," and "for the temporary relief of minor skin irritations and itching."

(3) One Category I external analgesic active ingredient that depresses cutaneous sensory receptors may be combined with one Category I antimicrobial active ingredient or with a Category I antimicrobial combination.

c. *Standards for Category II combination products*—(1) Combination products containing a Category II external analgesic ingredient or Category II labeling are classified as Category II.

(2) Combinations of three or more external analgesic active ingredients are classified as Category II because it is irrational to use more than one safe and effective ingredient to treat one labeled symptom for which the combination is intended.

(3) Any combination product containing hydrocortisone or hydrocortisone acetate and other active external ingredients is classified as Category II. The safety of hydrocortisone combinations for OTC use has not been established. At present, hydrocortisone combinations are available for use by prescription only.

(4) Combination products containing Category I external analgesic active ingredients combined with any active ingredient(s) not reviewed by this or other OTC Advisory Review Panels or found to be either unsafe or irrational are classifed as Category II.

(5) Combination products containing any external analgesic active ingredient and a sunscreen active ingredient are classified as Category II. Such combinations are considered to be unsafe because the external analgesic active ingredient may mask the symptoms of overexposure to the sun.

(6) Combination products containing Category I external analgesic active ingredients which depress cutaneous sensory receptors (topical analgesics, anesthetics, and antipruritics) combined with any Category I external analgesic which stimulates cutaneous sensory receptors (counterirritant) are classified in Category II. It is irrational to combine such ingredients because they act in opposition to each other. Such combinations are not only irrational but may also be unsafe.

(7) Combination products containing any Category I counterirritant combined with a skin protectant are classified as Category II. Protectants act in opposition to counterirritant ingredients and nullify their analgesic effect.

d. *Standards for Category III combination products*—(1) Combination products containing a Category III external analgesic active ingredient and no Category II external analgesic active ingredient or labeling are classified as Category III.

(2) Combination products containing two Category I external analgesic active ingredients are classified as Category III. It will have to be known or have to be shown that each active ingredient makes a contribution to the claimed effect and that the conditions concerning efficacy, therapeutic advantage, and safety described above are met.

References

(1) Adriani, J. and R. G. Zepernick, "Comparative Potency and Duration of Action of Topical Anesthetic Drugs in Man," *Anesthesiology*, 24:120–121, 1963.

(2) Cushny, A. R., "A Textbook of Pharmacology and Therapeutics," 7th Ed., Lea and Febiger, Philadelphia, pp. 197–198, 1918.

II. External Analgesics

A. Summary of the Categorization of Active Ingredients

The Panel has summarized its categorization of active ingredients in the table below.

Active ingredients that have been evaluated and found to be generally recognized as safe and not effective for OTC use are classified in Category I. Active ingredients that have been evaluated and found not to be generally recognized as safe and effective are classified in Category II. Those active ingredients for which the available data are insufficient to permit final classification at this time have been classified in Category III. In addition, the Panel has grouped external analgesic active ingredients by their pharmacologic activity as either depressors of cutaneous sensory receptors (anesthetics, analgesics, and antipruritics) or stimulators of cutaneous sensory receptors (counterirritants).

Categorization of External Analgesic (EA) Active Ingredients

Active ingredient	EA that depress cutaneous sensory receptors	EA that stimulate cutaneous sensory receptors
Allyl isothiocyanate	(1)	I
Ammonia water, stronger	—	I
Aspirin	III [2]	—
Benzocaine	I	—
Benzyl alcohol	I	—
Butamben picrate	I	—
Camphor	I	I
Camphorated metacresol	III	—
Capsaicin	—	I
Capsicum	—	I
Capsicum oleoresin	—	I
Chloral hydrate	II	II
Chlorobutanol	III	—
Cyclomethycaine sulfate	III	—
Dibucaine	I	—
Dibucaine hydrochloride	I	—
Dimethisoquin hydrochloride	I	—
Diphenhydramine hydrochloride	I	—
Dyclonine hydrochloride	I	—
Eucalyputus oil	—	III
Eugenol	III	—
Glycol salicylate	III	—
Hexylresorcinol	III	—
Histamine dihydrochloride	—	I
Hydrocortisone	(3)	—
Hydrocortisone acetate	(3)	—
Juniper tar	I	—
Lidocaine	I	—
Lidocaine hydrochloride	I	—
Menthol	I	I
Methapyrilene hydrochloride	I	—
Methyl nicotinate	—	I
Methyl salicylate	—	I
Phenol	I	—
Phenolate sodium	I	—
Pramoxine hydrochloride	I	—
Resorcinol	I	—
Salicylamide	III	—
Tetracaine	I	—
Tetracaine hydrochloride	I	—
Thymol	III	—
Triethanolamine salicylate	III	—
Tripelennamine hydrochloride	I	—
Turpentine oil	—	I

[1] The (—) symbol indicates an unacceptable pharmacologic activity for the ingredient.

[2] All ingredients classified as Category III were done so for effectiveness considerations except for camphorated metacresol which was classified as Category III for safety and effectiveness considerations.

[3] Hydrocortisone and hydrocortisone acetate are external analgesics only for use as topical antipruritics.

B. Categorization of Data

1. *Category I conditions under which external analgesic ingredients are generally recognized as safe and effective and are not misbranded.*

The Panel recommends that the Category I conditions be effective 30

days after the date of publication of the final monograph in the **Federal Register.**

Category I Active Ingredients

Allyl isothiocyanate
Ammonia water, stronger
Benzocaine
Benzyl alcohol
Butamben picrate
Camphor
Capsicum preparations
  Capsaicin
  Capsicum
  Capsicum oleoresin
Dibucaine
Dibucaine hydrochloride
Dimethisoquin hydrochloride
Diphenhydramine hydrochloride
Dyclonine hydrochloride
Histamine dihydrochloride
Hydrocortisone preparations
  Hydrocortisone
  Hydrocortisone acetate
Juniper tar
Lidocaine
Lidocaine hydrochloride
Menthol
Methapyrilene hydrochloride
Methyl nicotinate
Methyl salicylate
Phenol
Phenolate sodium
Pramoxine hydrochloride
Resorcnol
Tetracaine
Tetracaine hydrochloride
Tripelennamine hydrochloride
Turpentine oil

a. *Allyl isothiocyanate.* The Panel concludes that allyl isothiocyanate is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient stimulates cutaneous sensory receptors and should bear the labeling for topical counterirritants set forth below.

Allyl isothiocyanate, also known as volatile oil of mustard, is a colorless or pale yellow liquid with a very pungent, irritating odor and acrid taste. It is slightly soluble in water, and miscible with alcohol and most organic solvents. Its chemical formula is C_4H_5NS (Ref. 1).

Allyl isothiocyanate is derived from the powdered seeds of *Brassica nigra* (Black Mustard) and other species of mustard, or prepared synthetically by the reaction of allyl iodide and potassium thiocyanate.

Allyl isothiocyanate does not occur naturally in mustard seed. Instead, mustard seed contains a fixed oil, a glycoside (sinigrin), and the enzyme myrosin. In order to produce the volatile oil, the fixed oil must first be removed. Following this, the residue of dried powdered seed is moistened with warm water, and hydrolysis of the sinigrin occurs, yielding allyl isothiocyanate.

Poultices employing powdered mustard seed have been used as a counterirritant for many years. Mustard plaster, National Formulary XI, was actually a poultice prepared by applying powdered mustard seed, deprived of its fixed oil, with a suitable adhesive to cloth or paper at a concentration of 2.5 g/100 cm^2. The poultice is moistened in tepid water before applying to the intact skin, and the body temperature of the patient supports the ongoing enzymatic production of the volatile oil, allyl isothiocyanate (Ref. 2).

(1) *Safety.* Clinical use has confirmed that allyl isothiocyanate is safe in the dosage range used as an OTC external analgesic.

Black mustard is mentioned by Diocletian (300 A.D.) as a condiment, and both Theophrastus and Pliny mention its use in medicine (Ref. 3). Mustard is used chiefly as a condiment. In large quantities it causes violent irritation of the stomach and bowel, with vomiting, acute pain, purging and tenderness in the abdomen, and collapse. Mustard in warm water was formerly used as an emetic in cases of poisoning (Ref. 4). Small doses taken orally may increase apetite, stimulate secretion of digestive ferments, and increase peristalsis. Placed on the tongue, mustard causes prickling and burning. If swallowed, these effects occur in the throat and stomach (Ref. 5).

Dogs injected with 0.01 milliliter/kilogram (ml/kg) experienced a fall in blood pressure due to direct depression of the vasomotor center. The heart is alternately accelerated and slowed, and heart block may occur as the ventricles are more poisoned than the auricles. Death commonly occurs in mammals from respiratory paralysis before the heart is profoundly affected (Ref. 5).

Jenner et al. administered a 10-percent concentration of allyl isothiocyanate in corn oil to rats by intubation. After 2 weeks of observation, the LD_{50} was found to be 339 milligrams/kilogram (mg/kg) (Ref. 6).

In high concentration, volatile oil of mustard is rapidly absorbed from intact (unbroken) skin as well as from all mucous membranes. Penetration of the skin is rapid and, if not removed soon after application, it may cause ulceration (Ref. 5). Used as a poultice, erroneously termed a mustard plaster, the allyl isothiocyanate released by the presence of water may cause the infalmmatory action to go beyond erythema to vesication (Ref. 7).

Marketing experience has been good, with no reports of adverse reactions serious enough to require treatment in a user pupulation (Ref. 8). The safety of allyl isothiocyanate has been demonstrated by marketing data. Over the period 1962 to 1972, inclusive, nearly 15,000,000 package units were manufactured and marketed. Over this 11-year period, 43 letters of minor complaints were received. This represents a ratio of 1 complaint per 350,000 package units marketed. No reports of serious untoward effects were received (Ref. 8).

It is the opinion of the Panel that although the actual number of adverse effects attributed to the external use of mustard preparations is relatively low, care should be taken to assure that safety is maintained through adequate packaging, labeling, and application.

(2) *Effectiveness.* There are studies documenting the effectiveness of allyl isothiocyanate as an OTC external analgesic. In addition, due to the ingredient's wide use and clincial acceptance and on the basis of published reports in the literature, the Panel concludes that allyl isothiocyanate is effective for use as an OTC external analgesic.

Allyl isothiocyanate is a powerful counterirritant (Ref. 9). Mustard plaster, listed in the National Formulary IX, is a poultice. When moistened thoroughly with tepid water and applied to the skin, the poultice produces a decided warmth and reddening of the skin within 5 minutes (Ref. 10).

Peterson et al., in their study of the response of the skin to rubefacients (Ref. 11), applied nine different rubefacients (counterirritants), including 5 percent volatile mustard oil to the skin of five human subjects. The skin of the upper back was used for the application of rubefacients ointments. Eighty milligrams (mg) of each rubefacient ointment was applied with the same technique. Thereafter, the degree of erythema and skin temperature of each site were observed at 5-minute intervals for a minimum of 30 minutes. The Sargent Thermistor unit recorded changes in skin temperature. Erythema was graded 0 to 3+, (1+ for slight erythema, 2+ for moderate, and 3+ for marked erythema). Several of the preparations evoked no erythema or temperature elevation, including 5 percent tincture of capsicum, along with tincture of cantharides, methyl salicylate, Peruvian balsam, and Unibase control. Those producing erythema and Temperature changes were nicotinic acid, tetrahydrofurfuryl ester of nicotinic acid, camphor, and volatile mustard oil. With various other rubefacients, e.g., methyl nicotinate which did produce erythema, the quantitative inunction of rubefacients ointments had little or no effect on the resultant cutaneous response of the subject. The skin temperature elevation evoked by rubefacients seems to

quantitatively parallel the extent of erythema produced.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 5.0 percent concentration of allyl isothiocyanate to affected area not more than 3 to 4 times daily. For children under 2 years of age there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical counterirritant active ingredients. (See part III. paragraph B.1. below—Category I labeling.)

References

(1) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 41, 1976.

(2) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 763–764, 1973.

(3) Claus, E., V. Tyler and L. Brady, "Pharmacognosy," 6th Ed., Lea and Febiger, Philadelphia, p. 119, 1970.

(4) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, p. 952, 1975.

(5) Solis-Cohen, S. and T. S. Githens, "Pharmacotherapeutics-Materia Medica and Drug Action," D. Appleton and Co., New York, pp. 1030–1033, 1928.

(6) Jenner, P. M., E. C. Hagan J. M. Taylor, E. L. Cook, and O. G. Fitzhugh, "Food Flavorings and Compounds of Related Structure I. Acute Oral Toxicity," *Food and Cosmetics Toxicology,* 2:327–343, 1964.

(7) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 764, 1973.

(8) OTC Volume 060051.

(9) Todd, R. G., "Martindale, The Extra Pharmacopeia," 26th Ed., The Pharmaceutical Press, London, p. 1245, 1972.

(10) "The National Formulary IX," The American Pharmaceutical Association, Washington, DC, p. 342, 1950.

(11) Peterson, J. B., E. M. Farber, and G. P. Fulton, "Responses of the Skin to Rubefacients," *Journal of Investigative Dermatology,* 35:57–64, 1960.

b. *Ammonia water, stronger.* The Panel concludes that stronger ammonia water is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient stimulates cutaneous sensory receptors and should bear the labeling for topical counterirritants set forth below.

Stronger ammonia water is also known as Strong Ammonia Solution, National Formulary XIV. It is an aqueous solution of ammonia (NH_3) containing 27 to 30 percent weight in weight (w/w) of NH_3. Upon exposure to air, it loses ammonia rapidly. Stronger ammonia water is a colorless, transparent liquid, having an exceedingly pungent characteristic odor. It is miscible with alcohol. Even when well diluted it is strongly alkaline to litmus. It has a specific gravity of approximately 0.90.

Stronger ammonia water is a potent chemical reagent which is also used as a pharmaceutical necessity for the preparation of ammonia water by dilution. It is too strong for internal administration or topical application. The following precautionary statement is quoted from the National Formulary XIV.

Caution—Use care in handling Strong Ammonia Solution because of the caustic nature of the Solution and the irritating properties of its vapor. Cool the container well before opening, and cover the closure with a cloth or similar material while opening. Do not taste Strong Ammonia Solution, and avoid inhalation of its vapor.

Ammonia (NH_3) is a colorless, transparent gas having a density approximately 0.6 that of air, an exceedingly pungent odor, and an acrid taste. The gas is described as an irrespirable gas since it is so irritating that, upon contact, it produces an immediate spasm of the glottis (Ref. 1). Ammonia is very soluble in water. A portion of the dissolved ammonia gas reacts chemically with water to form ammoniun hydroxide. Ammonia and ammonium hydroxide react with acids to form salts containing the ammonium ion (NH_4+).

Ammonium ion in many respects acts in a manner analogous to the alkaline metals and has been called the volatile alkali. However, ammonium hydroxide is only feebly basic in comparison with the true alkaline metal hydroxides and is readily displaced from its salts by alkaline metal ions. Consequently, ammonium salts and particularly the ammonium salts of fatty acids (soaps) are not as stable as the corresponding products made by reaction with alkaline hydroxides. They are also more susceptible to thermal decomposition (Ref. 2).

Ammonia liniment, National Formulary IX, is prepared by adding 250 milliliters (mL) of diluted ammonia solution to 750 mL of a mixture of oleic acid and sesame oil. A portion of the ammonia reacts with the oleic acid to form ammonium oleate which, in turn, acts as an emulsifying agent for the water and sesame oil. The concentration of ammonia in the finished emulsion is approximately 2.5 percent (Ref. 3).

(1) *Safety.* Clinical use has confirmed that stronger ammonia water is safe in the dosage range used as an OTC external analgesic.

Ammonia is a naturally occurring product found abundantly in body tissues. It has been used internally as a reflex stimulant and as a carminative in veterinary medicine (Ref. 4). The ammonium ion serves a major role in maintaining the acid-base balance of normal body fluids. The ammonia liberated from deamination of amides provides the largest portion of this ammonia balance (Ref. 5). In man the major site of ammonia disposal is in the liver, where it is converted to urea. Patients with severe hepatic disease or with portocaval shunts often have elevated blood ammonia levels and often develop derangements of the central nervous system which are manifested by disturbance of consciousness, tremor, hyperreflexia, and EEG abnormalities (Ref. 5).

The fatal dose of ammonium hydroxide by ingestion is about 30 mL of a 25-percent concentration (Ref. 6).

The symptoms of poisoning from ammonia are due to local irritation rather than caustic effects. There is severe pain in the mouth, throat, and stomach, with vomiting and gastritis (Ref. 7). Inhalation of ammonia vapor casues sneezing and coughing, and in high concentrations causes the throat to produce immediate spasm and closure of the glottis, resulting in asphyxia (Ref. 7). Ammonia and ammonium hydroxide cause extremely painful irritation of all mucous membranes (Ref. 5). However, under normal circumstances, oral administration of relatively large doses of ammonium salts produce no significant alterations or toxic effects (Ref. 8). The reflex stimulant property of dilute concentrations of ammonia serves as a valuable protective device against the accidental or voluntary ingestion of topical products containing free ammonia.

This reflex stimulant property is utilized as the basis of the use of "smelling salts," which contain ammonium carbonate in their formulation. Ammonium carbonate is a mixture of ammonium bicarbonate (NH_4HCO_3) and ammonium carbamate (NH_2COONH_4). The latter reacts with water to form the carbonate [$(NH_4)_2CO_3$], which then decomposes to release free ammonia which is the respiratory stimulant.

Aromatic ammonia spirit, National Formulary XIV, is also used as a respiratory stimulant. This product derives its activity from two constituents: ammonium carbonate 3.5 percent and strong ammonia solution equivalent to approximately 1.9 percent available ammonia. It is administered orally in small doses, or held near the nostrils for inhalation of volatile vapor.

Ammonia preparations used externally have been found in the National Formulary, United States Pharmacopeia, and British

Pharmacopeia. Marketing data of four decades have yielded few adverse reactions (Ref. 9).

(2) *Effectiveness.* Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that stronger ammonia water is effective for use as an OTC external analgesic.

Few authoritative publications provide information regarding optimum concentrations of ammonia in counter-irritant products. The Merck Index suggests a lower limit of 1 percent and an upper limit of 5 percent (Ref. 10).

Numerous formulations for liniments containing ammonia can be found in the literature. Many of these are emulsions in which an extemporaneously prepared ammonia soap serves both as an emulsifying agent and a lubricant.

Ammonia liniments, National Formulary IX, is prepared by mixing 25 percent diluted ammonia solution (equivalent to 2.5 percent ammonia) with 1 percent oleic acid and 74 percent sesame oil. The ammonia reacts chemically with the oleic acid and free fatty acids present in the sesame oil to form a soap, which serves as the emulsifying agent for the water present in the diluted ammonia solution and the sesame oil (Ref. 11).

The British ammonia liniment (Ref. 12) is prepared by combining 25 percent diluted ammonia solution (equivalent to 2.5 percent ammonia), 2.5 percent oleic acid, and 72.5 percent liquid paraffin (Ref. 13).

A number of formulas for liniments containing ammonia are found in The Pharmaceutical Recipe Book (Ref. 14). Concentrations of ammonia range from approximately 0.5 percent to 2.65 percent. An older British formulation, ammoniated almond oil lotion, contains 3.5 percent ammonia (Ref. 15). Another British formula, ammoniated liniment of camphor, contains more than 7 percent ammonia (Ref. 11).

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 1.0 to 2.5 percent concentration available ammonia (NH_3) to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical counterirritant active ingredients. (See part III. paragraph B. 1. below—Category I Labeling.)

References

(1) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 24th Ed., J. B. Lippincott Co., Philadelphia, p. 65, 1950.

(2) Osol, A., "Remington's Pharmaceutical Sciences," 14th Ed., Mack Publishing Co., Easton, PA, p. 405, 1970.

(3) "The National Formulary IX," The American Pharmaceutical Association, Washington, DC, p. 39, 1950.

(4) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 69, 1976.

(5) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 794, 1975.

(6) Dreisbach, R. H., "Handbook of Poisoning," 7th Ed., Lange Medical Publications, Los Altos, CA, p. 187, 1971.

(7) Todd, R. G., "Martindale, The Extra Pharmacopeia," 26th Ed., The Pharmaceutical Press, London, p. 85, 1972.

(8) DiPalma, J. R. "Drill's Pharmacology in Medicine," 3d Ed., McGraw-Hill Book Co., New York, p. 710, 1965.

(9) OTC Volume 060009.

(10) Stecher, P. G., "The Merck Index," 5th Ed., Merck and Co., Rahway, NJ, p. 29, 1940.

(11) Osol, A., "Remington's Pharmaceutical Sciences," 11th Ed., Mack Publishing Co., Easton, PA, p. 298, 1956.

(12) "British National Formulary," Hazell, Watson, and Viney LTD, London, p. 122, 1960.

(13) Todd, R. G. "Martindale, The Extra Pharmacopeia," 25th., The Pharmaceutical Press, London, p. 95, 1971.

(14) "The Pharmaceutical Recipe Book," 2d Ed., The American Pharmaceutical Association, Washington, DC, p. 64, 1943.

(15) Todd, R. G., "Martindale, The Extra Pharmacopeia," 25th Ed., The Pharmaceutical Press, London, p. 96, 1971.

c. *Benzocaine.* The Panel concludes that benzocaine is safe and effective for use as an OTC external analgesic as specified in the dosage section discussed below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics as described below.

Benzocaine is an effective topical anesthetic that has enjoyed widespread and long-term usage since 1903. Benzocaine was also called anesthesin, orthocesin, and parathesin. It was official for many years in the United States Pharmacopeia. Benzocaine is also listed in the National Formulary XIV. Benzocaine is the ethyl ester of aminobenzoic acid. It may be prepared by reducing paranitrobenzoic acid to aminobenzoic acid and esterifying the latter with ethyl alcohol in the presence of sulfuric acid. Benzocaine is a white, crystalline, stable powder. Benzocaine melts at 88° to 92° C. It is odorless and has a somewhat bitter taste. The powder induces a sense of numbness when placed on the tongue.

Benzocaine is one of a group of several anesthetics which is often referred to as one of the "insoluble" topical anesthetics. This group includes the propyl ester of aminobenzoic acid (risocaine), the butyl ester (butamben), and two other chemically related compounds called orthocaine and orthoform new (Ref. 1). The safety of benzocaine is due to the fact that it is poorly soluble in water. One g of benzocaine dissolves in 2,500 mL water, 5 mL alcohol, 2 mL chloroform, and 4 mL ether. Benzocaine is lipophilic and is soluble in various oils such as olive, peanut, and almond oil. It is also soluble in petrolatum, dipropylene glycol, and various polyethylene glycols. Benzocaine is stable in air. However, if boiled with hydrochloric acid, it is hydrolyzed and converted to aminobenzoic acid and ethyl alcohol. Benzocaine is a base by virtue of the amino group on the benzoic acid nucleus. Because it is lipid soluble and poorly ionized, it readily penetrates the lipid barriers of the cell membranes. Benzocaine forms salts with hydrochloride acid, picric acid, and other acids. The hydrochloride salt is irritating to the mucous membranes and to the skin.

Benzocaine has slight antiseptic and bacteriostatic actions, but these actions are not clinically significant. Benzocaine acts, as do other topical anesthetics, on the axonal membrane to interrupt conduction. Like other topical anesthetics, it stabilizes the membrane to prevent the ingress of sodium ions into the axonal cytoplasm. Its anesthetic activity is decreased or lost when formulated in an acid medium because it forms salts (Refs. 1, 2, and 3) by the interaction of acids with the amino group. The salts are ionized and do not readily penetrate the lipid barriers or cell membranes.

(1) *Safety.* Clinical use has confirmed that benzocaine is safe in the dosage range used as an OTC external analgesic.

Benzocaine is one of the most widely used and safest topical anesthetics found in OTC preparations. The domestic production is approximately 1¼ million pounds (lbs) per year. In addition, there is a quantity of benzocaine imported which adds approximately 30 percent more to the domestically produced quantity (Ref. 4). Because it has a low degree of water solubility, the quantities absorbed are relatively insignificant, and plasma levels that cause systemic reactions characteristic of the soluble "caine" type drugs and their allies do not occur with benzocaine. The convulsions and cardiac depression characteristic of the "caine" type drugs do not occur with benzocaine and reports of such reactions with the use of benzocaine are nonexistent. Blood plasma contains pseudocholinesterases which hydrolyze

and detoxify esters of aminobenzoic acid such as procaine, butethamine, and tetracaine. The exact metabolic pathway for the biodegradation of benzocaine is not known (Ref. 1). However, it is likely that benzocaine undergoes hydrolysis into aminobenzoic acid and ethanol. The ethanol is oxidized and the aminobenzoic acid is conjugated with glycine or excreted unchanged into the urine. In studies conducted in rats, benzocaine has been isolated from tissues after topical application to the skin. Traces of unmetabolized benzocaine have been detected in the urine (Ref. 5).

Benzocaine has been administered orally to relieve stomach pain without any toxic effects. It causes some discomfort by the oral route probably because it forms the hydrochloride salt. The lethal dose in man is not known, but the Panel is unaware of any fatalities due to the oral ingestion of benzocaine. Lethal doses have been determined in animals when benzocaine has been administered by various routes. Astrom and Persson determined the toxicity of benzocaine in rabbits and compared it with that of several other topical anesthetics (Ref. 6). The anesthetics were applied to various mucous surfaces by the intravesicular, intranasal, and intratracheal routes. When administered by the intratracheal route, the LD_{50} for benzocaine was 146 mg/kg; for tetracaine it was 4.4 mg/kg; for cocaine, 30 mg/kg; and for lidocaine, 75 mg/kg. When the drugs were administered intranasally, the LD_{50} for benzocaine was 104 mg/kg, compared to 10 mg for tetracaine, 50 mg for cocaine, and 135 mg for lidocaine. Using tetracaine as a reference unit of toxicity and designating this unit as 1, the toxic dosage relationships would be tetracaine 1, cocaine 6.8, lidocaine 17.1, and benzocaine 33.2 when the drugs were administered by the intratracheal route. In other words, approximately 33 times more benzocaine would be required to cause a fatal response than would be required if tetracaine were used. By the intranasal route, the toxic dose relationship is tetracaine 1, cocaine 5, benzocaine 10.4 and lidocaine 13.5. These comparisons indicate that benzocaine is far less toxic than the other compounds tested when administered via the intratracheal route. The data also indicate that when the intranasal route is used, benzocaine is far less toxic than tetracaine and cocaine but slightly more toxic than lidocaine.

Acute lethal dose studies using the oral and intraperitoneal routes in mice also indicate that benzocaine manifests a low degree of toxicity.

Studies of the effects of benzocaine on the cornea of rabbits to determine its potential for producing irritation were reviewed (Ref. 7). The concentrations used ranged from 4 to 20 percent in polyethylene glycol-4000 dilaureate. Benzocaine caused no detectable irritation of the eyes. The effect of benzocaine was compared with the effects of the hydrochlorides of dibucaine, tetracaine, and pramoxine. Dibucaine hydrochloride 2 percent and tetracaine hydrochloride 2 percent caused irritation consisting of a red, swollen conjuctival sac with copious mucous secretions surrounding the area. This condition persisted in these animals for 48 hours. Pramoxine hydrochloride 3 to 4 percent caused extreme swelling and inflammation at the experimental site. The irritation was accompanied by excessive mucous secretion. After 24 hours the corneal areas became blue in appearance, suggesting blindness.

The systemic effects of benzocaine absorbed percutaneously were studied. These studies were designed to assess the effects of benzocaine on the hematopoietic system and were conducted in rabbits (Ref. 7). Benzocaine 20 percent in a Carbowax™ base was applied to abraded rabbit skin after which blood samples were drawn from a marginal ear vein. Hemoglobin and methemoglobin levels were determined. In addition, erythrocyte, leukocyte, and differential counts were made. The hemoglobin level decreased to the same approximate levels in both the control and experimental animals. Methemoglobin levels increased to a maximum of less than 3 percent of the total hemoglobin. This response was essentially identical to that occurring in the control and experimental animals. Erythrocyte levels decreased in both the control and experimental animals while the leukocyte count was elevated in both the test and control animals. Differential counts revealed an increase in polymorphonuclear leukocytes and a decrease in lymphocytes in both the control and experimental groups. It was concluded, even though some minor change occurred in each of the parameters studied, that these changes were indistinguishable in the control and experimental groups and that these effects were apparently due to some phenomenon other than that of applying the ointment to the abraded skin.

The percutaneous safety of benzocaine was reported by Zaroslinski (Ref. 7) in a study investigating the topical effects of repeated application of benzocaine to the abraded skin. The experiment was designed to establish whether the use of benzocaine applied repeatedly to the abraded skin of rabbits caused any irritation or allergic response as well as systemic adverse effects. The study was conducted in eight female albino rabbits weighing 2.2 to 3.4 kilograms (kg). The back of each animal was closely clipped and then abraded in a specific area by repeatedly scraping the skin with the edges of a piece of wire screen, the teeth of which were 1 millimeter (mm) apart. The rabbits were divided into two groups. One group received 5 g ointment twice daily applied to the abraded surface. The second group served as a control and no ointment was applied. Blood samples were drawn from the marginal ear vein of each animal before and after abrading and tested for the hemoglobin-methemoglobin content, changes in erythrocytes, leukocyte counts, and differential counts. The areas of the abrasion were varied, that is, they were 3, 6, and 12 square inches, respectively. In all instances the quantity of ointment applied was constant, i.e., 5 g. The weighed amount of ointment was spread uniformly over the abraded areas. The skin was then manipulated by rubbing to cause absorption of the ointment. The entire trunk of each rabbit was protected by a light, muslin bandage. The drug was applied twice daily, 5 days weekly, over a period of 20 days. During this time 200 g of the ointment was applied to the abraded skin area of each of the rabbits. No observable local irritation or signs of allergic reaction was noted, nor were there any demonstrable systemic effects as judged by observations of the hematological parameters. During this period each test animal was inuncted with approximately 80 grams/kilogram (g/kg) ointment. The variations observed in the hemoglobin and methemglobin values were similar in both the control and the experimental animals.

Human safety data are available. Historically, the use of benzocaine preparations for topical anesthesia, both on the skin and mucous membranes, and for use internally has been reported many times and has been associated with a high degree of safety. It is beyond the scope of this Panel to cite in detail the case reports and other references pertaining to the clinical use of benzocaine, both as a prescription drug and in OTC preparations, since its introduction in 1903 by Einhorn. Many of these reports appear in the older medical literature and are not readily available or are reports of uncontrolled studies. The Panel, however, cautions

users that benzocaine therapy is not absolutely without hazard. In reviewing the literature on benzocaine, two types of adverse reactions have been noted. These reactions are either due to sensitization and are allergic in type, or result in the development of methemoglobinemia. The data cited in the medical literature on adverse reactions to benzocaine often focus on isolated cases or a small number of cases documenting adverse reactions. Many of these data are retrospective and involve the use of combinations which contain benzocaine as one of the ingredients. It is difficult to extrapolate from the frequency of occurrence of these isolated cases the probability of occurrence of adverse reactions in the general population, since no data are furnished on the frequency of application or the number of subjects treated with the drug.

As is the case with other drugs, benzocaine can act as a haptene and combine with proteins to cause a sensitivity mediated by IgE immune globulin type of antibodies. These antibodies act on mast cells, basophiles, and other cells in susceptible individuals and cause anaphylaxis, rhinitis, intrinsic asthma, urticaria, and atopic dermatitis. Benzocaine can also activate the thymus lymphoid system and cause topical sensitization of the cytotoxic type in the skin after repeated applications. The mechanism for development of sensitization is described elsewhere in this document. (See part II. paragraph G. above—Safety of External Analgesics.)

Fisher and associates (Ref. 8) studied the ability of para-phenylenediamine, a hair dye, to act as a sensitizer on the skin to produce an allergic edematous contact type of dermatitis. He found that in a group of 50 para-phenylenediamine-sensitive patients, 46 were still sensitive when tested three to ten years later. Of these 46, 11 were found to be also sensitive to benzocaine. They also found that of 24 patients sensitized to benzocaine, 10 were also sensitive to para-phenylenediamine. In a similar study, using a patch test, Gaul (Ref. 9) found that in a group of 580 dermatologic patients, 50 were sensitive to para-phenylenediamine and 16 were sensitive to benzocaine. Of the benzocaine-sensitive patients, 3 were sensitive to benzocaine only and 3 were sensitive to para-phenylenediamine, procaine, and benzocaine. Patients showing sensitivity to a variety of substances were characterized as having cross-sensitivity, cross- and multiple sensitivity, and multiple sensitivity without cross-sensitivity. The Panel emphasizes that benzocaine is chemically dissimilar from para-phenylenediamine. Since benzocaine can act as a haptene and combine with a tissue protein to form strong covalent bonds to act as an allergen, these findings are not surprising to the Panel.

In the North American Dermatologic Study (Ref. 10), the incidence of benzocaine irritancy and sensitivity was less than 5 percent, equal to other commonly used drugs, and less than the more frequent sensitizers such as neomycin. These studies were performed on high risk allergic patients seeking treatment for dermatologic diseases. Benzocaine has often been referred to as a potent sensitizer and has been said to cause sensitization and cross-sensitization to other derivatives of amino-benzoic acid such as procaine, butamben, butethamine, tetracaine, and related compounds. The number of reported reactions has not been correlated with the total number of applications of the agent to individual subjects, with repeated applications, and with subjects who are not high risk (Ref. 11). Cross-sensitivity is defined as the capacity of an antibody to react not only with the substance responsible for the production but also with other antigens that are closely allied chemically. Mathieu, in reviewing the literature on cross-sensitivity, found few instances of cross-sensitivity among all the topical anesthetics (Ref. 12).

Prystowsky et al. did a prospective contact sensitivity study on 1,158 adult volunteers (Ref. 13). A pretest history of previous exposure to four allergens, including 5 percent benzocaine in petrolatum, was obtained before patch testing. The patch was removed at 48 hours and read at 5 days. The prevalence of positive reactions to 5 percent benzocaine was 0.17 percent. By history, 85 percent of the volunteers had been exposed to benzocaine. The investigators point out that 0.17 percent positive reactions in this study are in contrast to 1.6 percent positive reactions to benzocaine in a study of 127 patients referred to clinics for the evaluation of contact dermatitis. They concluded that "the results of this study indicate that contact dermatitis patient populations provide exaggerated estimates of the prevalence of sensitivity to contactants; figures in a general population are preferable in decision making concerning the safety of commercial products."

The Panel concludes that the available epidemiologic data on allergy, irritancy, and other reactions are inconclusive and in no way support the contention that benzocaine is a potent sensitizer. The number of adverse reactions are relatively few when one considers that benzocaine has been used since the early 1900's with wide marketing experience and very few complaints. It has been and is still one of the most widely used and safest topical anesthetics in OTC preparations (Refs. 7, 14, and 15). The Panel also believes that phrases such as "potent sensitizers," "common cross-sensitizers," and "highly allergic," etc. imply that these phenomena occur with greater frequency with benzocaine than with other drugs, and that such statements are unwarranted. The Panel finds little or no evidence of controlled, investigative, or epidemiological studies to support these contentions Calnan et al. (Ref. 16) evaluated sensitivity of various allergens by patch tests in 281 housewives exhibiting hand dermatitis in an effort to identify the offending allergen. Only 5 percent of these patients proved to be sensitive to benzocaine. However, substances occurring in household items or in chemicals such as balsams, nickel, and rubber were more common allergens than was benzocaine. Bandmann et al. (Ref. 17) in their reevaluation of some of the same data originally reported by Calnan et al. (Ref. 16) showed that the incidence of positive patch tests with benzocaine in male and female patients with allergic dermatitis was 3.3 percent and 4.5 percent. In view of the fact that only a fraction of the population exhibits any allergic dermatitis and that these tests were done on high risk populations, the Panel is of the opinion that the incidence of benzocaine sensitivity is quite low.

One death due to anaphylactic shock immediately following the administration of throat lozenges containing 10 mg benzocaine, 1 mg thyrothricin, and chlorophyll was reported by Hesch (Ref. 18). Circumstantial evidence cited by the author suggests that the death was drug related. However, it was impossible to state which of the components in the lozenge was the causative agent. The Panel is unaware of any similar cases of anaphylaxis that could be attributable to benzocaine or benzocaine-containing products applied to the skin, and concludes that even though benzocaine can act as a haptene and induce an IgE-mediated anaphylactic response, particularly on damaged skin, that the occurrence of anaphylaxis is extremely rare.

The use of 20 percent benzocaine ointment in 132 patients suffering from 22 types of dermatologic conditions was documented by White and Madura (Ref.

19). Included among these were 10 cases of infantile eczema, both dry and weeping, and 10 cases of varicose ulcers. Of the 132 cases, the relief obtained with benzocaine was inadequate in only two cases of atopic dermatitis and in two cases of lichen simplex chronicus. There were no cases of irritation or sensitivity reactions directly attributable to benzocaine. However, there were two cases of exacerbation of dermatitis veneata (poison ivy). Thus relief due to benzocaine was adequate to excellent in 126 out of 132 patients. The incidence of side effects was 2 out of 132 patients and these were not of a serious nature. This type of study in a population selected on the basis of dermatologic disease rather than on the basis of history of drug allergy tends to provide a better estimate of the incidence of sensitivity in the general population.

Adriani and Campbell (Ref. 20), in a study of the absorption of tetracaine applied on the mucous membranes in various areas of the body, comment that even though benzocaine was not included in this study, the systemic absorption of benzocaine is poor. It is to this lack of significant absorption that they attribute the absence of untoward reactions in 10,000 patients treated with 20 percent benzocaine ointment as a lubricant anesthetic for obtundation of pharyngeal and tracheal reflexes during introduction of tracheal catheters. Adriani and Zepernick (Ref. 21) reported a lack of adverse reactions in over 144,000 cases in which 20 percent benzocaine was used in hospitalized patients. The majority of these cases involved single applications for the lubrication of endotracheal tubes, oropharyngeal airways, and other instruments used in the pharynx and trachea during clinical anesthesia. These studies were performed at Charity Hospital, New Orleans. Since that time there has been a continuous use of benzocaine for the same purpose. It is estimated that the number of usages since their report was published is an additional 200,000, all without any adverse or allergic reaction.

Methemoglobinemia has been reported following the topical application of benzocaine on both the skin and the mucous membranes. However, this is an uncommon occurrence. It is alleged to occur in subjects less than 1 year of age (Reg. 3); however, it actually occurs at any age. Isolated reports of cases of methemoglobinemia, following the use of benzocaine-containing products have appeared in the literature since 1949.

Haggerty (Ref. 22) reported a case of a 1-month-old infant who became cyanotic after being treated for weeping diaper rash with an ointment containing 3 percent benzocaine, 1 percent methapyrilene hydrochloride, calamine, zinc oxide, and camphor. The diagnosis of methemoglobinemia was made by spectroscopic examination of the blood. The condition was reversed with methylene blue. Goluboff and MacFadyen (Ref. 23) reported one case of methemoglobinemia in a 3-month-old patient treated for severe eczema and pruritus with several products. One of these products contained salicylic acid, colloidal sulfur, and coal tar; another product contained one percent hydrocortisone in an ointment base; and one product contained 1.5 percent crude coal tar, 7.5 percent titanium dioxide, 7.5 percent zinc oxide, 2.5 percent calamine, 1 percent cetyltrimethyl ammonium bromide, and 5 percent benzocaine in a special water-soluble base. In addition the patient received intramuscular terramycin and oral elixir of phenobarbital. Treatment with methylene blue successfully reversed the methemoglobinemia. Determination of the causative agent was impossible due to the multiplicity of ingredients in the preparations.

Other isolated cases of a similar nature have been reported but the Panel believes that little would be added to understanding the nature of this reaction by reporting these additional cases in detail. Although the preponderance of reported cases of methemoglobinemia following topical use of benzocaine has occurred in infants, cases have been reported involving older children and adults. Bloch (Ref. 24) reported a case in a 6-year-old child and Bernstein (Ref. 25), in three adults. It has been suggested that the susceptibility in infants might be due to a deficiency of DPNH-dependent methemoglobin reductase, resulting in a diminished capacity to physiologically protect against methemoglobin-inducing foreign compounds. The experiences recorded by Bloch (Ref. 24) in a 6-year-old child suggest that a far less severe methemoglobinemia occurs in older children than in infants. The reactions in the three adults reported by Bernstein (Ref. 25) suggest that the reactions are mild. He found that definitive therapy was unnecessary. The methemoglobin imparts a bluish color (cyanosis) to the skin of white and lightly pigmented individuals. In black and heavily pigmented subjects, the cyanosis can be detected in the nailbeds or in the mucous membranes. The rapidity of development of the bluish color depends upon the rate and amount of benzocaine absorbed. In some cases it develops within 30 minutes to an hour after application.

Steinberg and Zepernick (Ref. 26) reported a case of methemoglobinemia during anesthesia which occurred in a 38-month-old black boy at the Charity Hospital in New Orleans. The boy had been anesthetized with cyclopropane on two previous occasions. On the first occasion, anesthesia was uneventful. On the second occasion, induction of anesthesia was followed by the development of cyanosis which was detected by observing the nailbeds. Anesthesia was discontinued and the operation was deferred until a week later. On the third occasion, anesthesia was induced in the usual manner with cyclopropane and the patient intubated. Cyanosis developed within 15 minutes and anesthesia was discontinued. He remained cyanotic even though he was awake and receiving 100 percent oxygen. There was no change in pulse or blood pressure. Within 4 hours he regained his normal color and had no apparent ill effects from the experience. A review of the anesthetic records revealed that anesthesia in the first instance, which was uneventful, was conducted by using an endotracheal tube that had been lubricated with petrolatum. On the second and third occasions the endotracheal tube had been lubricated with an ointment containing 20 percent benzocaine in propylene glycol. The child was studied further by Adraini and Zepernick (Ref. 27). Reapplication of 20 percent benzocaine to the mucous membranes of the mouth and on the tongue promptly produced cyanosis without the respiratory distress and the changes in pulse and blood pressure which would be anticipated if suboxygenation had been the causative factor. Blood drawn at this time was chocolate color. When analyzed spectroscopically, the absorption spectrum was characteristic of that produced by methemoglobin. The cyanosis promptly disappeared after the intravenous administration of 1 mg/kg methylene blue in a 1-percent solution. On subsequent days various drugs were applied to the mucous membranes and the blood was analyzed for methemoglobin. Since benzocaine is chemically allied to procaine, the latter being the diethylaminoethanol ester of aminobenzoic acid, procaine was applied to the mucous membranes and the blood analyzed for the presence of methemoglobin. None was found. A saturated aqueous solution of aminobenzoic acid was likewise applied on the mucous membranes with no

resultant cyanosis or evidence of methemoglobinemia. A paste consisting of propylene glycol and butamben was likewise applied without any development of methemoglobinemia. Since ethyl alcohol is used to esterify aminobenzoic acid to form benzocaine, it also was applied to determine whether there was cross-sensitization with the components of benzocaine. Alcohol, likewise, did not produce cyanosis nor did the blood show any increase in methemoglobin. Similarly, results using 1 percent lidocaine hydrochloride on the mucous membranes were negative. Propylene glycol applied to the mucous membranes likewise caused no methemoglobinemia. It appears obvious from these studies that the formation of the methemoglobin was due to the ethyl ester alone and that there was no cross-reactivity between aminobenzoic acid or any of its derivatives.

The majority of the reports the Panel has reviewed concerning the formation of methemoglobinemia following the use of benzocaine are single, solated cases or one, two, or three occurrences. It is difficult to extrapolate from these isolated cases the incidence of methemoglobinemia in the general population because the occurrences have not been in any way correlated with the total number of applications. Adriani and Zepernick (Ref. 21) reported no cases of sensitivity nor any other adverse reactions in over 144,000 cases after the use of a preparation containing 20 percent benzocaine for lubrication of endotracheal tubes and airways in hospitalized patients. Of these 144,000 cases, there was only one occurrence of methemoglobinemia following the application of the benzocaine ointment as a lubricant.

In a more recent survey performed by Adriani at Charity Hospital, it was found that 11,328 vials containing 20 percent benzocaine in propylene glycol were utilized from 1974 to 1977. It was estimated that 10 applications were made per vial. The total number of applications was estimated to be 116,360. The preparation was used by the anesthesia department for lubrication of airways and endotracheal tubes. During this period one 6-month-old infant devloped methemoglobinemia. This child was also receiving other drugs for the treatment of burns, presumably derivatives of sulfonic acid.

The action of benzocaine differs from drugs and chemicals such as acetanilid, sulfanilamide, the analine dyes, and the nitrites. Unlike benzocaine, these drugs and chemicals are oxidizing agents and cause methemoglobin to form at a more rapid rate than can be reduced by the enzyme, even though the reductase is present in adequate quantities in the red cell.

Methemoglobinemia is not life threatening, particularly when caused by the small amounts of benzocaine absorbed percutaneously or from the mucous membranes following a single application. Methemoglobin is also known as ferrihemoglobin and is incapable of carrying oxygen since the iron has been converted from the ferrous to the ferric state. There is an equilibrium between the concentration of ferrous and ferric components of iron in the hemoglobin. Normally, not more than 1 percent of the iron is in the ferric state. However, concentrations of methemoglobin up to 8 percent of the total hemoglobin can be present without cyanosis. Cyanosis becomes apparent when 10 to 15 percent of the total hemoglobin has been converted. Methemoglobinemia becomes symptomatic when 30 to 45 percent methemoglobin levels are attained if acutely induced. The symptioms are fatique, dyspnea, weakness, tachycardia, and headache, and are due to hypoxia produced by the lowered oxygen capacity of the blood.

There are at least three recogognized enzymatic processes which tend to keep the heme moiety of hemoglobin in the ferrous state and reduce the iron to the ferric state as rapidly as the ferrihemoglobin forms. The first mechanism employs an electron donor, nicotinamide adenine dinucleotide ($NAHDH_2$), which is formed from the oxidation of glucose and reduces the ferric heme to the ferrous state in the presence of the enzyme methemoglobin reductase. This pathway is the most important of the three and accounts for 67 percent of the conversion of the ferric iron to the ferrous state in red blood cells. The second pathway by which reduction of methemoglobin is accomplished involves the generation of nicotinamide adenine dinucleotide phosphate ($NADPH_2$), formed in a pentose pathway. In this reaction, methemoglobin can act as a cofactor that facilitates and accelerates the reaction. This pathway accounts for only 55 percent of the reduction of the iron in the red blood cells from the ferric to the ferrous state. The third mechanism involves a glutathione pathway. $NADPH_2$ in the presence of glutathione reductase (GR) reduces the oxidized glutathione to reduced glutathione The reduced glutathione in the presence of glutathione peroxidase is capable of destroying oxidant compounds capable of oxidizing hemoglobin. This pathway accounts for 12 percent of the methemoglobin converted to normal hemoglobin. Ascorbic acid is a reducing agent and can also be involved in the conversion. It reduces 16 percent of the methemoglobin; however, this is a nonenzymatic process.

The etiologic factors which alter equilibrium between ferrous and ferric iron can be classed into primary and secondary factors. Primary factors are hereditary. In the hereditary states, methemoglobinemia is due to a deficiency of $NAHDH_2$-dependent methemoglobin reductase and hereditary methemoglobinemia with an abnormal hemoglobin. These conditions are rare. The secondary factors are oxidant drugs.

Recently, Rao, Naraghi, and Adriani (Ref. 28) studied the blood levels of methemoglobin following the instillation of 1 g benzocaine in propylene glycol in the mouths of infants under 6 months of age and in adults. The methemoglobin levels in the controls ranged from 0.1 to 3.5 percent expressed in terms of diminution in oxygen-carrying capacity of the total hemoglobin. In infants there was an increase in the degree of unsaturation during the first hour to an average of 4.5. This is not as striking as one would anticipate. There was a gradual decrease in the methemoglobin content during the second hour, but it did not return to the pretreatment level in any subject until after the third hour. Surprisingly, the mean level in adults was higher than that found in infants. This is in direct opposition to what has been postulated concerning the ease of development of methemoglobinemia in infants following the use of the drug. The Panel concludes that the occurrence of methemoglobinemia following the use of benzocaine is rare. Normal infants and children are no more prone to its development than adults. Why this simple nonoxidizing chemical compound should cause this response on rare occasions is not known, but the Panel concludes it can be classified as an uncommon idiosyncratic response that is in no way injurious or life threatening.

(2) *Effectiveness.* There are studies documenting the effectiveness of benzocaine as an OTC external analgesic.

Benzocaine is an effective topical anesthetic on the skin and mucous membranes. There are many reports in the medical literature of its long, continued, and successful use as an analgesic, anesthetic, and antipruritic in the form of ointments, lotions, and dusting powders that attest to its efficacy (Refs. 3, 14, 21, and 29). These

studies, however, are subjective and uncontrolled. Benzocaine is not suitable for infiltration or perineural injection. When properly formulated with ingredients that insure its stability and continuous contact with a cutaneous or mucous surface, it provides prolonged analgesia or anesthesia (Ref. 14). When incorporated in a medium that is sufficiently alkaline to release bioactive quantities of the free base, it penetrates both the intact and the damaged skin (Ref. 14). Percutaneous absorption occurs, but the resulting blood levels are insignificant. Its pain relieving action is entirely within the skin or mucous membranes. The quantity circulating in the blood is insufficient to provide analgesia or anesthesia to parts of the body distal to the site of application or in the structures beneath the skin, such as the muscles, tendons, or joints. Although traces of benzocaine have been identified in muscles and tendons of rats, claims that the benzocaine present in muscles or joint tissues affords relief in areas other than the skin are regarded as Category II claims by the Panel.

The amount absorbed by the intact skin is insufficient to induce the subjective sensation of numbness even when 20 percent concentrations are used, however, enough is absorbed to elevate the pain threshold to produce analgesia. Numbness may be perceived when concentrated solutions in organic solvents or the crystals are applied to abraded skin surfaces, cuts, or open wounds. Aqueous solutions are too dilute to be effective. When solvents such as propylene or polyethylene glycol are used to formulate preparations, bioactive quantities are made available to the tissue fluids, and partial or complete blockade occurs relieving pain, burning, or itching. The ease with which benzocaine passes from an ointment or solvent is important. In vitro experiments performed by Ayres (Ref. 7) using cellophane membranes reveal that the rate of dialysis of benzocaine from an ointment varies with the type of ingredients used to prepare an ointment. These experiments indicate that the rate of dialysis of benzocaine is greater from water-soluble bases than from oleaginous bases or petrolatum. There is an increase in the quantity that dialyzes as the concentration of benzocaine is increased in the ointment. Although cellophane differs from skin and these results cannot be extrapolated to the penetration of benzocaine through human skin, they do suggest, and it can be inferred, that bioactive quantities pass into the skin more readily from water-soluble bases than from oleaginous bases.

Campbell and Adriani (Ref. 30) noted that topical anesthetics in oleaginous or petrolatum bases were not released as readily as they were from water-soluble bases and that blood levels were less and attained their peaks more slowly when the preparations studied were applied to mucous membranes. They were unable to detect the presence of topical anesthetics when these ointments were applied to first, second, and third degree burns produced experimentally in dogs. Since the introduction of newer and more suitable solvents, such as the glycols, there has been a renewed interest in the use of benzocaine as a topical analgesic because of greater efficacy of preparations formulated with these solvents compared to the oleaginous bases and dusting powders used previously. The concentration of bioactive benzocaine in the tissue fluids is insufficient to penetrate large nerve trunks. The effect of benzocaine is entirely at the terminal pain receptors in the skin.

Techniques for performing controlled studies to determine the efficacy of topical anesthetics on the intact normal skin and the intact damaged skin have not been satisfactory. There is a paucity of data to support claims of efficacy on the skin from controlled studies. Misconceptions are still prevalent regarding percutaneous absorption of drugs. The belief that most drugs are not readily absorbed through the skin is widespread. Data on percutaneous absorption of benzocaine have been obtained from uncontrolled studies and have not been substantiated by controlled studies.

Recently, Adriani and Dalili (Ref. 29) devised a method for stimulating the pain receptors in the skin using an electric current and producing the sensation of itch. That permitted them to perform controlled studies of topical anesthetics applied to the intact skin. They used an alternating pulsatile current delivered from a Grass SS–44 model stimulator which selectively activates the receptors for itch. The current that was used consisted of impulses of sine waves of 30 cycles per second of 5 milliseconds duration, with a 2-millisecond delay. Repeated stimulation produced the sensation of itch and burning without injury to the dermal structures. A subminimal stimulus excites the pain receptors and they respond with the sensation of itch. A further increase in the intensity of the current converts the sensation of itch to one of pain. From 25 to 40 volts were necessary to deliver the required current. The necessary amperage varied from subject to subject. The volar surface of the forearm was used as the test site. An indifferent electrode was fixed to the dorsum of the forearm over guaze soaked with saline. A pinpoint metal tip was used as the exploring electrode. Controlled values were established at multiple points over the test sites. A film of the preparation to be evaluated was applied over a given area and allowed to remain for 30 minutes. Areas 1 x 1 centimeter (cm) were then wiped dry at 5-minute intervals and stimulated at 1- to 2-second intervals until itching was perceived. Generally, 1 hour elaspsed before the entire area was wiped and tested. A single application of the preparation to be tested for 30 to 60 minutes established whether the preparation was clinically useful.

The study was conducted on 150 volunteers. Each preparation was tested in six randomly selected subjects. The number was increased until a definite rating could be established when responses were not uniform in all six subjects. These authors felt that a preparation requiring more than 30 minutes to establish its analgesic effects was not clinically useful. The identities of the preparation were known to the evaluators but not to the subjects. Comparisons were made with placebos. The responses to electrical stimulation were graded as 0 when the response to stimulation was not obtunded, 1+ when the block to the electrical stimulation was partial (increasing the current reproduced the sensation of itch), and 2+ when no sensation of itching, pricking, or burning resulted from the electrical stimulation even when the intensity of the current was increased. These workers found that benzocaine base 5 to 20 percent caused a partial to complete blockade of the receptors to the sensation of itch or burning. The duration of analgesia ranged from 4 to 6 hours if the film of the ointment or solution remained undisturbed. These authors found that benzocaine was not effective in less than 5 percent concentration. The blockade was not complete at 5 percent because increasing the intensity of the current caused the receptors to respond. This ability to respond decreased in intensity as the concentration of benzocaine was increased from 5 to 20 percent (Ref. 16).

The effects of the salts and bases of individual topical anesthetics in obtunding itching and burning of pathologic origin induced by first degree burns was also determined (Ref. 16). The burns were produced on the volar aspects of the forearm with ultraviolet

light from a GE Model F Type 2 lamp held 50 cm from the skin for 2 to 3 minutes. The burns caused an erythema in 90 percent of the subjects 2 to 3 hours after exposure to the ultraviolet light. The subjects not only complained of itching and burning but also commented that the erythematous areas were hypersensitive to touch and pressure. As soon as the subjects complained of symptoms, benzocaine was applied to the burns in concentrations ranging from 1 to 20 percent. Relief was obtained for periods of 4 to 6 hours with concentrations of 5 to 20 percent benzocaine in propylene glycol. The preparation was allowed to remain in contact with the skin for 30 minutes before the areas were tested by electrical stimulation. While the subjects treated with benzocaine in concentrations of 5 percent of more did not respond to the electrical stimulation, those with placebos did. Subjective manifestations were graded according to what the patient said concerning the pain. That both cold and touch could still be perceived after application of a preparation was assumed by these authors to be confirmatory evidence that the drug does not block all the sensory nerve receptors in the subepidermal areas and that receptors are still active after the burn. They added hydrochloric and lactic acids to 20 percent benzocaine in propylene glycol. Acidification completely nullified the activity of the benzocaine. Their study clearly demonstrates that the basic form of benzocaine is bioactive and penetrates the intact normal and the intact damaged skin and obtunds the sensation of pain, burning, and itch. One phase of their study involved the testing and comparison of 30 commercially available OTC topical anesthetics, sprays, creams, and ointments promoted as topical analgesic, anesthetics, and antipruritics. The data from this phase of the study are quite revealing. Among the 10 benzocaine-containing preparations, only one was effective—this consisted of 20 percent benzocaine base in propylene glycol.

These authors concluded that the lack of efficacy of the manufactured preparations, all of which were combinations or contained the salt form of the topical anesthetic, may be due to one or a combination of the following factors: (i) The preparations contain insufficient active ingredient. All 10 preparations contained less than 5 percent benzocaine except the one which was effective.

(ii) The bases of the topical anesthetics, being less stable than the salts, may have undergone chemical change. Benzocaine, however, is more stable than the soluble "caine" bases.

(iii) Nonanesthetic ingredients present in a mixture nullify the action of the local anesthetic.

(iv) The anesthetic was retained by the solvent so that a bioactive quantity was not delivered to the receptors in the skin.

(v) Ingredients in the preparation may have augmented the cutaneous barrier effect and decreased penetration.

(vi) The burn caused by the ultraviolet light altered the epithelial barrier and decreased penetrability of the active ingredients.

Thus the Panel concludes that benzocaine when properly formulated is an effective and safe topical analgesic, anesthetic, and antipruritic on the intact or damage skin.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 5 to 20 percent concentration of benzocaine to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(2) Adriani, J., "Local Anesthetics," *in* "The Pharmacology of Anesthetic Drugs," 5th Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 131–145, 1970.

(3) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 269, 1977.

(4) Letter solicited by John Adriani, M.D. from Dr. A. Shansky, in OTC Volume 060150.

(5) OTC Volume 060118.

(6) Astrom, A. and N. H. Persson, "The Toxicity of Some Local Anesthetics After Application on Different Mucous Membranes and Its Relation to Anesthetic Action on the Nasal Mucosa of the Rabbit," *Journal of Pharmacology and Experimental Therapeutics*, 132:87–90, 1961.

(7) OTC Volume 060073.

(8) Fisher, A. A., A. Pelzig, and N. B. Kanof, "The Persistence of Allergic Eczematous Sensitivity and the Cross-Sensitivity Pattern to Paraphenylenediamine," *Journal of Investigative Dermatology*, 30:9–12, 1958.

(9) Gaul, L. E., "Types of Sensitization Disclosed by Positive Patch Testing to Paraphenylenediamine and Benzocaine," *Annals of Allergy*, 18:738–745, 1960.

(10) North American Contact Dermatitis Group, "Epidemiology of Contact Dermatitis in North America 1972," *Archives of Dermatology*, 108:537–540, 1973.

(11) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Practitioner*, 25:82–86, 1962.

(12) Mathieu, A., "Allergic Reactions to General and Local Anesthetics," *in* "Handbook of Refresher Courses—220," American Society of Anesthesiologists, Park Ridge, IL, pp. 1–5, 1975.

(13) Prystowsky, S. D. et al., "Contact Sensitivity to Nickel, Neomycin, Ethylenediamine, and Benzocaine in a General Population: Relationships Between Age, Sex, History of Exposure, and Reactivity to Standard Patch Tests," *American Federation for Clinical Research*, (Abstract) Meeting, April 18 to May 1, 1978.

(14) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics*, 12:913–919, 1971.

(15) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 186–197, 1973.

(16) Calnan, C. D., H. J. Bandmann, E. Cronin, S. Fregert, N. Hjorth, B. Magnusson, K. Malten, C. L. Meneghini, V. Pirila, and D. S. Wilkinson, "Hand Dermatitis in Housewives," *British Journal of Dermatology*, 82:543–548, 1970.

(17) Bandmann, H., C. D. Calnan, E. Cronin, S. Fregert, N. Hjorth, B. Magnusson, H. Maibach, K. Malten, C. Meneghini, V. Pirila, and D. Wilkinson "Dermatitis from Applied Medicaments," *Archives of Dermatology*, 106:335–337, 1972.

(18) Hesch, D. J., "Anaphylactic Death from the Use of a Throat Lozenge," *The Journal of the American Medical Association*, 172:12–15, 1960.

(19) White, C. J. and J. W. Madura, "Topical Anesthesia in Dermatology," *Post Graduate Medicine*, pp. 519–520, 1951.

(20) Adriani, J. and D. Campbell, "Fatalities Following Topical Application of Local Anesthetics to Mucous Membranes," *Journal of the American Medical Association*, 162:527–530, 1956.

(21) Adriani, J. and R. Zepernick, "Clinical Effectiveness of Drugs Used for Topical Anesthesia," *Journal of the American Medical Association*, 188:711–716, 1964.

(22) Haggerty, R. J., "Blue Baby Due to Methemoglobinemia," *The New England Journal of Medicine*, 267:1303, 1962.

(23) Goluboff, N. and D. J. MacFayden, "Methemoglobinemia in an Infant," *Journal of Pediatrics*, 47:222–226, 1955.

(24) Bloch, A., "More on Infantile Methemoglobinemia due to Benzocaine Suppository," *Journal of Pediatrics*, 67:509–510, 1965.

(25) Bernstein, B. M., "Cyanosis Following the Use of Anesthesin (Ethyl Aminobenzoate)," *Review of Gastroenterology*, 19:411–412, 1952.

(26) Steinberg, J. B. and R. G. Zepernick, "Methemoglobinemia During Anesthesia," *Journal of Pediatrics*, 61:885–886, 1962.

(27) Adriani, J. and R. Zepernick, "Summary of Methemoglobinemia: Study of Child Receiving Benzocaine." Letter to the Commissioner in OTC Volume 060150.

(28) Rao, V. K., M. Naraghi, and J. Adriani, "Methemoglobinemia Following the Use of

Topical Local Anestetics," Draft of unpublished paper, in OTC Volume 060150.

(29) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia*, 50:834–841, 1971.

(30) Campbell, D. and J. Adriani, "Absorption of Local Anesthetics," *Journal of the American Medical Association*, 168:873–877, 1958.

d. *Benzyl alcohol.* The Panel concludes that benzyl alcohol is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Benzyl alcohol is one of the alcoholic or hydroxy type topical anesthetics. Benzyl alcohol is phenyl methanol. It may also be looked upon as methyl alcohol with a phenyl group replacing one of its hydrogen atoms. It is also known as phenmethylol hydroxy toluene. It is found in nature in a free state in oil of jasmine (6 percent) and in the form of esters in Peru balsam, tolu balsam, and storax. The commercial product is synthetic and made by hydrolyzing benzyl chloride or by reducing benzaldehyde. Benzyl alcohol is a colorless liquid with a faint aromatic odor. It has a sharp burning taste. It boils at 206° C. It has a specific gravity of 1.042 to 1.047. One g dissolves in approximately 30 g water, making solutions of approximately 4 percent concentration. Aqueous solutions are neutral. Solutions may be sterilized by boiling. Benzyl alcohol is soluble in alcohol (1 g in 1.5 mL). It is miscible with alcohol, ether, and chloroform. It dissolves in vegetable oils. Oxidation coverts it to benzaldehyde. Slow oxidation occurs if it is exposed to the air for days or weeks. It is stable in stoppered containers (Refs. 1 and 2).

(1) *Safety.* Clinical use has confirmed that benzyl alcohol is safe in the dosage range used in an OTC external analgesic.

Benzyl alcohol is relatively nontoxic. It has been used orally as an antispasmodic agent and rectally as a topical anesthetic. It has been used rectally in combination with paraldehyde to anesthetize the mucosa and prevent explusion of the drug (Refs. 2 and 3). It is converted to hippuric acid in the body and this metabolite is excreted into the urine (Ref. 2). The effect of large doses was studied in animals by Macht (Ref. 4). The minimum lethal dose of pure benzyl alcohol in white mice is 1 mL/kg. The minimum lethal dose in rats ranges from 1 to 3 mL/kg. In dogs, 2 mL/kg of benzyl alcohol injected intravenously, peritoneally, subcutaneously, and intramuscularly were never fatal. Convulsions and cardiac depression, characteristic of the "caine" type of topical anesthetics, have not occurred when therapeutic or toxic doses of benzyl alcohol have been administered to man or animals. Lethal doses in mice cause respiratory failure and in some cases, convulsions. Larger animals, such as dogs, do not manifest these responses. Although benzyl alcohol can, like any other drug, act as a haptene and be antigenic, cases of sensitization have not come to the Panel's attention. The potential for sensitization is lower than it is with the "caine" type of topical anesthetics (Ref. 5).

(2) *Effectiveness.* There are studies documenting the effectiveness of benzyl alcohol as an OTC external analgesic.

Benzyl alcohol belongs to the hydroxy group of topical anesthetics and differs in chemical behavior from the "caine" type drugs. Benzyl alcohol is lipophilic and penetrates the intact or damaged skin. Aqueous solutions of benzyl alcohol are neutral. It does not form salts. Benzyl alcohol is not ionized and penetration into the skin and pharmacologic activity do not depend upon pH. It temporarily relieves itching and burning of painful cutaneous lesions when it is applied topically (Refs. 5, 6, and 7).

Macht (Ref. 4) studied the topical anesthetic effects of benzyl alcohol. He obtained anesthesia by applying aqueous solutions to the mucous membranes of the mouth, tongue, gums, and lips of human beings. The pure alcohol produces a stinging effect when applied to the tongue, followed by a sensation of numbness which may last as long as 2 hours. Macht was able to obtain anesthesia of the skin by direct application of the pure alcohol. Solutions of 1 percent (aqueous) produced corneal anesthesia in rabbits. Solutions of benzyl alcohol produce sensory and motor blockade when they are applied to isolated nerves of frogs. Macht (Ref. 4) obtained both motor and sensory blockade by applying 1 percent solutions of benzyl alcohol to isolated sciatic nerves of dogs. Benzyl alcohol has been used for infiltration and perineural block. Stronger solutions are locally irritating and may cause tissue damage.

Benzyl alcohol manifests varying degrees of bacteriostatic and antiseptic activity. However, this effect does not apply to all pathogenic bacteria, and reliance cannot be placed upon it. Benzyl alcohol is effective topically on the skin to relieve itching and other discomfort due to cuts, insect bites, or abrasions. Solutions composed of equal parts (33 percent) of benzyl alcohol, water, and ethyl alcohol are effective in relieving itching and burning on the skin (Ref. 2). Ointments consisting of 10 percent benzyl alcohol in large doses have been used for topical application to the skin.

The duration of action of benzyl alcohol in the usual therapeutic doses is brief and depends upon the area of application. The latent period on the mucous membranes is approximately 2 minutes. The duration of action is usually less than 30 minutes. The duration of analgesic action on the skin is variable, usually depending upon the surface to which it is applied (Refs. 2 and 8). The effect is sustained if ointments or lotions that permit continuous contact are used.

The pure alcohol causes smarting and burning initially when it is applied to the skin. Although benzyl alcohol is effective as a topical anesthetic, Adriani and Zepernick (Ref. 8) found its efficacy to be less than that of the "caine" type drugs. However, the Panel concludes that benzyl alcohol is safe and effective for use on the intact or damaged skin in the dosage range used as an OTC external analgesic.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 10 to 33 percent concentration of benzyl alcohol to effected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (see part III. paragraph B.1. below—Category I Labeling.)

References

(1) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway NJ, p. 148, 1976.

(2) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B., Lippincott Co., Philadelphia, PA, p. 190, 1973.

(3) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Practitioner*, 25:82–86, 1962.

(4) Macht, D. V., "A Pharmacological and Therapeutic Study of Benzyl Alcohol as a Local Anesthetic," *Pharmacy and Experimental Therapeutics*, 11:263–279, 1918.

(5) Adriani, J., "Local Anesthetics," *in* "The Pharmacology of Anesthetic Drugs," 5th Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 131–145, 1960.

(6) Barnes, M. E., "Death Following the Administration of Thymol," *Journal of the American Medical Association*, 79:964–965, 1922.

(7) Sollmann, T., "A Manual of Pharmacology and Its Application to

Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, PA, p. 340, 1957.

(8) Adriani, J. and R. G. Zepernick, "Comparative Potency and Duration of Action of Topical Anesthetic Drugs in Man," *Anethesiology*, 24:120, 1963.

e. *Butamben picrate.* The Panel concludes that butamben picrate is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Butamben is the butyl ester of *p*-aminobenzoic acid. It is made by esterifying *p*-aminobenzoic acid with butyl alcohol. Butamben is a primary amine and is therefore a base. Butamben is a white, crystalline, tasteless, and odorless powder that melts at between 57° to 59° C. When boiled with acids it is slowly hydrolized to the alcohol and acid. It is similar in its pharmacologic actions to benzocaine (Refs. 1 and 2). Butamben has also been called butesin, butaform, plantoform, and sturoform. Butamben belongs to the group of topical anesthetics classified as the insoluble topical anesthetics (Ref. 1).

As with benzocaine, butamben has a low degree of water solubility. One g dissolves in 7 liters of water. It is soluble in the glycols, dilute solutions of acids, chloroform, ether, and fatty oils. Like other nitrogenous bases, butamben forms salts and esters with acids. Butamben unites with two molecules of picric acid (trinitrophenol) to form a yellow complex, butamben picrate. Both butamben base and butamben picrate are topical anesthetics acting primarily at terminal nerve endings and not on the nerve trunks (Refs. 2 and 3). Both products were introduced in 1926 at approximately the same time.

Butamben picrate is an odorless powder with a bitter taste. It melts at between 109° to 110° C. One g dissolves in 2 liters of water. It is soluble in fatty oils and oleaginous bases. The powder is yellow and is incorporated into ointments for topical application. Butamben picrate slowly releases butamben and picric acid when in contact with moisture. The picric acid stains the skin and other objects. As is the case with salts of topical anesthetics, the butamben picrate complex does not penetrate the intact skin, but will be absorbed when the stratum corneum has been disrupted or the epithelial barriers are destroyed (Refs. 1 and 4).

(1) *Safety.* Clinical use has confirmed that butamben picrate is safe in the dosage range used as an OTC external analgesic.

Due to the ingredient's low water solubility and poor absorbability, systemic toxicity which may occur with the local anesthetics of the "caine" type is not observed with butamben. The base penetrates the intact skin where it exerts its blocking action on the nerve endings of pain receptors. Due to its poor solubility in water, quantities absorbed from the skin that pass into the blood are relatively minute. Plasma levels that cause cardiac depression and central nervous stimulation characteristic of the "caine" type of topical anesthetics are virtually unknown. The toxic dose for animals is high. By the intraperitoneal route, 1,000 mg/kg butamben picrate killed 2 of 3 mice while 1,500 mg/kg killed 3 of 3 animals (Ref. 5). When administered orally to mice, 2,000 mg/kg caused no deaths in 3 of 3 mice. The mice were observed for 72 hours.

The oral toxic dose for man is not known. Due to the ingredient's poor water solubility and the lack of reports on systemic toxicity, the Panel feels justified in assuming that the toxicity of butamben is extremely low. The Panel also emphasizes that the animal toxicity cited above may be due to the picric acid and not the free base. Irritancy of butamben picrate is low due to the solubility characteristics. The sensitizing and irritancy potential of butamben appears to be low. Reports of irritancy by the base have not been submitted to the Panel, and standard textbooks and other pertinent medical literature do not mention reactions due to sensitization or irritation. Such terms as "potent sensitizer" and "frequent sensitizer," which have been used to characterize cutaneous reactions from the use of benzocaine, are not applied to butamben. Sensitization has been reported following the use of butamben picrate (Ref. 6). This aspect of adverse reactions due to this salt is discussed below. Although the Panel states that butamben has a low potential for sensitization, it emphasizes that butamben is not totally without hazard and can, like benzocaine and other drugs, be antigenic and cause anaphylaxis and other types of allergic reactions. Toxic systemic reactions, with the exception of sensitization, have not occurred (Ref. 7).

The Panel concludes that any adverse effects occurring from butamben picrate are due to the picric acid that is released and not to the butamben. Saturated aqueous solutions of picric acid have been used externally in burn dressings. Alcoholic solutions of picric acid are irritating. The picric acid is readily absorbed and causes systemic toxicity. Locally, the handling of the dry powder of picric acid produces an eczematous dermatitis ("picric itch"). Systemically toxic doses destroy red blood cells and cause gastroenteritis, nephritis, and hepatitis. The tissues are stained yellow. A part of the absorbed picric acid is excreted unchanged and some is converted to picramic acid by the liver and excreted into the urine (Refs. 8 and 9).

Butamben picrate has not produced irritation, but cases of sensitization have been reported in approximately 1 of 6,000 cases in which it was used. It can be stated from available data that sensitization is not infrequent. Patch or contact tests should be done cautiously because generalized reactions may follow in susceptible individuals. Whether the dermatitis that has occurred is due to the butamben or to the picric acid is not established, but the Panel believes, from evidence submitted and past experiences with picric acid used alone for burns, that picric acid is the offender.

(2) *Effectiveness.* There are studies documenting the effectiveness of butamben picrate as an OTC external analgesic.

The analgesic effects of butamben picrate are due to the release of butamben, which possesses a topical anesthetic effect and whose pharmacologic effects closely resemble those of benzocaine. When applied to the mucous membranes, butamben in concentrations of 1 to 12 percent in propylene glycol provides topical anesthesia.

Butamben in the form of the base is effective as a topical analgesic, anesthetic, and antipruritic on the intact and damaged skin (Refs. 10 and 11). The pharmacologic and topical analgesic action of the base are due to its lipophilic action. It is absorbed in minute quantities through the skin. Data on its metabolic fate in the body are not available. Because it is an ester of aminobenzoic acid and most aminobenzoic acid ester topical anesthetics are hydrolyzed by the pseudocholinesterases in the body, the Panel regards hydrolysis by the esterases as a possible metabolic pathway. It exerts its analgesic effect superficially in the skin. It does not penetrate in sufficient quantities to exert any beneficial effect on structures beneath the skin or systemically (Ref. 7).

Butamben reacts with acid to form salts which are ionized and do not readily penetrate epithelial barriers. The picrate is effective on damaged skin but not effective on the intact skin. Butamben is less potent and effective than benzocaine. It has a longer latent

period and a shorter duration of action than benzocaine, probably due to its poor water solubility (benzocaine is approximately 2½ times more soluble in water than butamben). The powder is effective if dusted on abraded skin and other open cutaneous lesions.

Butamben picrate is effective on the skin for the temporary relief of pain due to cutaneous lesions in which the skin is damaged and the drug has ready access to the terminal pain receptors. Adriani and Dalili (Ref. 12) found that 1 percent butamben picrate did not obtund the sensation of pain and itch elicited by electrical stimulation of the intact skin. They likewise noted that when butamben picrate was applied to intact erythematous skin burned with ultraviolet light, it did not relieve the discomfort due to the burn. Likewise, the receptors for pain and itch in the burned areas continued to respond to electrical stimulation, indicating that butamben picrate had not penetrated the intact skin and blocked these receptors.

An aqueous solution of 1:2,000 of the picrate is anesthetic to the conjunctiva and cornea and has been used in the eye. However, regardless of the vehicle, picrate is not used or recommended for this purpose for OTC use.

Butamben picrate is an analgesic, anesthetic, and antipruritic agent and can be used for all Category I indications. However, it has been recommended particularly for burns. The claim is made that it combines the anesthetic property of butamben and the antiseptic properties of trinitrophenol (Ref. 5). Picric acid has a phenol coefficient of 4.5. The value of picric acid in the treatment of burns was described by a French medical student in 1896 (Ref. 5). Butamben picrate allegedly leaves the surfaces of the burn flexible and pliable (Ref. 5). Presumably, it acts by coagulating proteins. Butamben picrate possesses some antimicrobial activity, believed to be due to the released picric acid. The current labeling on a product containing butamben picrate ascribes its antimicrobial action to nitromersol which is added to the finished product, but the submission for this product, evaluated by the Panel, ascribes this effect to picric acid (Ref. 5). The Panel concludes that the use of picric acid for treatment of burns is obsolete. Picric acid is not an analgesic and contributes no part to the relief of pain or itching obtained by applying the picrate to cutaneous lesions.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 1 percent concentration of butamben picrate to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warnings:*

(i) "Do not use over extensive areas of the body."

(ii) "This product stains the skin and tissues, clothing, and other objects yellow."

References

(1) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(2) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, pp. 192–193, 1976.

(3) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics,* 12:913–919, 1971.

(4) Adriani, J. and R. G. Zepernick, "Comparative Potency and Duration of Action of Topical Anesthetic Drugs in Man," *Anesthesiology,* 24:120–121, 1963.

(5) OTC Volume 060039.

(6) Lane, C. G. and R. Luikart, "Dermatitis from Local Anesthetics with a Review of One Hundred and Seven Cases from the Literature," *Journal of the American Medical Association,* 14:717–720, 1951.

(7) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Practitioner,* 25:82–86, 1962.

(8) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics, 5th Ed., Macmillan Publishing Co., Inc., New York, p. 391, 1975.

(9) Sollmann, T., "A Manual of Pharmacology and Its Applications to Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, pp. 340, 1957.

(10) Adriani, J., R. Zepernick, J. Arens, and E. Anthement, "The Comparative Potency and Effectiveness of Topical Anesthetics in Man," *Clinical Pharmacology and Therapeutics,* 5:49–62, 1964.

(11) Monash, S., "Topical Anesthesia of the Unbroken Skin," *Archives of Dermatology,* 76:752–756, 1957.

(12) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia,* 50:834–841, 1971.

f. *Camphor.* The Panel concludes that camphor is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient, at a concentration of 0.1 to 3.0 percent, depresses cutaneous receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below. In concentrations higher than 3 percent, but not exceeding 11 percent, camphor stimulates cutaneous receptors and should bear the labeling for topical counterirritants set forth below (Refs. 1 and 2).

Camphor is a member of a cyclic group of hydroaromatic substances known as terpenes (Refs. 1, 3, and 4). Camphor is 2-bornanone, a 2-ketone of heptane which occurs in nature in the camphor tree *(Cinnamum camphora),* an evergreen native to eastern Asia. Natural camphor is obtained from all parts of the camphor tree. Camphor is also made synthetically from alpha-pinene, a constituent of turpentine. Approximately three-fourths of the camphor used is prepared synthetically. Natural camphor is dextrorotatory, while the synthetic preparation is racemic and optically inactive. Both forms are pharmacologically active. Camphor melts at 179.75° C at atmospheric pressure. It sublimes readily. At 25° C, 1 g dissolves in 800 mL water, 1 mL ether, 1 mL alcohol, 0.5 mL chloroform, 0.4 mL acetone, and 1.5 mL oil of turpentine. Camphor, because it is a ketone, is converted by reduction to borneol, a secondary alcohol. Camphor has a peculiar tenacity and cannot be powdered in a mortar until it is moistended with an organic solvent. It liquefies when triturated with menthol, thymol, phenol, and resorcinol. It is not compatible with oxidants such as potassium permanganate. Camphor forms complexes with cresol (camphor metacresol) from which both ingredients can be released. Camphor is freely miscible with volatile and fixed oils. When applied to the skin, camphor produces a feeling of warmth and a mild local anenthetic action that may be followed by numbness (Refs. 1 and 3).

Several camphor products are described in the official compendia. Camphor liniment, National Formulary X, contains 20 percent camphor in cottonseed oil. This preparation is commonly called "camphorated oil." Other topical products containing camphor are camphor and soap liniment, United States Pharmacopeia XIII (4.5 percent camphor); camphor spirit, National Formulary X (10 percent camphor); and camphor ointment, National Formulary IX (20 percent camphor) (Ref. 5).

(1) *Safety.* Clinical use has confirmed that camphor is safe in the dosage range used as an OTC external analgesic.

Camphor is metabolized if ingested orally or assimilated by other routes. Camphor is first oxidized by the liver to campherol and the campherol is then conjugated with glucuronic acid by the liver. The conjugate is excreted into the

urine. Camphor is absorbed from the mucous membranes and at the mucocutaneous junctions. Camphor is absorbed if injected subcutaneously. It is also absorbed from the intact and damaged skin because it is nonionized and lipophilic. Excessive doses may be fatal (Ref. 1).

The minimal lethal dose for rabbits is 2 g/kg. The median lethal dose subcutaneously for rats is 2.2 g/kg. The oral median lethal dose for guinea pigs is 180 mg/kg. In mice, the LD_{50} is 30 mg/100 g when administered intraperitoneally. The estimated minimal lethal dose for man is 2 g when ingested orally. One adult survived ingestion of 1.5 g camphor. Ingesting 0.7 to 1.0 g camphorated oil proved fatal to a child (Ref. 6). Accidental poisoning has occurred from ingesting the oil when it has erroneously been administered for castor oil. Cases continue to the reported. The Panel considered various comments, reports, and editorials submitted to it concerning the toxicity and frequency of poisonings from camphor-containing preparations, particularly in children. The Panel has taken cognizance of these cases of poisoning and those that continue to occur. However, the Panel is unaware of any case of poisoning that has occurred from topical administration despite the fact that camphor, due to its lipophilic nature, is know to penetrate the skin. The Panel is also aware of its use as a component of paregoric (camphorated tincture of opium) which is widely used as an antidiarrheal in adults and children and as a sedative and analgesic in infants and children. The Panel, therefore, considers camphor to be safe for topical use. Camphor in oil was once used parenterally as an analgesic. Systemically, camphor stimulates the central nervous system. Excessive doses produce convulsions which may be fatal. But cases of systemic poisoning from topical application have not been reported. Camphor is not a common skin sensitizer but can, in concentrations above 3 percent, be an irritant. It is used as a counterirritant in topical antirheumatic preparations (Ref. 2).

Of the submissions to the Panel, 12 with claims of counterirritancy contain camphor. In reviewing these submissions, the Panel observed that in no instance was camphor the sole, or even the principal irritant in the formula. Only 1 of these 12 products had a camphor content greater than 6 percent. Eleven of the products had a camphor content ranging from approximately 1 to 6 percent. The average camphor content was approximately 4 percent (Refs. 7 through 16).

Topical camphor products of the counterirritant type have an excellent safety record. Marketing figures from 1972 indicate that 6 counterirritant products containing camphor accounted for 12,000,000 or more sales. Customer compliants were no greater than 1:1,000,000 (Refs. 8 through 10 and 12 through 14).

As previously indicated, the Panel does not consider concentrations of 20 percent camphor poisonous or harmful for topical use. However, the Panel has been unable to find any acceptable reasons for the continued employment of camphor alone as a topical counterirritant at this concentration. In present self-medication practices, the Panel concludes that a maximum camphor content of 11 percent is appropriate and probably no less effective a counterirritant than are higher concentrations. The concurrent use of other irritants, and advances in vehicle formulations support this conclusion. The Panel recommends 11 percent as the maximum concentration of camphor that may be marketed, with appropriate label warnings, in OTC counterirritant self-medication products.

(2) *Effectiveness.* There are studies documenting the effectiveness of camphor as an OTC external analgesic. Due to the wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that camphor is effective for use as an OTC external analgesic.

The Panel has evaluated the topical use of camphor as an analgesic, anesthetic, and antipruritic, and as a counterirritant. In concentration of 3 percent or less by weight, camphor is an effective antipruritic and relieves the discomfort due to skin lesions characterized by itching and burning on the skin at the site of application. It is believed to act upon sensory receptors in the skin in the same manner as the hydroxy or alcohol types of topical anesthetics. In concentrations exceeding 3 percent, particularly when combined with other ingredients that produce conterirritation, camphor stimulates the nerve endings in the skin and induces relief of pain and discomfort in muscle joints and other subcutaneous structures at a site distal to its application on the integument. The counterirritant effects and dosage forms are described below. The Panel emphasizes that two distinct and dissimilar mechanisms are involved in the effectiveness of camphor as a topical analgesic. By one mechanism, the activity of the pain receptors in the skin is obtunded, and by the second mechanism, the receptors inducing pain and other stimuli are stimulated and act by counterirritation (Refs. 1 and 2). Numerous clinical reports regarding the ability of camphor to relieve itch are available (Refs. 1, 2, and 17). Controlled double-blind studies are not available.

Camphor most likely exerts its antipruritic effects in a manner similar to those exerted by the hydroxy or alcohol type of compounds. When applied to the skin it produces a sense of warmth followed by a sensation of numbness. Topically, camphor is weakly antiseptic, but this attribute is of no practical significance as far as effective antimicrobial activity is concerned. In addition to camphor's use as an antipruritic, the Panel evaluated it as a counterirritant. After careful consideration of the irritant characteristics of camphor and the various formulations in which it is currently used, the Panel concludes that camphor is an effective counterirritant (Refs. 7, 8, 9, 11, 12, 14, and 15). The odor of camphor may play a role in the relief of pain (Refs. 1, 2, and 17). The psychological component of the effect of drugs in causing pain relief by their placebo effect cannot be ignored.

(3) *Dosage*—(i) *For use as a topical analgesic, anesthetic, and antipruritic: For adults and children 2 years of age and older:* Apply a 0.1 to 3.0 percent concentration of camphor to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(ii) *For use as a topical counterirritant: For adults and children 2 years of age and older:* Apply a 3 to 11 percent concentration of camphor to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* Based upon the dosage, the Panel recommends the applicable Category I labeling for products containing topical analgesic, anesthetic, antipruritic, or counterirritant active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 220, 1973.

(2) Swinyard, E. A., "Demulcents, Emollients, Protectives and Adsorbents, Antiperspirants and Deodorants, Absorbable Hemostatics, Astringents, Irritants, Sclerosing Agents, Caustics, Keratolytics, Antiseborrheics, Melanizing and Demelanizing Agents, Mucolytics, and Certain Enzymes." *in* "The Pharamacological Basis of Therapeutics," 4th Ed., Edited by

Goodman, L. S. and A. Gilman, The Macmillan Co., New York, p. 993, 1970.

(3) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 219, 1976.

(4) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, Ill., pp. 398–473, 1962.

(5) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 24th Ed., J. B. Lippincott Co., Philadelphia, pp. 208–209, 1950.

(6) Smith, A. G. and G. Margolis, "Camphor Poisoning. Anatomical and Pharmacologic Study; Report of a Fatal Case; Experimental Investigation of Protective Action of Barbiturate," *American Journal of Pathology*, 30:857–869, 1954.

(7) OTC Volume 060008.

(8) OTC Volume 060009.

(9) OTC Volume 060029.

(10) OTC Volume 060030.

(11) OTC Volume 060031.

(12) OTC Volume 060040.

(13) OTC Volume 060050.

(14) OTC Volume 060051.

(15) OTC Volume 060054.

(16) OTC Volume 060062.

(17) Sollmann, T., "A Manual of Pharmacology and Its Applications to Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, pp. 249–252, 1957.

g. *Capsicum preparations (capsaicin, capsicum, capsicum oleoresin).* The Panel concludes that capsicum preparations (capsaicin, capsicum, capsicum oleoresin) are safe and effective for use as OTC external analgesics as specified in the dosage section below. The ingredients stimulate cutaneous sensory receptors and should bear the labeling for topical counterirritants set forth below.

Capsicum is the dried, ripe fruit of *Capsicum frutescens Linne*, known in commerce as African chilies, or of *Capsicum annuum Linne var. conoides Irish*, known in commerce as tabasco pepper, or of *Capsicum annuum var. longum Sendt*, known in commerce as Louisiana long pepper, or of a hybrid between the Honka variety of Japanese capsicum and the old Louisiana sport capsicum known in commerce as Louisiana sport pepper (Fam. Solanaceae). Capsicum must be labeled to indicate which of the above varieties is contained in the package (Ref. 1). Capsicum was first referred to in 1494 by Chauca, a physician who accompanied Columbus on his second voyage to the West Indies (Ref. 1).

The action of capsicum is due to 0.1 to 1 percent capsaicin, a crystalline neutral principle that produces a persistent burning of the tongue in a dilution of 1:100,000 (Ref. 2). Capsicum oleoresin is a concentrate containing all of the active ingredients of capsicum, prepared by percolation of powdered capsicum with appropriate volatile solvents (Ref. 3).

Because of variations between lots of capsicum, the concentration range for this drug cannot be expressed in percentages but must be calculated for each lot from quantitative analytical data.

(1) *Safety.* Clinical use has confirmed that capsicum preparations (capsaicin, capsicum, capsicum oleoresin) are safe in the dosage range used as OTC external analgesics.

Capsicum is a powerful local stimulant. When swallowed, it produces a sensation of heat in the stomach, and a general glow over the body without any narcotic effect. Much used as a condiment, it has also been used for atony of the stomach or intestines (Ref. 4).

The toxicity of capsicum is low. Gastric administration of 28 mL of the oleoresin to fasting young rabbits caused diarrhea and loss of weight, followed by complete recovery; 56 mL was fatal (Ref.2).

Bevan reports that a reflex hypotensive response resulted following the injection of capsaicin (20 micrograms per kilogram (μg/kg)) in the pulmonary arterial tree of the cat. No significant difference was found when the injection was made into the right and left pulmonary arteries both distal to the bifurcation. The hypotensive response was almost absent when the injection was given into the right and left pulmonary hila. Following vagotomy, the hypotensive response disappeared. The results would indicate that sensory afferent endings stimulated by capsaicin are situated somewhere in the pulmonary artery and in the right and left branches proximal to the level of the hilus (Ref. 5).

In anesthetized dogs, intravenously injected capsaicin caused a transient apnea, bradycardia, and hypotension. Blood flow in the mesenteric, renal, and femoral arteries was decreased. However, that of the carotid artery was increased even in a small dose (10 to 25 mg; 45 mg/kg), causing changes in respiration, heart rate, and blood pressure. Cardiac muscle contractility was depressed principally, while capsaicin increased contractility of isolated guinea pig atrium. There is considerable shortening of the apneic phase and lack of bradycardia after vagi were cut. On the other hand, capsaicin caused a drastic increase in blood pressure and characteristic behavioral changes in the unanesthetized dog (Ref. 6).

Smith et al. (Ref. 7) undertook studies to determine whether the erythema and burning sensation caused by the application of capsaicin to human skin is related to lysosomal labilization. They compared its effects with cantharadin and Triton X–100™, both known lysosomal labilizers, on epidermal lysosomes and as vesicants to human glabrous skin. Patch testing of capsaicin 0.1 molar (M) produced erythema and a burning sensation in seven human subjects. The onset of the burning sensation was instantaneous in some cases and required up to 3 minutes to be established in others. Erythema was noted after 5 minutes and lasted up to 3 hours. Erythema was produced with 0.01 M capsaicin in six of the seven subjects and a burning sensation occurred in five of the seven subjects. Only one of the seven subjects developed erythema and a burning sensation with 0.001 M capsaicin applied to glabrous skin. No blisters or wheals were observed.

To summarize, the studies showed the following: Capsaicin produces erythema and a burning sensation without vesication when applied to the human skin. It also labilizes rat liver lysosomes but does not labilize rat epidermal lysosomes. Triton X–100™, a potent liver and epidermal lysosomal labilizer, does not produce blistering on human skin. Cantharides is a potent vesicant and liver lysosomal labilizer but does not labilize rat epidermal lysosomes. Thus, the hypothesis that blistering can result from primary labilization of epidermal lysosomes cannot be supported by experimental evidence from these studies (Ref. 7).

The safety of capsicum is well documented by marketing data. One product containing capsicum has sold more than 38,500,000 units and another in excess of 22,300,000 during the period 1960 to 1972 (Refs. 8 and 9). Another manufacturer reports annual sales of greater than 500,000 trade packages per year (Ref. 10). These manufacturers reported a total of 16 customer complaints for 1972 with none being of a serious nature.

(2) *Effectiveness.* There are studies documenting the effectiveness of capsicum preparations (capsaicin, capsicum, capsicum oleoresin) as OTC external analgesics. In addition, due to their wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that capsicum preparations are effective for use as OTC external analgesics.

When applied to the skin, preparations of capsicum extractions at first produce a sensation of warmth and, with greater concentration, eventually produce an almost intolerable burning sensation. Capsicum differs from other local irritants in producing practically no reddening of the skin even when there is a very severe subjective sensation. While it has a pronounced

irritant effect on the endings of sensory nerves, it has little action upon capillary or other blood vessels. Therefore, it does not cause blistering, even in high concentrations (Ref. 4).

Peterson et al. (Ref. 10), in their study of responses of the skin to counterirritants (rubefacients), applied nine different conterirritants, including 5 percent tincture of capsicum, to the skin of five human subjects. The skin of the upper back was used for the application of the counterirritant ointments. Eighty mg of each counterirritant ointment preparation was applied with the same technique. Thereafter, the degrees of erythema and skin temperature of each site were observed at 5-minute intervals for a minimum of 30 minutes. The Sargent Thermistor unit recorded changes in skin temperature. Erythema was graded 0 to 3+ (1+ for slight erythema, 2+ for moderate, and 3+ for marked erythema). Several of the preparations which evoked no erythema or temperature elevation included 5 percent tincture of capsicum along with tincture of cantharides, methyl salicylate, Peruvian balsam, and Unibase ™ control. Those producing erythema and temperature changes were nicotinic acid, tetrahydro-furfuryl ester of nicotinic acid, camphor, and mustard oil. The quantitative inunction of counterirritant ointments had little or no effect on the cutaneous response of the subject using other counterirritants, e.g., methyl nicotinate, that did produce erythema. The degree of rubor and the temporal development of rubor were unaffected by the gradation of inunction. Graded inunction resulted in only minor deviation in degree of skin temperature elevation and likewise in temporal development of same. The skin temperature elevations evoked by counterirritants seem to parallel quantitatively the extent of erythema produced. Maximal erythema usually precedes maximal temperature rise by several minutes (Ref. 5).

Although capsicum and its derivatives are powerful counterirritants, they do not have rubefacient activity. They produce practically no redness and have little effect upon the capillaries or other blood vessels. The therapeutic effectiveness of topically administered capsicum or its derivatives has not been adequately studied. However, the sensation of warmth produced upon application is an important consideration which is highly acceptable to the patient.

In all submissions to the Panel, either capsicum oleoresin or capsaicin was employed in combination with other counterirritant ingredients in a manner considered both rational and appropriate by the Panel (Refs. 9 through 12).

Capsicum preparations have been effectively used as OTC external analgesics in concentrations of 0.025 to 0.25 percent capsaicin, or an equivalent concentration of capsicum or capsicum oleoresin.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.025 to 0.25 percent concentration capsaicin, or a percent concentration of capsicum or percent concentration of capsicum oleoresin that yields the equivalent of 0.025 to 0.25 percent concentration capsaicin, to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical counterirritant active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Claus, E., V. Tyler, and L. Brady, "Pharmacognosy," 6th Ed., Lea and Febiger, Philadelphia, pp. 211–212, 1970.

(2) Sollmann, T., "A Manual of Pharmacology and Its Application to Therapeutics and Toxicology," 8th Ed., W. B. Saunders and Co., Philadelphia, p. 162, 1957.

(3) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 24th Ed., J. B. Lippincott Co., Philadelphia, p. 216, 1950.

(4) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 223, 1973.

(5) Bevan, J. A., "Action of Lobeline and Capsaicine on Afferent Endings in the Pulmonary Artery of the Cat," *Circulation Research*, 10:792–797, 1962.

(6) Neno, A., "Cardiovascular Action of Capsaicin in Dogs and Unanesthetized Dogs with Radiotelemeter Folio," *Pharmacology (Japanese)*, 67:572–579, 1971.

(7) Smith, J. G., R. G. Crounse, and D. Spense, "The Effects of Capsaicin on Human Skin, Liver, and Epidermal Lysosomes," *Journal of Investigative Dermatology*, 54(2):170–173, February, 1970.

(8) OTC Volume 060030.

(9) OTC Volume 060033.

(10) OTC Volume 060077.

(11) OTC Volume 060031.

(12) OTC Volume 060040.

h. *Dibucaine.* The Panel concludes that dibucaine is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Dibucaine is a synthetic topical anesthetic of the "caine" type, derived from quinoline (Ref. 1). It was introduced in 1929 by McElwain (Refs. 2 and 3). Its chemical name is butyl oxychinchoninic acid diethyl ethylenediamide. It is in no way related to quinine as its name may suggest. Thus, it is not an ester but an amide. It was one of the first of the amides to be adopted for clinical use. Its chemical configuration follows closely the general characteristics of the "caine" type of drugs (Refs. 2 and 4).

Dibucaine is a tertiary amine and, therefore, a base that reacts with acids to form salts, the most common of which is the hydrochloride. The free base is a colorless or almost colorless powder that melts at 63° to 64° C. The powder darkens on exposure to air. As is the case with other bases of the topical anesthetics of the "caine" type, it is poorly soluble in water. It is readily soluble in ether and various other organic solvents, in fatty oils, and in oleaginous bases.

The hydrochloride salt is a white, tasteless powder which melts at 90° to 98° C. The melting point is not sharp. It is very soluble in water (one part dissolves in 0.5 part water) and in organic solvents such as benzene, acetone, and chloroform. It is insoluble in ethers and oils. Aqueous solutions have pH range of 6.2 to 6.5. Alkaline substances such as hydroxides, carbonates, and bicarbonates readily precipitate the base from aqueous solutions. Solutions must be prepared in distilled water and stored in alkaline-free glass; otherwise, the drug will precipitate out due to the action of alkali in the glass. Solutions of salts of dibucaine are stable when boiled. Dibucaine is compatible with epinephrine. Dibucaine has also been marketed under such names as percain (British), chinchocaine sovcaine, benzoline, and cincaine. The U.S.P. name and the one that is accpeted is dibucaine. The hydrochloride salt is more stable than the base (Refs. 1, 2, 4, and 5). The salt is poorly soluble in oils or nonwater-soluble bases but soluble in glycols.

(1) *Safety.* Clinical use has confirmed that dibucaine is safe in the dosage range used as an OTC external analgesic.

Dibucaine is a synthetic amide type topical anesthetic derived from quinoline (Refs. 2 and 6). It is a base that forms salts with various acids. The most frequently used salt is the hydrochloride. Dibucaine is a "caine" type drug and closely follows the chemical configuration of " caine" type drugs in having an amino group, dimethylene chain, and aromatic nucleus. Dibucaine is one of the most potent and longest lasting of the topical

anesthetics. Dibucaine is approximately 15 times more potent and toxic than procaine, which has been used as the reference standard in clinical studies. Consequently, only one-fifteenth as much dibucaine would be required to achieve the same effect as a given amount of procaine. The absolute toxicity is 15, but the relative toxicity compared to procaine is 1. Toxicity, of course, depends upon the site and mode of application, and the vascularity of the tissues as well as the mode and rate of biotransformation. The lethal dose in man, therefore, is unknown. In mice, the acute LD_{50} intravenously is 2.8 mg/kg compared to 21 mg/kg, for procaine and 11 mg/kg for cocaine. In rabbits, intravenous dibucaine is six times as toxic as cocaine (Ref. 7). Dibucaine produces central nervous system stimulation and myocardial depression characteristic of the "caine" type of drugs when recommended doses are exceeded and high plasma levels result. Fatalities have been reported from use of the maximal tolerable dose following infiltration, perineural injection, or topical application to the mucous membranes. Ten cases of acute intoxication in children were reported after oral ingestion of topical preparations. Four were fatal. Six children survived the reaction to the overdose. An additional case was reported after rectal use of an ointment marketed for OTC rectal use. This case was a fatal reaction following rectal instillation in a 2-month-old infant. These cases were documented in an adverse reaction reporting system extending from 1951 to 1972 (Ref. 8).

During the long period of marketing experience, cutaneous reactions due to irritancy and allergy have been low. Patch testing in controlled studies in man and a review of the literature by Lane and Luikart (Ref. 9) reveal that the incidence of sensitization reactions is low and no greater than that observed with procaine, tetracaine, benzocaine, and cylcomethycaine (Ref. 9). Dibucaine can act as a haptene and be antigenic. Anaphylactic and other allergic-type reactions are possible but have not been reported after topical use.

Dibucaine has been regarded as a toxic anesthetic by physicians. Relatively speaking, however, it is no more toxic than procaine, tetracaine, lidocaine, and similarly acting drugs. Dibucaine's chief danger lies in its potency, because one-tenth to one-fifteenth as much of it would be required as of lidocaine or procaine. Although systemic reactions from application to the intact skin are uncommon, it could be obsorbed if used too liberally in topical application over wide areas of damaged or abraded skin or mucous membranes. This systemic absorption may result in convulsions, myocardial depression, and death (Ref. 5).

Dibucaine must not be ingested orally because it is absorbed from the intestines. Fatalities have been reported from accidental ingestion by children. Sensitization can occur but is uncommon. Marketing history shows 2.6 cases of adverse reactions per million units sold (Ref. 8).

(2) *Effetiveness.* There are studies documenting the effectiveness of dibucaine as an external analgesic.

Dibucaine is one of the most potent and longest lasting topical anesthetics. It is approximately 15 times more potent than procaine and 3 to 6 times more potent than cocaine. Like other topical anesthetics, dibucaine acts by stabilizing the neuronal membrane of the pain receptors in the skin. It has been used extensively for spinal anesthesia, topical anesthesia on the mucous membranes and skin, and to a lesser extent, for infiltration and nerve blocking. Its period of latency when used intrathecally may be as long as 10 minutes. Its duration of action intrathecally is approximately 3 hours. This latency and long duration are also manifested when dibucaine is used by other routes (Ref. 2).

Adriani and Dalili (Ref. 10) noted that a concentrated solution in propylene glycol, alcohol, and water obtunded the response of receptors for pain and itch within 15 minutes. This effect lasted as long as a moist film remained on the skin, which was as long as 4 hours in some cases. When the film was wiped from the skin, response to the stimulation was reestablished within 15 minutes.

Dibucaine base readily penetrates the intact skin. Its action on the skin is superficial because it acts on the cutaneous receptors and remains in direct contact continuously when incorporated in a suitable medium that provides a film that remains moist. The concentrations absorbed systemically from the skin are insufficient to relieve pain in subcutaneous structures or in muscles, tendons, or other deeper structures. It is suitable, therefore, only for those situations involving pain, burning, or itching of the skin as specified in the labeling section below. The usual effective dosage range applied topically on the skin is 0.25 to 1 percent.

(3) *Dosage—For adults and children 2 years of age or older:* Apply a 0.25 to 1.0 percent concentration of dibucaine to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not use in large quantities, particularly over raw surfaces or blistered areas."

References

(1) Adriani, J., "Local Anesthetics," *in* "The Pharmacology of Anesthetic Drugs," 5th Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 131–145, 1970.

(2) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(3) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, p. 990, 1975.

(4) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 413, 1973.

(5) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Practitioner,* 25:82–86, 1962.

(6) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics,* 12:913–919, 1971.

(7) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, p. 435, 1955.

(8) OTC Volume 060013.

(9) Lane, C. G. and R. Luikart, "Dermatitis from Local Anesthetics with a Review of One Hundred and Seven Cases from the Literature," *Journal of the American Medical Association,* 146:717–720, 1951.

(10) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia,* 50:834–841, 1971.

i. *Dibucaine hydrochloride.* The Panel concludes that dibucaine hydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

The general characteristics of dibucaine hydrochloride have been discussed elsewhere in this document. (See part III. paragraph B.1.h. above—Dibucaine.)

(1) *Safety.* Clinical use has confirmed that dibucaine hydrochloride is safe in the dosage range used as an OTC external analgesic.

The remarks above concerning the safety of dibucaine base are also applicable to the hydrochloride. (See part III. paragraph B.1.h.(1) above—

Safety.) As with other topical anesthetics, dibucaine hydrochloride penetrates damaged epithelial barriers and exerts an analgesic effect on pain receptors and other receptors in the skin and on receptors in structures immediately beneath the epithelial layers. It passes into the tissue fluids and gains access to the systemic circulation. Even though dibucaine hydrochloride is about 15 times more potent and toxic than procaine, a proportional reduction in the quantity used results in a hazard no greater than that found with other local anesthetics. Therefore, reactions from the use of therapeutic doses on the skin are uncommon.

Systemic absorption may result in convulsions, myocardial depression, and death (Ref. 1). Dibucaine hydrochloride is absorbed from open lesions and damaged and abraded skin, but not from the intact epithelial barriers (Refs. 2 and 3). The possibility that sufficient quantities may be absorbed from extensive areas of damaged skin exists. The Panel, therefore, recommends that statements to this effect be included in the labeling and that the use of dibucaine hydrochloride preparations be restricted to areas not exceeding 25 percent of the body surface. Obviously, a statement defining areas of body surface will have little meaning to users of OTC products in most cases. Because the hydrochloride is more soluble in the water of tissue fluids than is the base, the Panel calls attention to the greater hazard that exists from the rapid absorption from damaged skin and the greater possibility of systemic reactions when hydrochloride preparations are used.

Sensitization has been reported but is uncommon.

(2) *Effectiveness.* There are studies documenting the effectiveness of dibucaine hydrochloride as an OTC external analgesic. In addition, due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that dibucaine hydrochloride is effective for use as an OTC external analgesic.

When absorbed by the buffering mechanisms in the tissues, dibucaine hydrochloride is converted to the base (Ref. 4). Its mechanism of action is similar to dibucaine base. Dibucaine hydrochloride penetrates the intact skin so slowly that quantities absorbed are not effective. Adriani and Dalili (Ref. 5) reported that the sensation of pain and itch elicited by electrical stimulation of the skin were not obtunded by application of 1 to 2 percent ointments and creams containing dibucaine hydrochloride. They also noted that these same preparations afforded no relief to the burning and itching sensation of both intact and damaged skin that had been exposed to ultraviolet light. On the other hand, saturated solutions of the base in 40 percent propylene glycol, 20 percent alcohol, and 40 percent water were effective and abolished both the discomfort and the ability of receptors in this area of skin to respond to electrical stimulation that had continued to exist when the hydrochloride preparations were used. On damaged skin, dibucaine hydrochloride is as effective as the base in concentrations ranging from 0.25 to 1.0 percent. Claims for effectiveness on the intact skin cannot be made for any of the salts (Ref. 5). Therefore, the Panel does not recommmend a dose for use on the intact skin.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.25 to 1.0 percent concentration of dibucaine hydrochloride to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not use in large quantities, particularly over raw surfaces or blistered areas."

References

(1) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Parctitioner,* 25:82–86, 1962.

(2) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics,* 12:913–919, 1971.

(3) Monash, S., "Topical Anesthesia of the Unbroken Skin," *Archives of Dermatology,* 76:752–756, 1957.

(4) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp 398–473, 1962.

(5) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia,* 50:834–841, 1971.

j. *Dimethisoquin hydrochloride.* The Panel concludes that dimethisoquin hydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Dimethisoquin is an aminoethoxy derivative of isoquinoline (Refs. 1 and 2). It is chemically allied to dibucaine, which is a quinoline derivative, but differs from dibucaine because dimethisoquin is derived from isoquinoline and is not an amide. Also, dimethisoquin differs from other local anesthetics in that it is a modification of the configuration common to the "caine" type drugs. The dimethylene chain or pivot is linked to the 2 position of the isoquinoline nucleus by an ether linkage. It is a tertiary amine having 2 methyl groups in addition to the main portion of the molecule on a nitrogen atom. Dimethisoquin is, therefore, a base that combines with acids to form salts, the most important of which is the hydrochloride. The base is a liquid that boils between 155° to 157° C. The hydrochloride, the ingredient used in OTC preparations, is a white crystalline powder. One g dissolves in approximately 8 mL of water, 3 mL of alcohol, and 2 mL of chloroform. It is very slightly soluble in ether. The crystals of the salt melt at approximately 146° C (Refs. 2 and 3). It has also been known as isochinol, pruralgen, and pruralgin.

(1) *Safety.* Clinical use has confirmed that dimethisoquin hydrochloride is safe in the dosage range used as an OTC external analgesic.

The oral LD_{50} of dimethisoquin hydrochloride in rats in approximately 250 mg/kg. Intraperitoneally the LD_{50} is 45 to 50 mg/kg; intravenously the LD_{50} ranges between 4.5 to 5.0 mg/kg. It is far less toxic than dibucaine. Comparable doses of dibucaine are within a 2.0 to 2.5 mg/kg range. In rabbits, the LD_{50} of dimethisoquin hydrochloride administered intravenously was 4 to 6 mg/kg, compared with the LD_{50} of dibucaine, which was 2.0 to 2.5 mg. In dogs anesthetized with sodium pentobarbital, dimethisoquin caused cardiac and respiratory depression. Because the barbiturate nullifies the central nervous system stimulating effects of local anesthetics, it could not be determined from these studies whether dimethisoquin causes convulsions.

Chronic toxicity studies of dimethisoquin hydrochloride were done in which relatively large quantities of the drug were administered intraperitoneally to guinea pigs for a period of 30 days, after which the animals were sacrified. The tissues were examined histologically. No discernible pathologic changes were found that could be attributed to the tested substance (Ref. 5). Similar studies in

guinea pigs were likewise negative as far as histological examinations were concerned (Ref. 5).

Convulsions, cardiac depression, and other manifestations of local anesthetic toxicity characteristic of the "caine" type drugs have not been observed or reported in humans.

In the early clinical studies of dimethisoquin hydrochloride, it was administered in lozenges containing 5 to 7 mg of the drug to 254 patients for various pharyngeal and laryngeal infections that were accompanied by pain. The drug was also administered to patients with peptic ulcers. No evidence of systemic toxicity with dimenthisoquin was observed after oral ingestion. Marketing experience reveals a lack of data on any adverse reactions in humans. Since the marketing of dimethisoquin, there were no reports from 1951 to 1972 of any reactions attributed to the topical anesthetic.

There is no significant data indicating that dimethisoquin causes any local irritancy when applied as an ointment or a lotion to the skin and mucous membranes. Dimethisoquin hydrochloride-containing preparations have a low sensitizing potential. Only 4 cases of sensitivity were reported to the manufacturer in over 2,200 cases (Ref. 5). Two were believed to be due to the vehicle rather than to the active ingredients. Two other cases of sensitivity reactions of dimethisoquin hydrochloride ointment have been reported in the literature since the products were marketed (Ref. 5). One patient had a patch test that was positive to dimethisoquin hydrochloride. In the other case that was reported it was undetermined whether the patch test was due to the material in the ointment or to the active ingredient itself. Since dimethisoquin hydrochloride can act as a haptene, the possibility that allergic reactions may occur cannot be discounted, but the extensive marketing experience, in the opinion of the Panel, indicates that allergy is not a problem of any magnitude or seriousness.

Fellows and Macko (Ref. 6) conducted studies of the inhibition of cell growth by various topical anesthetics using human epidermis. They reported that the order of increasing inhibition of cell growth is saline, procaine, boric acid, resorcinol, dimethisoquin, dibucaine, and mercuric chloride.

(2) *Effectiveness.* There are studies documenting the effectiveness of dimethisoquin hydrochloride as an OTC external analgesic.

Dimethisoquin hydrochloride is effective topically on the mucous membranes and on abraded and scarified skin. Fellows and Macko (Ref. 6) reported that dimethisoquin hydrochloride was 1,000 times more active than cocaine and 10 times more active than dibucaine when applied to the cornea of rabbits. The intradermal potency was found to be 100 times greater than procaine. Although these studies do not establish its effectiveness on the intact and damaged (broken) skin, they do establish that dimethisoquin possesses topical anesthetic activity.

Adriani et al. (Ref. 4) also observed that dimethisoquin possessed topical anesthetic activity when applied to the tip of the tongue. The duraton of action was less than 10 minutes, compared to 50 minutes for dibucaine. Anesthesia was only partial, and complete obtundation was not obtained. Complete abolition of the sensation or pain induced by electrical stimulation was not obtained even with potent drugs such as cocaine, tetracaine, dibucaine, lidocaine, and others. These subjects, however, felt numbness in other areas of the oral cavity. Because the tip of the tongue appears to these investigators to be more difficult to anesthetize, they conceded that dimethisoquin does possess topical anesthetic activity, but not to the degree that corneal anesthesia in the rabbit would suggest.

Whether dimethisoquin hydrochloride penetrates the intact (unbroken) skin is debatable, because this does not appear to be so with other topical anesthetics that are more potent and more effective when applied directly to nerve tissues. Studies on the penetration of the base (dimethisoquin) of this derivative are not available.

Dimethisoquin is not used for perineural injection. Its mode of action is presumed to be similar to that of the other nitrogen-containing anesthetics, i.e., by stabilization of the neuronal membrane. There are an adequate number of claims for effectiveness for the relief of pruritus and painful conditions of the skin based on subjective studies. (Reports are available on over 1,700 patients with various forms of dermatitis and proritus treated with dimethisoquin hydrochloride ointment and lotion (Ref. 6)). In most cases, the concentration of dimethisoquin hydrochloride in the preparation was 0.5 percent, although some of the early investigations used both lower and higher concentrations in an attempt to determine the most effective and least irritating level.

The most extensive experiences with dimethisoquin hydrochloride ointment and lotion have been those of the group at the Hospital of the University of Pennsylvania under the direction of D. M. Pillsbury. In 1952, this group prepared a report detailing experiences with 1,000 patients who had been treated with dimethisoquin preparations over a period of 3 years. The investigators stated that "in a strength of 0.3 to 0.5 percent dimethisoquin hydrochloride ointment produced the relief of pruritus in 85 to 90 percent of the patients to whom the treatment was given. This is approximately 20 percent more than obtained any degree of relief from the ointment base alone" (Ref. 5).

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.3 to 0.5 percent concentration of dimethisoquin hydrochloride to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(2) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 436–437, 1973.

(3) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 427, 1976.

(4) Adriani, J., R. Zepernick, J. Arens, and E. Authement, "The Comparative Potency and Effectiveness of Topical Anesthetics in Man," *Clinical Pharmacology and Therapeutics*, 5:49–62, 1964.

(5) OTC Volume 060026.

(6) Fellows, E. J. and E. Macko, "The Topical Anesthetic Activity of an Isoquinoline Compound," *Journal of Pharmacology and Experimental Therapeutics*, 103:306–309, 1951.

k. *Diphenhydramine hydrochloride.* The Panel concludes that diphenhydramine hydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Diphenhydramine is an amine derived from ethylene diamine. It is a base that forms a salt with hydrochloric acid (Refs. 1 and 2). Diphenhydramine possesses various pharmacologic actions which include anticholinergic, antihistaminic, antiemetic, topical anesthetic, and hypnotic activities. It is used orally, intravenously, and topically. It is most effective when used systemically.

Diphenhydramine hydrochloride occurs as a white, odorless, crystalline powder. It slowly darkens on exposure to light. The solution is practically neutral to litmus. One g dissolves in 1 mL water, 2 mL alcohol, 2 mL chloroform, and 50 mL acetone. It is very slightly soluble in benzene and in ether. Diphenhydramine hydrochloride melts between 166° and 170° C.

Diphenhydramine was the first antihistaminic drug available in the United States. It has served as a standard for comparison in the study of the many other antihistamines now available. In 1945, Loew et al. (Ref. 3) applied the antihistaminic concept by using diphenhydramine as an antagonist to histamine. Its efficacy in the relief of urticaria was demonstrated by Curtis and Owens (Ref. 4), and its effectiveness in hay fever and vasomotor rhinitis, by others (Refs. 5).

(1) *Safety.* Clinical use has confirmed that diphenhydramine hydrochloride is safe in the dosage range used as an OTC external analgesic.

If drowsiness is included, the incidence of side effects obtained with the systemic use of diphenhydramine hydrochloride is high, being 46 percent of 1,210 patients reported by Sachs (Ref. 6), 61 percent of 655 cases reported by Loveless (Ref. 7), and 77 percent of 52 cases reported by McGavic et al. (Ref. 8). If drowsiness is excluded, the incidence of side effects is low. Other side effects include dizziness, dry mouth, lassitude, and nausea. In ambulatory patients, drowsiness and dizziness create an accident-causing hazard due to impaired psychomotor function. Despite its sedative and hypnotic effect, diphenhydramine hydrochloride has no tendency to cause dependence. Asthmatic seizures have been precipitated by diphenhydramine hydrochloride in some asthmatics after oral or parental use. Barbiturate and other hypnotic sedation is prolonged when used concomitantly with diphenhydramine hydrochloride, orally or parenterally.

Toxic doses in animals produce a complex syndrome predominately neurogenic in origin, involving the motor, sensory, and autonomic nervous systems (Ref. 9). Manifestations include excitement, irritability, spastic ataxia, mydriasis, hyperesthesia, and convulsions. Respiratory and cardiac failure may result from massive overdosage.

Death of a 2-year-old child following accidental ingestion of 474 mg diphenhydramine hydrochloride has been reported (Ref. 10). The symptoms included lethargy, coma, shallow respiration, and cyanosis followed by nervousness, twitching, convulsions, fever, and tachycardia. The child died 13 hours later. A 3-year-old child who accidentally swallowed 780 mg diphenhydramine hydrochloride recovered. When convulsions occur after ingestion of diphenhydramine hydrochloride, they are of the intermittent clonic type. The pupils become dilated and fixed. Coma associated with apnea, cyanosis, and vascular collapse develops.

Studies of the metabolism of diphenhydramine hydrochloride in rats and guinea pigs reveal that the highest concentration of the drug is found in the lung, spleen, and liver 1 hour after oral or parenteral administration. After 6 hours, little can be found in the animal. Only 5 to 15 percent of a dose can be found unchanged in the urine in 24 hours. Studies of the drug labeled with radioactive carbon ^{14} indicate that degradation products are formed and excreted in the urine. The tissue presence of enzymes that have such a degrading action was demonstrated by Glazko and Dill (Ref. 11).

Diphenhydramine hydrochloride is absorbed from damaged skin and, like other drugs absorbed from the skin, gains access to the blood stream. In view of diphenhydramine hydrochloride's low degree of toxicity when used orally or parenterally, the Panel does not consider systemic toxicity from topical application to be a question of major importance. The Panel is unaware of any instance of systemic toxicity reported from the topical use of diphenhydramine hydrochloride. The incidence of topical irritancy is low. The Panel does caution that diphenhydramine hydrochloride can act as a haptene and cause sensitization and systemic as well as topical allergic manifestations, particularly after repeated frequent use.

The increasing incidence of acquired sensitivity to the antihistaminic creams is discussed by Ellis and Bundick (Ref. 12). These authors indicate that the antipruritic action of topical antihistaminic drugs is most useful for 1 to 2 weeks to prevent continued trauma of scratching and to permit permanent healing. However, the loss of efficacy is frequent after using the drugs for 3 to 4 weeks. Sensitivity often develops after this period of use. The Panel does not recommend use for longer than 7 days except under the advice and supervision of a physician.

(2) *Effectiveness.* There are studies documenting the effectiveness of diphenhydramine hydrochloride as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that diphenhydramine hydrochloride is effective for use as an OTC external analgesic.

Diphenhydramine hydrochloride and other antihistaminic drugs are specific blocking agents that when administered systemically, diminish or abolish the effects of histamine on smooth muscle and in the exocrine glands (Refs. 1, 13, and 14). They inhibit the spasmogenic action of histamine on smooth muscle in the uterus. Diphenhydramine hydrochloride prevents histamine from increasing the permeability of capillary endothelium and inhibiting the vasodilating action on the capillaries. In therapeutically effective doses, diphenhydramine does not inhibit the stimulating action of histamine on gastric secretion. The antiallergic reaction of diphenhydramine hydrochloride is due to its antagonistic effect on histamine. It binds at cell receptors for histamine, thereby preventing histamine from acting on a cell because the cell receptor is already occupied when histamine is released. This is the rational basis for its use as a prophylactic agent (Ref. 14). Therapeutic doses have no significant effect on the blood pressure, heart, and gastrointestinal tract. Diphenhydramine hydrochloride protects the body from the effects of both exogenous and endogenous histamine (Ref. 14).

Diphenhydramine hydrochloride does not overcome the various physiologic responses to histamine by an opposing pharmacologic action as is the case with epinephrine, aminophylline, and other drugs. Diphenhydramine hydrochloride provides symptomatic relief in allergic disorders by protecting the cells from the effects of free histamine released from pathologic conditions. Any effect antihistamines exert topically is due to their antagonistic effect on histamine. Histamine may be released in the skin and subcutaneous structures due to the action of allergen-antibody responses, and from trauma due to mechanical, chemical, and other causes. It is generally conceded that if the receptors are occupied by histamine, the antihistamine cannot act. Diphenhydramine hydrochloride has a feeble anticholinergic and topical anesthetic effect (Ref. 15). The anticholinergic effect is of no consequence in considering topical use. Diphenhydramine hydrochloride acts in the same manner as do topical anesthetics and does not penetrate the epithelial barrier when the drug is applied to the intact skin (Ref. 1).

Diphenhydramine hydrochloride is used orally, parenterally, and topically

for the symptomatic treatment of urticaria, hay fever, and other allergic disorders caused by histamine. Diphenhydramine hydrochloride has considerable sedative action that is utilized orally or parenterally where sedation is therapeutically useful, but should be avoided in individuals engaged in hazardous activities. Sedation is not a problem of concern when the drug is used topically on the skin in localized areas of the body. Diphenhydramine hydrochloride has been effectively used as a topical antipruritic ingredient in concentrations ranging from 1 to 2 percent (Ref. 16).

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 1 to 2 percent concentration of diphenhydramine hydrochloride to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredient. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 441–442, 1973.

(2) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 442, 1976.

(3) Loew, E. R., M. E. Kaiser, and V. Moore, "Synthetic Benzhydryl Alkamine Ethers Effective in Preventing Fatal Experimental Asthma in Guinea Pigs Exposed to Atomized Histamine," *Journal of Pharmacology*, 83:120–129, 1945.

(4) Curtis, A. C. and B. B. Owens, "Beta Diphenhydramine Benzhydryl Ether Hydrochloride (Benadryl) in Treatment of Urticaria," *Archives of Dermatology and Syphilology*, 52:239–242, 1945.

(5) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, pp. 1060–1061, 1975.

(6) Sachs, B. A., "The Toxicity of Benadryl: Report of a Case and Review of the Literature," *Annals of Internal Medicine*, 29:135–144, 1948.

(7) Loveless, M. H., "Therapeutic and Side Effects of Pyribenzamine and Benadryl, A Comparative Study Based Upon a Survey of 26 Clinical Reports in the Literature," *American Journal of Medicine*, 3:296–308, 1947.

(8) McGavack, T. H., J. Weissbergh, and L. I. Boyd, "Comparison of the Toxic Manifestations Produced by Beta-Dimethylaminoethyl Benzhydryl Ether Hydrochloride (Benadryl) and Tripelennamine (Pyribenzamine)," *Journal of Laboratory and Clinical Medicine*, 33:595–601, 1948.

(9) Gruhzit, O. M. and R. A. Fisken, "A Toxicologic Study of Two Histamine Antagonists of the Benzhydryl Alkamine Ether Groups," *Journal of Pharmacology*, 89:227–233, 1947.

(10) Davis, V. H. and M. H. Hunt, "Accidental Benadryl Poisoning: Report of a Fatal Case," *The Journal of Pediatrics*, 34:358–361, 1949.

(11) Glasko, A. J. and W. A. Dill, "Biochemical Studies on Diphenhydramine (Benadryl) Distribution in Tissues and Urinary Excretion," *Journal of Biological Chemistry*, 17:403–408, 1949.

(12) Ellis, F. A. and W. R. Bundick, "Appraisal of Topical Use of Antihistamines," *Journal of the American Medical Association*, 150:773–776, 1952.

(13) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 1090–1098, 1977.

(14) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 146–150, 1973.

(15) Adriani, J., R. Zepernick, J. Arens, and E. Authement, "The Comparative Potency and Effectiveness of Topical Anesthetics in Man," *Clinical Pharmacology and Therapeutics*, 5:49–62, 1964.

(16) OTC Volume 060095.

1. *Dyclonine hydrochloride.* The Panel concludes that dyclonine hydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Dyclonine does not conform to the general configuration of the commonly used topical anesthetics of the "caine" type drugs, such as lidocaine and tetracaine (Ref. 1). Dyclonine is a propiophenone derivative. One end of the dimethylene chain of the ketone is attached to the nitrogen atom of the piperidine group of the first carbon atom which carries the ketonic group. This is attached directly to a benzene ring which is attached to a butoxy group in the para position. Thus, unlike procaine and lidocaine, it is neither an amide nor an ester, nor can it be considered an ether, as is the case with pramoxine. Dyclonine is a base that forms salts with hydrochloric acid (Ref. 2).

Dyclonine hydrochloride is a white crystalline powder. One g dissolves in approximately 50 mL water. It is soluble in acetone, alcohol, and chloroform. The crystals melt at between 173° to 178° C. It is also soluble in washable cream bases. The chemical name is 4-*n*-butoxy-*beta*-piperidinopropiophenone hydrochloride (Ref. 2).

(1) *Safety.* Clinical use has confirmed that dyclonine hydrochloride is safe in the dosage range used as an OTC external analgesic.

Although dyclonine is a nitrogenous base, its chemical structure departs from that of the "caine" type drugs (Refs. 2 and 3). For this reason, acute systemic toxicity characterized by convulsions, myocardial depression, hypotension, etc., which are characteristic of the so-called "caine" type drugs, do not occur.

The acute LD_{50} for dyclonine hydrochloride was studied by Abreu and associates (Ref. 4) in dogs and albino rats. In rats, the LD_{50} intraperitoneally was approximately 45.8 mg/kg, and in dogs, the LD_{50} was approximately 9.5 mg/kg. Abrue also noted that in anesthetized dogs, doses of 2 mg/kg intravenously did not significantly affect blood pressure or pulse, nor did they reduce the cardiovascular response to acetylcholine. They also did not increase the response to epinephrine, as demonstrated by a lack of parasympatholytic activity. Doses of 5 mg/kg in anesthetized dogs may cause respiratory failure, but this is reversible and the animals recover if respiration efforts are used.

The cardiovascular effects of dyclonine were investigated in dogs anesthetized with sodium barbital. The drug was administered over a 25-second period with a dose range of 0.25 to 10 mg/kg in 10 dogs. Dyclonine lowered arterial pressure approximately 10 mm mercury at a dose of 1 mg/kg. There was a progressive increase in response at doses of 1, 2, 3, 4, and 5 mg/kg with death being produced at a dose of 10 mg/kg. The mechanism of this reduction in activity was due to a decrease in cardiac output as well as to peripheral arterial dilatation. Initially, dyclonine hydrochloride induces some respiratory stimulation when the drug is administered intravenously to dogs. As the dosage is increased, depression of respiration and oxygen consumption occurs. Dyclonine was demonstrated to act as an anticonvulsant, a multisynaptic and spinal reflex depressant of the central nervous system (Ref. 5).

Chronic toxicity studies were done with dyclonine hydrochloride in the albino rat and in the dog. Dyclonine hydrochloride did not significantly affect the growth rate of male or female weanling albino rats as compared to controls when it was administered intraperitoneally for 30 consecutive days. A total of 48 rats divided evenly as to sex, drug groups, and controls were employed using one-fourth and one-half the intraperitoneal LD_{50} of the adult rat. At the end of the experimental period, half the animals were sacrificed, at which time no gross pathologic changes were observed. When mated, the drug-treated survivors did not differ from controls in their reproductive

capacity. Upon weaning, the offspring of the first group, when subjected to the same experiment, also did not differ from their controls either in growth rate or reproductive capacity. No gross pathologic changes were observed in these animals when sacrificed. Experimental observations in dogs given doses varying from 5 to 12 mg/kg twice daily likewise showed no gross pathologic changes, intramuscularly or subcutaneously. No significant changes from normal were noted in hemoglobin concentration, red and white blood cell counts, and white cell differential counts which were measured at biweekly intervals (Ref. 5).

In man, dyclonine hydrochloride possesses a relatively low degree of toxicity. When the ingredient was applied topically to the skin of 3,656 patients in the form of a cream and to 2,000 additional cases in the form of a solution for topical anesthesia, only 2 cases of proven sensitivity were reported. It was concluded from these studies that the sensitizing potential of dyclonine hydrochloride under conditions of clinical use is low. In a study using a dyclonine hydrochloride solution, no adverse effects were found.

In a study dealing with the safety of dyclonine hydrochloride following oral administration, 35 patients were given from 300 to 600 mg daily for periods of time varying from 1 to 12 weeks. No undesirable side effects occurred. It was concluded that the compound would be entirely safe for human consumption (Ref. 5). Adriani and Campbell (Ref. 6) emphasized that the two safest topical anesthetics for use on the mucous membranes for endoscopic procedures are benzocaine and dyclonine hydrochloride, because they show the lowest incidence of systemic reactions.

(2) *Effectiveness.* There are studies documenting the effectiveness of dyclonine hydrochloride as an OTC external analgesic.

Dyclonine hydrochloride is a highly effective topical anesthetic, particularly on mucous surfaces and on the abraded and damaged skin. Although it is also an effective nerve-blocking agent, it is irritating and may produce slough in the tissue. It is, therefore, recommended for topical use only. Dyclonine hydrochloride blocks transmission at nerve endings in the same manner as do other topical anesthetics closely related to, or of, the "caine" type drug. Dyclonine is a base and, like other topical anesthetics, is not absorbed through the intact skin. The base is unstable. The product is marketed as a salt (hydrochloride). Dyclonine hydrochloride is not absorded through the intact skin in quantities sufficient to produce analgesia. In studies on mucous membranes conducted by Adriani, Zepernick, and co-workers (Ref. 7), dyclonine ranked fourth (after dibucaine, cocaine, and tetracaine) in effectiveness in producing analgesia. One percent dyclonine produced analgesic action of 27 minutes, with a latent period of 2 to 3 minutes. The fact that dyclonine is effective on the mucous membranes is established. Dalili and Adriani (Ref. 8) noted that a 1-percent solution of the hydrochloride did not obtund the effect of electrical stimulation while eliciting the sensation of burning and itching on the skin. When the skin was burned with ultraviolet light, the application of the solution produced an exaggeration of the discomfort rather than relief (Ref. 7). Concentrations as low as 0.5 percent have been found to be effective as a topical analgesic on damaged skin.

Morginson et al. (Ref. 5) observed the antipruritic proper ties of a 1-percent dyclonine hydrochloride cream in a study of 222 patients with various forms of dermatoses. The preparation was effective in controlling pruritus in 127 (57 percent) of the patients and was without effect in 95 patients (43 percent). A 1-percent dyclonine hydrochloride cream and also the vehicle without dyclonine hydrochloride were used in paired studies in 33 patients (Ref. 5). The dyclonine hydrochloride cream produced relief from itching in every case. No relief was produced by the vehicle alone.

Employing a double-blind study, Orentreich, Berger, and Auerbach (Ref. 5) evaluated the degree of anesthetic effect of a 1-percent dyclonine hydrochloride cream used on 58 patients with various pruritic and/or painful dermatoses. Thirty patients showed improvement, 4 patients became worse, and 24 patients showed no change.

Marks conducted a study of the effect of 1 percent dyclonine hydrochloride cream in post-anorectal surgical patients throughout the healing period (Ref. 5). The anesthetic action of the 1-percent dyclonine hydrochloride preparation was prompt and satisfactory, with wounds remaining clean. Waterlogging was absent, and granulations were firm with rapid epithelialization.

Gomez observed the anesthetic action of a 1-percent dyclonine hydrochloride cream on 50 patients who had undergone episiotomies (Ref. 5). The effects of the 1-percent dyclonine hydrochloride cream were compared with the effects produced by known topical anesthetics in 25 other patients who had undergone episiotomies. Further comparison was made, under similar circumstances, between the effects of the 1-percent dyclonine hydrochloride cream and the effects produced by sterilized vaseline in 10 additional patients. In patients who were treated with the 1-percent dyclonine hydrochloride cream, results were good to excellent in 44 patients (88 percent), and little or no effect was observed in 6 patients (12 percent). Of the 25 patients who were treated with known topical anesthetics, good to excellent results were noted in 68 percent (17 patients). The remaining 32 percent (8 patients) received little or no benefit from the known topical anesthetics. Good results were obtained in 2 (20 percent) of the 10 patients treated with sterile vaseline. Little or no effect was observed in the rest of this group (Ref. 5).

Shelmire et al. conducted a study in which patients with various forms of pruritic and painful lesions received topical application of a 1-percent dyclonine hydrochloride cream (Ref. 5). Of a total of 200 patients who received an adequate followup, 113 (56.5 percent) experienced complete relief from pain and/or pruritus, and 31 patients (15.5 percent) received no benefit.

Noojin investigated the effect of a 1-percent dyclonine hydrochloride cream in 335 patients with pruritic dermatoses (Ref. 5). Improvement was observed in 256 patients (76.4 percent), while there was no change observed in 48 patients (14.3 percent). In 31 patients (9.2 percent), the pruritus worsened.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 1.0 percent concentration of dyclonine hydrochloride to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Adriani, J., "Absorption and Systemic Toxicity of Local anesthetics," *General Practitioner*, 25:82–86, 1962.

(2) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 467–468, 1973.

(3) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(4) Abreu, B. E., A. B. Richards, L. C. Weaver, G. R. Burch, C. A. Bunde, E. R. Bockstahler, and D. L. Wright, "Pharmacologic Properties of 4-Alkyloxy-Beta-(1-Piperidyl) Propiophenones," *The Journal of Pharmacology and Experimental Therapeutics*, 115:419–426, 1955.

(5) OTC Volume 060025.

(6) Adriani, J. and D. Campbell, "Fatalities Following Topical Application of Local Anesthetics to Mucous Membranes," *Journal of the American Medical Association,* 162:527–530, 1956.

(7) Adriani, J., R. Zepernick, J. Arens, and E. Authement, "The Comparative Potency and Effectiveness of Topical Anesthetics in Man," *Clinical Pharmacology and Therapeutics,* 5:49–62, 1964.

(8) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics,* 12:913–919, 1971.

m. *Histamine dihydrochloride.* The Panel concludes that histamine dihydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient stimulates cutaneous sensory receptors and should bear the labeling for topical counterirritants set forth below.

Histamine dihydrochloride ($C_5H_9N_3.2HCl$) is the salt of the histamine base. Histamine is partly responsible for the actions of aqueous extracts of ergot, and was formerly named ergamine and ergotidine. It is found in many tisses, generally in the inert form. It is derived from histadine by the loss of the carboxyl from the amido groups, by bacterial action in the intestines, and by putrefaction (Refs. 1 and 2).

(1) *Safety.* Clinical use has confirmed that histamine dihydrochloride is safe in the dosage range used as an OTC external analgesic.

Marketing data support the safety of histamine dihydrochloride. One manufacturer reported sales of more than 22,300,000 units between 1960 and 1972, with 6 complaints in 1971 and 10 complaints in 1972 (Ref. 3). A second manufacturer has averaged more than 500,000 trade packages per year, with an average of 2 to 4 complaints per year (Ref. 4).

Histamine is present and bound in some inactive form in most tissues of the body, notably the lungs, mast cells, and leukocytes (Ref. 5). When administered by mouth it has little effect because it is destroyed in the digestive tract, but when it is injected subcutaneously or intravenously it produces intense direct stimulation of the tonus or rhythm of smooth muscle (Ref. 2). The acute toxicity differs considerably among various species and circumstances. Mice show a high resistance to histamine toxicity with an LD_{50} of 2.5 g/kg after intraperitoneal injection. Their resistance appears connected with the adrenal medulla. Excision of the adrenals increases the toxicity a hundred times to 0.025 g/kg (Ref. 2).

The systemic effects of histamine dihydrochloride are increases in heart rate, cardiac output, pulmonary ventilation, and metabolic rate (Ref. 6). As the concentration increases, there is a decrease in blood pressure, a feeling of generalized flushing and warmth about the head and neck, and sometimes headache. Overdosage with histamine is rare and symptoms are commonly, if not always, more alarming than dangerous (Ref. 7). The topical effects are similar to topical heat application (Ref. 8). There is vasodilation. The response suggests mediation by a nerve-conducting mechanism.

Shelley and Melton (Ref. 9) observed that penetration of histamine base through intact skin was accelerated by increasing the concentration of histamine in the vehicle, using histamine in the form of the base and a suitable liquid vehicle. The skin is permeable to the base and impermeable to the salt (Ref. 9). The slightest break in the integrity of the skin led to a very rapid penetration of histamine. No systemic manifestations of histamine toxicity were noted in this study (Ref. 9).

Kling (Ref. 10) in 1934 demonstrated pronounced effects on the peripheral circulation when a 1:100 histamine solution infiltrated skin through a needle prick or was applied to a scratch on the skin's surface. The disadvantage of using this technique was that the scratches persisted for about 1 week.

Hummon has used histamine dihydrochloride, in the form of a 1:1,000 solution or a 1-percent ointment, in the administration of histamine by ion transfer (Ref. 6). Hummon stated, "In all our experience with histamine ion transfer we have observed 8 unfavorable reactions, none of them severe, the patients usually complaining of a fullness and throbbing in the head and headache. All of the patients had histamine ion transfer without difficulty at other times, either before or after the unfavorable reaction" (Ref. 6).

The Panel does not question the safety of using low concentrations of histamine dihydrochloride (0.025 to 0.10 percent) for OTC use.

(2) *Effectiveness.* There are studies documenting the effectiveness of histamine dihydrochloride as an OTC external analgesic.

To be effective as a counterirritant, histamine dihydrochloride must penetrate healthy intact skin. Histamine was first administered percutaneously by iontophoresis to produce local dilation of blood vessels (Ref. 11). Kling found that vigorous massage was required in order to cause percutaneous absorption of histamine from an ointment vehicle containing other medical agents (Ref. 12).

Fulton el al. applied histamine to the cheek pouch of hamsters and observed increased circulation produced through dilation of small arterioles (Ref. 8). Shelley and Melton found aqueous vehicles superior to ointments for percutaneous administration of histamine. Application of histamine at the 1-percent level to the intact skin of human subjects showed marked subject-to-subject variation, while 0.1 percent solution of histamine salt or base was generally ineffective. They noted that the slightest break in skin integrity led to very rapid penetration of histamine (Ref. 9).

A report published in 1953 states that the penetration of histamine through the skin is greatly enhanced by topical inunction of a histamine-containing product which also contains methyl nicotinate (Ref. 4). In the report it is postulated that the methyl nicotinate "opened the door" of the skin to the histamine. However, the Panel finds no additional evidence to support the theory that methyl nicotinate may serve as a vector to promote the percutaneous absorption of histamine salts (Ref. 13).

Selle (Ref. 14) reported that the application of histamine dihydrochloride by iontophoresis during physical therapy resulted in vasodilitation and caused an increase of blood flow in the area and a resultant increase in temperature. Histamine dihydrochloride and not the base is used when the administration of histamine is desired. Histamine dihydrochloride, in an aqueous solution or ointment, hydrolyzes into histamine ion, hydrogen ion, and chloride ion. The administration of histamine by ion transfer has been used by Hummon in the treatment of the various forms of arthritis and peripheral vascular diseases (Ref. 6). Hummon observed that in patients with acute traumatic and post-traumatic conditions, treatment by histamine ion transfer resulted in improvements equal to or better than those obtained with heat, massage, and exercise.

Histamine has been used to relieve myalgia. Two methods of application of histamine have been used in conjunction with iontophoresis. In one method, a gauze pad was connected to the positive pole of the apparatus and moistened with a 1:5000 solution of histamine. Then a current of 5 to 15 milliamperes was applied for 5 to 30 minutes. The second method consisted of applying a 2-percent histamine ointment to the skin under an anode. The anode consisted of a gauze pad moistened with isotonic sodium chloride solution. A current of 5

to 15 milliamperes was again applied for 5 to 30 minutes. (Ref. 14).

Histamine dihydrochloride has been effectively used as a topical counterirritant in concentrations of 0.025 to 0.10 percent.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.025 to 0.10 percent concentration of histamine dihydrochloride to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical counterirritant active ingredients. (See part III. paragraph B. 1 above—Category I Labeling.

References

(1) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 583–585, 1973.

(2) Sollmann, T., "A Manual of Pharmacology and Its Application To Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, pp. 538–540, 1957.

(3) OTC Volume 060033.

(4) OTC Volume 060077.

(5) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, p. 1056, 1975.

(6) Hummon, I. F., "Histamine Ion Transfer: A Five Year Evaluation," *Archives of Physical Therapy*, 25:212–216, 1944.

(7) Goodson, W., D. Hahn, T. Hunt, and D. Y. K. Leung, "Augmentation of Some Aspects of Wound Healing by a 'Skin Respiratory Factor,' " *Journal of Surgical Research*, 21:125–129, 1976.

(8) Fulton, G. P., G. M. Farber, and A. P. Moreci, "The Mechanism of Action of Rubefacients," *The Journal of Investigative Dermatology*, 33:317–325, 1959.

(9) Shelly, W. B. and F. M. Melton, "Factors Accelerating the Penetration of Histamine through Normal Intact Human Skin," *Journal of Investigative Dermatology*, 13:61–71, 1949.

(10) Kling, D. H., "Histamine Therapy of Rheumatic Affections and Disturbances of the Peripheral Circulation," *Annals of Surgery*, 99:568–576, 1934.

(11) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, p. 649, 1955.

(12) Kling, David H., "A Histamine Ointment for Cataphoresis and Inunction in Rheumatic Affections and Diseases of the Peripheral Circulation," *Medical Record*, p. 291, 1939.

(13) Freeman, G. R., "DMSO in Otology." *Laryngoscope*, 86:921–929, 1976.

(14) Selle, W. A., "Histamine—Its Physiological, Pharmacological and Clinical Significance," *Texas Reports on Biology and Medicine*, 4:138, 1947.

n. *Hydrocortisone preparations (hydrocortisone, hydrocortisone acetate).* The Panel concludes that hydrocortisone and hydrocortisone acetate are safe and effective for use as OTC antipruritics as specified in the dosage section below. The ingredients depress cutaneous sensory receptors and should bear the labeling for topical antipruritics set forth below.

Hydrocortisone is a naturally occurring steroid found in the adrenal cortex. It is cortisone in which the ketone group on carbon 11 has been converted to a hydroxyl group by the addition of two hydrogen atoms. It is also known as cortisol.

Hydrocortisone is a white powder that is very slightly soluble in water, chloroform, or ether, but is soluble in alcohol. Hydrocortisone is also available as the acetate, which is likewise insoluble in water, and as the phosphate, sodium phosphate, and sodium succinate, which are freely soluble in water.

Hydrocortisone has been marketed in the United States since 1952 as a prescription drug. An effort to change this status was attempted 4 years after its introduction. From August 15 to 17, 1956, FDA held open hearings in Washington, D.C. to examine a petition request for possible transfer of hydrocortisone and hydrocortisone acetate from prescription to OTC status for preparations intended for topical use.

Major discussion centered around three questions: (1) Are ointments and lotions containing not more than 2.5 percent hydrocortisone or hydrocortisone acetate safe for use without a prescription when they are applied to the skin not more than twice daily for not more than 5 days, for the relief of itching and inflammation associated with minor skin irritations? (2) Are ointments or lotions of hydrocortisone or hydrocortisone acetate safe for use without prescription under other conditions of composition and/or labeling? Is a warning against use of such preparations in the presence of infection necessary for safe use without a prescription when the hydrocortisone or hydrocortisone acetate is combined with antibiotic drugs such as oxytetracycline hydrochloride or neomycin sulfate?

Based on this hearing, the Commissioner of Food and Drugs, in a statement published in the **Federal Register** of January 17, 1957 (22 FR 353), denied the proposed exemption of hydrocortisone and hydrocortisone acetate from current prescription status. The resulting action was based on a failure to show safety for self-medication and a need for more testing for percutaneous absorption.

In the **Federal Register** of April 28, 1971 (36 FR 7982), FDA listed the pre-1962 topical corticosteroid products recognized as safe and effective. The listing was a result of a review by the National Research Council of the National Academy of Sciences, which had been submitted a short time before. This document stated that 0.5, 1.0, and 2.0 percent hydrocortisone products in different types of vehicles are generally recognized as safe and effective. It was thus established that FDA recognizes that topical hydrocortisone in concentrations of 0.5 to 2.0 percent is safe and effective for steroid-responsive dermatoses when the drug is used as directed as a prescription drug.

(1) *Safety.* Clinical use as a prescription drug has confirmed that hydrocortisone and hydrocortisone acetate are safe in the dosage range recommended by the Panel for use as OTC external analgesics.

(i) *Animal safety data.* The acute oral LD_{50} of hydrocortisone was found to be 1,800±520 mg/kg in male mice, 800±150 mg/kg in female mice, more than 6 g/kg in rats, approximately 175 mg/kg in guinea pigs, and approximately 400 mg/kg in cats (Ref. 1).

A determination was made by Tonelli as to the acute toxicity of corticosteroids, including hydrocortisone in rats, resulting from single subcutaneous injections of each test material in a vehicle containing 0.5 percent carboxymethyl cellulose, 0.4 percent polysorbate 80, and 0.9 percent sodium chloride (Ref. 2). Five groups of eight rats each were injected with 360, 720, 1,080, 1,440, or 1,800 mg/kg of the hydrocortisone preparation. Deaths did not occur until the seventh day following administration. The median lethal dose was determined to be greater than 1,800 mg/kg at day 7,591 mg/kg at day 14, and 449 mg/kg at day 21. Throughout the study there were no deaths among the rats treated with the vehicle alone. Autopsies of several corticosteroid-treated animals revealed multiple small abscesses in the lungs, kidneys, and/or liver.

To test his hypothesis that the principal causes of death among the test animals were due to supervening infections and generalized septicemia, Tonelli repeated the above study and added 0.1 percent chlortetracycline, a broad-spectrum antibiotic, to the diet of one-half of the test animals. The number of deaths among the hydrocortisone-treated rats receiving the medicated diet was significantly reduced. During the 21-day study, only 4 of 40 hydrocortisone-treated rats receiving the medicated diet died, compared with 29 of 40 hydrocortisone-treated animals receiving the nonmedicated diet. The median lethal dose for the hydrocortisone-treated animals receiving a medicated diet was greater

than 2,400 mg/kg at days 7 and 14 and approximately 2,400 mg/kg at day 21. Tonelli concluded that "Corticosteroid lethality increased with time. The principal cause of death was a generalized septicemia, as evidenced by abscess formation in major organs presumably due to suppression of the animal's immune-response mechanism. Concomitant administration of a broad-spectrum antibiotic reduced the toxicity of four of the five corticosteroids tested." The Panel notes that Tonelli also concluded that hydrocortisone was found, based upon median lethal dose determinations, to be significantly less toxic than any of the six other glucocorticoids (i.e., triamcinolone, triamcinolone acetonide, dexamethasone, prednisolone, 21-deoxytriamcinolone acetonide, and 9 *alpha*, 11 *beta*-dichloro-21-hydroxy-16 *alpha*, 17 *alpha*-(isopropylidenedioxy)-1, 4-pregnadiene-3,20-dione) tested in both of the above studies.

Subacute toxicity studies performed by various investigators viewed the effects of corticosteroids on total body weight loss, and the long-term effects of inhibition or reduction of deoxyribonucleic acid (DNA) synthesis on various body structures including circulating lymphocytes.

Such studies performed by Stevens et al. in adrenalectomized mice supported previous findings that corticosteroids with certain molecular structures "diminish the mass of lymphatic tissue and decrease the number of circulating lymphocytes" apparently "by bringing about destruction and enhancing the maturation and death of lymphocytes as well as inhibiting their proliferation" (Ref. 3). The test animals received intraperitoneal injections of 1 mg hydrocortisone acetate in 0.25 mL 0.9 percent saline, and then received injections of 1 microcurie thymidine-2-^{14}C at various times before being sacrificed 30 minutes after the later injection. The time intervals studied ranged from 7 to 360 minutes after the administration of the hydrocortisone acetate preparation. There was a significant decrease in the weight of the spleen per 100 g of body weight after 120 and 360 minutes and in the weight of the thymus per 100 g of body weight after 360 minutes. Neither the spleen, thymus, nor lymph nodes showed a significant change in the total amount of DNA or ribonucleic acid (RNA) apparently "due to the phagocytosis of nuclear and cytoplasmic debris by macrophages and preferential loss of other cytoplasmic constituents." The lymph nodes and thymi showed a significant decrease in the incorporation of thymidine-2-^{14}C into DNA at 120 minutes and thereafter. Stevens et al. concluded that "whatever other effects corticosteroids have on lymphocytes, they do inhibit the synthesis of DNA as measured by the incorporation of thymidine-2-^{14}C." According to Stevens et al., two factors may be responsible for the inhibition of DNA synthesis in the thymi and lymph nodes produced by hydrocortisone: a destructive effect of the hormone on the lymphocytes and the effect of the hormone on metabolic processes in such cells, the result of which is a decrease in DNA synthesis.

Ingle et al. demonstrated the quantitative differences in the biologic properties of corticosterone and its oxygenated derivative, hydrocortisone (Ref. 4). Subcutaneous injections of various amounts (0.5 to 5.0 mg daily) of each compound in a sesame oil vehicle (0.5 mL per injection) were administered in divided daily doses to 5 infection-free male rats immediately following force feedings of a high carbohydrate diet. At the 5-mg daily dose, glycosuria with hyperglycemia was induced in 80 percent of the test animals receiving hydrocortisone (maximum glycosuria value of more than 9 g of gulcose daily) as opposed to 40 percent of those receiving corticosterone (maximum glycosuria value of over 2 g daily). At this daily dosage level, hydrocortisone produced a more marked loss of body weight and a greater increase in the excretion of sodium, chloride, potassium, and nitrogen. At lower daily doses, hydrocortisone, but not corticosterone, produced a temporary increase in sodium, chloride, and nitrogen excretion and caused a definite loss of body weight.

As a followup to published reports that glucocorticoids inhibit mitosis and have been demonstrated autoradiographically to inhibit the healing of gastric ulcer and regeneration of the liver after partial hepatectomy, Lahtiharju et al. (Ref. 5) conducted an autoradiographic study comparing the effect of a single corticosteroid dose on DNA synthesis of cells of the stomach and other organs in white male mice. The abdominal cavities of the test animals were injected with single doses of 1.0 mg hydrocortisone or 0.05, 0.1, or 0.5 mg dexamethasone followed by an injection of 1 microcurie per gram (μC/g) of ^{3}H-thymidine 5 hours later. Control animals initially received injections of physiological saline. The animals were decapitated 1 hour after receiving the ^{3}H-thymidine injection. Autoradiograms of tissue samples were prepared, and the percent ratio (thymidine index) of the labeled cells was counted. After a single does of either of the two corticosteroids, "a significant decrease in DNA synthesis was established autoradiographically in the epithelial cells of the mouse stomach and a slight decrease was established in the duodenal cells and the cells of the liver mesenchyma." The investigators observed that the corticosteroid-treated mice showed no evidence of hepatocyte inhibition.

Ingle and Meeks studied the biologic effects of continuous subcutaneous injections of hydrocortisone and cortisone in normal male rats force-fed a medium carbohydrate diet (Ref. 6). Aqueous solutions of 1, 2, or 4 mg of each corticosteroid in 5 percent ethanol and 0.9 percent sodium chloride were administered by continuous subcutaneous injection for 10 days. The third load remained constant at 20 mL/rat/day. The investigators reported that "the indices of hypercorticalism were weight loss, negative nitrogen balance, glycosuria, atrophy of the adrenal cortex and of the thymus, and gross pathologic changes, such as renal damage and stomach ulcers. The extent of response was related to the dose of each steroid. The quantitative activity of hydrocortisone was approximately twice that of cortisone as indicated by each of the several indices of hypercorticalism."

Investigation into the safety of hydrocortisone use on healing tissues has also been reviewed by the Panel. Reynolds and Buxton observed aberrations produced by exogenously administered hydrocortisone in healing regenerative tissue of male albino rats (Ref. 7). The test animals were wounded by excising a 2-cm circle of skin, extending to, but not including, underlying fascia, from the shaved dorsum of each animal. On the fifth postwounding day, 15 test animals received intramuscular injections of 25 mg/kg hydrocortisone daily for 6 days. The investigators reported that "administration of exogenous hydrocortisone inhibits contraction of open skin wounds, with lysis of cell components and increasing both protein and non-protein nitrogen components, but particularly the non-protein fraction." The large amounts of non-protein nitrogen fragments suggested, and microscopic examination confirmed, a reduction in fibril formation, and high glutamic oxalacetic transaminase (GOT) concentrations indicated a sustained cell destruction which was also confirmed by microscopic examination. A simultaneous accumulation of sialic acids indicated a continuing polysaccharide matrix. A hypocellular

and hypofibrillar wound with delayed contraction and little tensile strength thus resulted.

Vogel studied the effects of corticosteroids on wound tensile strength in male rats when the corticosteroids were administered at various phases in the wound-healing process (Ref. 8). An incision approximately 3 cm long was made down to the fascia in the shaved dorso-lumbar region of each test animal. The test animals received daily subcutaneous injections of 5 or 50 mg/kg hydrocortisone and were sacrificed on days 3, 6, 9, 12, or 20 following wounding. Wound tensile strength was decreased between days 3 and 9 in direct proportion to the dose administered, with the greatest decrease occurring on day 6. Vogel reported the following:

On the 12th day and even more distinctly on the 20th day after operation, a reversal of this effect could be observed. Low doses of glucocorticoids resulted in an increase in wound tensile strength, whereas high doses, already toxic after prolonged administration, still caused a decrease. If treatment was started at the end of the collagen phase (11th day), only an increase in wound tensile strength was seen, regardless of the dose of glucocorticoid administered. Short-term treatment during the scar phase (day 19 to 20) resulted in an increase in wound tensile strength which correlated with the dose and potency of the glucocorticoid given. It is therefore concluded that scar tissue of wounded skin reacts like normal connective tissue as far as the increase in tensile strength induced by glucocorticoids is concerned.

Corticosteroids can alter the functions of various enzymes and hormones in the body, as shown by various studies of these effects and their relation to the organ system. Pomerantz and Chuang found that subcutaneous injections of hydrocortisone in hamsters resulted in a decrease in tyrosinase activity which could be prevented by concurrent administration of B-melanocyte stimulating hormone (MSH) (Ref. 9). The investigators reported that hydrocortisone may lower tyrosinase by blocking the release of endogenous MSH and that "it seems likely that conditions in man and other mammals that result in elevated levels of MSH are associated with increases in skin tyrosinase and that the increased enzyme produces the dark skin or hair pigmentation."

Hall and Hall administered 0.5 mg of the water-soluble phosphate form of hydrocortisone twice daily by subcutaneous injection to nine female Holtzman strain rats for 21 days. Then one test animal was sacrified. No appreciable thymic or adrenal atrophy was evident in this test animal at necroscopy, and none of the remaining animals showed significant growth retardation. One mg of a microcrystalline acetate suspension of hydrocortisone was administered once daily by subcutaneous injection to the eight remaining test animals. All animals were sacrificed on day 51 of the study. The investigators reported that inhibition of growth rate was slight during the first 11 days when the phosphate ester of hydrocortisone was administered but became pronounced when the acetate form was substituted (Ref. 10). Macroscopic examination at the time of autopsy showed marked adrenal and thymic atrophy and hypertrophy of the preputial glands. Histologic examination revealed no evidence of cardiac pathology, although the glomeruli of the kidneys "showed intense and irregular capillary dilatation with hypertrophy of the visceral lamina of Bowman's capsule, and the presence of the same curious vesicular structures as have been found to result from cortisone overdosage."

A number of the published studies reviewed by the Panel discuss effects of various doses of corticosteroids on both thymolytic activity and permeability changes in the vascular systems of the body. The systemic anti-inflammatory activities as measured by thymolytic activity of hydrocortisone, betamethasone, and six commercially available topical steroid preparations (i.e, 0.1 percent betamethasone valerate lotion, 0.025 percent fluocinolone acetonide lotion, 0.1 percent triamcinolone acetonide lotion, 0.05 percent flurandrenolone cream, 0.1 percent fluperolone acetate ointment, and 0.02 percent flumethasone pivalate lotion) were compared by Child et al. in intact male and female weanling WAG strain albino rats and female ICI mice. The results were comparable to their topical vasoconstrictor activity in healthy human subjects (Ref. 11). The steroids were injected subcutaneously into the test animals twice daily for 2 successive days, and the thymus glands were removed and weighed on day 3. The relative potency of each steroid was calculated using as metameters the logarithm of the dose and the thymus weight (mice) or the square root of the thymus weight (rats) with covariance corrected for initial body weight. Using the vasoconstrictor test described by McKenzie and Atkinson (Ref. 12), Child et al. applied serial dilutions of each steroid to the flexor surfaces of both forearms of male and female human subjects. After 16 hours the occulsive dressings were removed and the forearms were examined for vasoconstricted patches. Hydrocortisone was found to be the least active, both topically and systemically, among all the steroids tested. Except for betamethasone and betamethasone valerate, there was close correlation betwen the topical and systemic activity rankings of each steroid within the group. The topical activity of hydrocortisone was calculated to be less than 0.1 based on a value of 100 established for fluocinolone acetonide. Hydrocortisone ranked sixth in the group in terms of topical activity. It is important to note that Child et al. concluded, "Although comparison of activity in animals and man is limited by species variation and route of administration, the agreement shown between the ranking orders of topical and systemic activities suggest that in general they are related."

Weston et al. investigated the cellular effect of hydrocortisone on tuberculin reactions in guinea pigs relative to determining the mechanism by which hydrocortisone suppressed delayed hypersensitivity reactions (Ref. 13). One week after sensitization with complete Freund's adjuvant, tuberculin-sensitized Hartley strain guinea pigs received intraperitoneal injections of 10 mg (0.4 mL) hydrocortisone daily for 4 days. Control animals received daily injections of 0.4 mL intraperitoneal saline for 4 days. The investigators reported that "differential cell counts of biopsy specimens revealed that cortisol treatment resulted in a greater reduction in macrophages than small lymphocytes. This disproportionate reduction in macrophages, viewed from the migration inhibitory factor (MIF) model of delayed hypersensitivity, shows that either the sensitized lymphocyte is unable to produce and release MIF or the macrophage itself cannot respond to MIF when treated with cortisol." It was further reported that hydrocortisone therapy consistently resulted in an actual decrease in the diameter of both erythema and induration, and that it significantly reduced the intercellular edema of the epidermis associated with tuberculin skin tests. Retesting three months following hydrocortisone therapy showed the skin tests of the treated and untreated animals were quite similar, thus indicating that the suppressive effect of hydrocortisone was not permanent under the conditions of this study. Weston et al. concluded that the study suggests that hydrocortisone "is exerting its effect on the recruitment or migration of non-

sensitized cells, rather than by eliminating the sensitized lymphocyte itself."

Lykke, Willoughby, and Houck (Ref. 14) studied the effects of hydrocortisone-released protease preparations from rat skin upon the vascular permeability of the rat as a followup to the findings of Houck and Patel (Ref. 15) and Spector (Ref. 16). Houck and Patel observed that, after the injection of hydrocortisone, the extracellular and extrafibrillar compartment of rat skin contains a nonlysosomal, neutral pH optimal proteolytic enzyme that can be inhibited by both soybean trypsin inhibitor and salicylates (Refs. 15 and 17). Spector determined that some proteolytic enzymes are capable of increasing the permeability of the microcirculation (Ref. 16) Hydrocortisone-released protease preparations were prepared from the shaved and cleaned skin of 3 groups of 12 male Sprague-Dawley rats 26 hours after the subcutaneous injection, and 2 hours after the intraperitoneal injection, of 3 mg/kg hydrocortisone. For control purposes, similar preparations were prepared from rats that received injections of the carrier solvent for the above hydrocortisone preparation. Lykke, Willoughby, and Houck (Ref. 14) determined that extracts from the hydrocortisone-treated rats contained a protease, whereas this protease was lacking in extracts from the skin of untreated rats. These investigators reported that intradermal injections of low concentrations of the hydrocortisone-released protease preparation into the shaved abdominal skin of rats resulted in increased vascular permeability and emigration of leukocytes. They concluded, however, that "this protease appears to exert its vascular permeability-enhancing effect by a mechinism that would not seem to rely on the release or activation of many of the well recognized mediators" (i.e., release of histamine and serotonin or formation of vasoactive kinins). According to Lykke et al., a potent permeability factor associated with the systemic treatment of rats with steroids "could well explain the apparent lack of effect of steroids on acute inflammation consisting mainly of increased vascular permeability * * * whereas it is effective against the more chronic type of inflammatory lesion."

Paulsen and Rerup demonstrated that hydrocortisone was capable of penetrating the skin of rats and exerting systemic effects as indicated by involution of the thymus (Ref. 18). One-tenth mL of the acetate or free alcohol form of various concentrations (0.25, 0.5, or 1.0 percent) of hydrocortisone solutions or suspensions in several vehicles (i.e., polyethylene glycol, olive oil, chloroform plus olive oil, physiological saline, or ointment base) was evenly applied once daily for 3 days to the shaved backs of 24- to 28-day-old female rats. Immediately after each application, the treated area was protected by a collar placed around the neck, and the animals were then isolated in glass jars for 2.5 hours. After that time, the shaved areas were washed with acetone to remove possible residues of the hydrocortisone compound. The test animals were sacrificed 72 hours after the first application, and the thymus of each rat was then removed and weighed. The control animals were shaved, handled, and isolated in the same manner as the hydrocortisone-treated animals. The investigators reported that "both the absolute thymus weights and the thymus weights per 10 g of body weight were reduced to less than 30% of those of the control group after cutaneous application of hydrocortisone" and that the difference was highly significant (p = less than 0.001). Paulsen and Rerup could detect no significant difference in results between the various media in which hydrocortisone was dissolved or suspended. A significant dose-response relationship was established once the values were corrected for body weight variance.

In a study conducted by Tonelli, Thibault, and Ringler, the thymolytic activity in rats of various concentrations (250 to 16,000 μg/mL) of hydrocortisone in a 1-percent croton oil vehicle was determined. Each test material was applied topically to the right ear of each of six rats. For control purposes, the vehicle was applied to the right ears of 10 rats. Six hours later both ears of each animal were removed and weighed. Forty-eight hours after application of the above hydrocortisone preparations and vehicle, the test animals were sacrificed, and the thymi were then removed, weighed, and expressed as mg thymus/100 g of body weight. The investigators reported that the effects of the 500 and 1,000 μg/mL concentrations of hydrocortisone on thymus weight were not significant but were highly significant at higher concentrations. They further determined on the basis of radioactivity data that between 22.7 and 28.8 percent of the amount of hydrocortisone applied to the animals' ears was absorbed during the first 6 hours following application (Ref. 19).

The Panel recognizes that demonstration of safety is an essential factor for consideration in topical application of cortisones to the skin. The following animal studies were reviewed by the Panel to observe effects due to systemic absorption or alterations to the skin surface when directly treated.

Baker and Montes noted histochemical changes in the skin of rats following topical applications of a 1-percent hydrocortisone in 25 percent ethanol solution for a period from 61 to 140 days (Ref. 20). Twice daily throughout the study, 0.1 mL of the hydrocortisone solution was applied to an area just caudal to the right ears of 39 Long-Evans rats. The hair in this area was clipped initially and at weekly intervals thereafter. For control purposes, 0.1 mL of the 25-percent ethanol solvent was similarly applied to identical test sites on 39 Long-Evans rats of the same average body weight (314 g). Skin samples were excised from both the treated area on the right side of each animal's neck and from the left, or untreated, side at the termination of the study, with the result that each animal served as its own control. The investigators reported that "treatment with alcohol alone did not modify the skin significantly." They noted, however, that after prolonged local application of hydrocortisone, "Nonspecific esterase was reduced in sebaceous glands. Total DPN diaphorase and lactic dehydrogenase activities were reduced in epidermis coincident with thinning of this structure. These enzymes, in addition to succinic dehydrogenase and cytochrome C oxidase, remained active in the smaller cells of the treated epidermis. Nonspecific esterase, DPN diaphorase, lactic dehydrogenase, and cytochrome C oxidase were depleted from connective tissue cells and the external epithelial sheath of the hair follicle as they underwent involution due to hormone action."

Castor and Baker observed cutaneous modifications resulting from prolonged topical application of various adrenocortical hormones, including hydrocortisone on nontraumatized skin (Ref. 21). Various adrenocortical hormones in a 25-percent alcohol solution were applied daily to the skin of the neck, caudal to the right ear, of 43 adult rats for as long as 180 days. Cortisone and hydrocortisone were administered in daily doses of 25 to 100 mg dissolved in 0.1 mL 25 percent alcohol. Several animals received 0.1 mL daily of a 25-percent alcohol solution of an extract derived from hog adrenal glands which, in terms of liver glycogen units, was equivalent to 1 mg/mL cortisone. For control purposes, 23 test animals received daily applications of

0.1 mL of the 25-percent alcohol solvent. At various times during the study, microscopic examinations were made of biopsies of skin taken from symmetrical areas behind the ears. The investigators summarized their findings as follows:

> The prolonged percutaneous application of adrenocortical hormones modified the histology of the skin, the changes induced being limited to the area of treatment. The epidermis became thinner and, in males, the size of the epidermal cells was reduced. Growth of hair ceased and sebaceous glands became smaller. The thickness of the dermis was reduced, apparently due to loss of substance from the collagenous fibers,the elastic fibers remaining numerous in spite of the treatment. Fibroblasts and other cells of the dermal connective tissue were fewer in number.
>
> The development of a state of refractoriness to the action of the hormones was demonstrated by the resumption in growth of hair in the area of application when treatment was continued for 180 days.

(ii) *Human safety data.* On review of the literature, the Panel found no report on aggravation of cutaneous bacterial, fungal, or virus infection attributable to the topical application of hydrocortisone-containing products (Ref. 22).

A submission reviewed by the Panel made reference to the reports of more than 90 clinical studies, involving more than 12,000 human subjects, that have been published during the first 21 years following the introduction of topical hydrocortisone preparations in 1952 (Ref. 23). Only 222 adverse reactions were reported in these studies. These were all of a minor nature and were primarily attributed to the vehicle or to a contaminant rather than to hydrocortisone. In these studies, hydrocortisone was substantiated as being the causative agent in only 2 of 95 subjects who were treated with topical hydrocortisone preparations and who experienced sensitization or irritation reactions characterized by erythema, desquamation, and itching. In most instances the effects were minor among the 95 subjects who complained of mild itching and burning at the site of application. These effects were attributed to the irritating properties of the vehicle and did not result in discontinuance of treatment. The available literature contains infrequent reports of cases of allergic contact dermatitis from topical hydrocortisone preparations, but in most of these cases patch testing did not demonstrate that hydrocortisone was the sensitizing agent (Ref. 23).

This submission included copies of 19 publications reporting striae formation, atrophy, telangiectasia, and other dermal manifestations which followed topical applications of flourinated steroids and topical applications or systemic use of corticosteroids other than hydrocortisone (Ref. 23). Adam and Craig in 1965 indicated that "no cases of striae formation have been reported with the older steroids, such as hydrocortisone, which suggests that the newer steroids have a more potent effect on dermal connective tissue elements" (Ref. 24).

Hydrocortisone and other steroids are used to treat a variety of dermatologic conditions, especially those accompanied by inflammation. The following set of studies deals with safety considerations concerning histological changes in tissue structure or the possibility of super-infection.

Sneddon noted aggravation and extension of telangiectasia in 14 patients suffering from rosacea and treated by prolonged topical application of flourinated steroids. Termination of treatment in most cases was followed by severe rebound inflammatory changes characterized by edema and acute pustular eruption. Sneddon reported that hydrocortisone, used together with oral tetracycline, did not produce the same effects (Ref. 25). Stevanovic, however, reported corticosteroid-indiced atrophy of the skin with telangiectasia in six patients. One patients was a female who applied a hydrocortisone preparation to the upper eyelids as a cosmetic for several years (Ref. 26). According to Stevanovic, histological examination "suggested that the first changes in the dermal tissue occur in the ground substance, followed by those of elastic and collagen fibers. These changes are ascribed mainly to the incomplete inhibition of fibroblasts by the corticosteroid." Stevanovic indicated that the atrophy with telangiectasia induced by hydrocortisone "can best be explained by its very prolonged used and the special microanatomical features of infected skin."

Goldman, O'Hara, and Baskett reported that 45 biopsies performed on normal skin areas following local intradermal injections of a hydrocortisone acetate suspension produced "hematoxylinophilic masses persistent over a considerable period of time" and that "Preliminary histochemical studies suggest that these are ground substance changes" (Ref. 27). These investigators further reported that 42 biopsies performed on skin with a variety of inflammatory conditions, and following local injection of a hydrocortisone acetate suspension, "revealed definite inhibition of inflammation in the eczematous, toxic (not too severe), tuberculin, psoriatic, sarcoidal, neurodermatitic keloidal, lymphomatous and leukemic skin reactions and also in some miscellaneous disorders." In contrast, "Biopsies of the urticarial reaction and the local histamine wheal have revealed no significant changes." Goldman later reported that "detailed studies, after local application of both ointments and lotions of the hydrocortisone acetate and free alcohol . . . have shown no histopathologic reactions in normal skin" and that "chromatographic and colorimetric assay controls with hydrocortisone acetate and free alcohol also have revealed no evidence of absorption, in spite of definite local clinical responses" (Ref. 28).

In studies conducted by Fleischmajer, two patients treated with prolonged topical applications of a 2.5-percent hydrocortisone ointment for pathologic skin conditions "developed pustular eruptions and crusting, apparently as a result of secondary infection in skin areas affected by severe excoriations from scratching" (Ref. 29). The infection disappeared, however, following local and systemic administration of antibiotics, without any interruption of the topical hydrocortisone treatment. In another study, 708 patients, most of whom suffered from various types of eczema confined to small skin areas, were treated with topical applications of hydrocortisone, in various formulations, as the acetate or free alcohol, and in concentrations ranging from 0.25 to 2.5 percent. The eczematous lesions worsened in 22 cases (approximately 3 percent) following such treatment (Ref. 30). The investigators reported that "sometimes changing to another ointment base was helpful." Patch testing never showed hypersensitivity to hydrocortisone, but occasional intolerance to all available hydrocortisone products has been shown. Its complete failure, in certain cases where a response might be expected, is unexplained. In a few cases, increased infection has occcured, e.g., *Staphylococcus aureus* in seborrhoeic eczema. On the other hand, it was reported that there seems to be little or no evidence that hydrocortisone ointment positively favors superficial infections. More recent double-blind studies conducted by Carpenter et al. (Ref. 31) revealed that topical applications of a 1.0 percent hydrocortisone cream, three times daily, to patients with acute dermatoses (primary diagnosis of contact, eczematoid, or atopic dermatitis, neurodermatitis, or intertriginous eruption, complicated by suspected

secondary bacterial or fungal infections, produced no increase in infection 7 to 10 days after the initiation of treatment. There was a significantly greater overall response of the lesion and symptomatic improvement, compared with patients treated similarily with the base or cream alone. Pathogens were distributed evenly among the two treatment groups, and *Staphylococcus aureus* was the most frequent contaminant. Seven to 10 days following the initiation of treatment, 31 percent (21 of 68 patients) of the hydrocortisone-treated group were pathogen-negative, compared with 27 percent (18 of 68 patients) of the base cream-treated group.

Wachs, Clark, and Hallett (Ref. 32) treated 100 patients suffering from psoriasis, atopic dermatitis, or various eczemas and dermatoses, with topical applications of either betamethasone valerate or fluocinolone acetonide two or three times daily for 3 weeks. Both of these corticosteroids are more potent than hydrocortisone and were applied in a random, double-blind manner without the use of occlusive dressings. The above investigators reported "no change either in the patient's bacterial flora or in the incidence of fungal isolation" and concluded that "it may be that the threat of overgrowth after routine topical treatment does not exist, or has been overemphasized."

A submission reviewed by the Panel referred to eight clinical studies, published between 1954 and 1957, in which some patients experienced irritation or aggravation of their condition after topical applications of hydrocortisone preparations. In almost all instances, the irritation or aggravation subsided with continuing treatment or a change in the hydrocortisone vehicle base (Ref. 23).

The Panel thoroughly reviewed literature concerning the safety of hydrocortisone. Strong emphasis was placed on isolating cases of adverse reactions. According to a submission reviewed by the Panel, only three cases of serious adverse effects from the use of topical hydrocortisone preparations have been documented in the literature between 1952, when such preparations were first introduced, and late 1973, when the submission was prepared (Ref. 23).

In 1962 Fanconi reported a case of an infant with generalized eczema who experienced a temporary retardation of growth while receiving total body inunction with a 1.0-percent hydrocortisone ointment, twice daily for 6 months (Ref. 33).

Benson and Pharoah in 1960 reported a case of a 5½-year-old boy who had suffered from chronic eczema since the age of 6 months and who had been treated with a nongreasy 1-percent hydrocortisone alcohol ointment for 16 months before being hospitalized. He had developed vomiting and coughing that continued for 1 week before hospitalization. The child also experienced bilateral frontal headaches 3 days before treatment was sought (Ref. 34). Upon examination, the subject showed evidence of growth retardation (i.e., 42-inch height was less than third percentile), bilateral papilledema of moderate severity due to benign intracranial hypertension, and accelerated weight gain during topical hydrocortisone treatment. Hydrocortisone treatment was discontinued at the time of hospitalization, and the symptoms disappeared in a few days. The papilledema also disappeared rapidly and the fundi regained their normal appearance within 4 weeks.

Feinblatt et al. in 1966 reported a case of a 3-week-old male infant who received topical applications of 0.25 percent hydrocortisone with tetracycline phosphate complex and amphotericin B in an "acid-mantle lotion," three times daily for a period of 8½ days, for the treatment of epidermolysis bullosa lesions. During that period the infant received a total of 300 mg hydrocortisone or 2,100 mg/m ^{2} of body surface area. By the fourth day of treatment, a rapid gain in body weight was noted; puffy eyelids and pitting edema of the legs were also observed. At that point the use of the lotion was discontinued. Two days later the rapid increase in body weight ceased, but the infant remained edematous for about 1 week (Ref. 35).

In the three cases cited above, the topical applications of hydrocortisone preparations were excessive. The applications were made either for prolonged periods of time or were made over extensive areas of the body. In each case, however, the clinical status of the subject returned to normal following the discontinuance of topical hydrocortisone treatment. The latter two patients cited in the cases above showed abnormal vital signs. The 3-week-old infant experienced rapid breathing, and the 5½-year-old boy had a pulse rate of 90/ minute and a blood pressure of 95/95. Their vital signs, however, returned to normal after topical hydrocortisone treatment was discontinued.

In more than 12,000 subjects treated with topical hydrocortisone and 90 clinical studies and almost 30 experimental or safety studies, no other abnormal vital signs were reported (Ref. 23). These same studies also revealed no abnormal laboratory findings for blood chemistry, liver function tests, or routine urinalysis.

During the last 20 years a variety of absorption, excretion, and metabolism studies have been conducted to evaluate the extent of percutaneous absorption of topically applied hydrocortisone preparations and the systemic effects of percutaneous absorption. These studies have established that percutaneous absorption does indeed occur, but that it is always at such a low level that it is unlikely to cause systemic effects similar to those that occur following systemic administration of the drug (i.e., Collagen degeneration, cutaneous striae formation, osteoporosis, overt diabetes or high blood glucose, hypokalemia, electrocardiographic abnormalities, muscular weakness, detectable psychological abnormalities, peptic ulcer, and supression of the adrenal axis).

In 1956 Scott and Kalz conducted autoradiographic studies of skin biopsies after topical application of a 1-percent radioactive hydrocortisone ointment to the normal skin of the upper back of six subjects. Results suggested that some systemic absorption occurred. Autoradiographs of normal skin 1 hour after application of the ointment demonstrated that the readioactive hydrocortisone had been "distributed through the epidermis, with slightly more dense accumulation near the surface. After 2 hours, there was a high concentration of the material in the basal layer of cells. Dispersion of C^{14} was seen to have occurred through the dermis after 6 hours, with apparent collection of the material around the blood vessels; the basal layer still contained a quantity of the isotope however. After 16 hours, little or no radioactive particles remained in the section of skin, suggesting the systemic absorption of the C^{14}" (Ref. 36). These investigators observed that there appeared to be no difference in the course of absorption, whether the preparation remained on the skin 2 hours or 6 hours. They concluded that "once epidermal penetration had occurred, the process of subsequent absorption proceeded without interruption." Their investigation reportedly dispels the hypothesis that the main route of topical hydrocortisone absorption is via the hair follicles and the orifices of glands. They noted that there was no more rapid appearance of C^{14} in the skin adjacent to such structures than in the remainder of the skin immediately subjacent to the epidermis on other sites.

Later studies reported by Malkinson in 1958 (Ref. 37) revealed that no significant absorption of hydrocortisone by normal skin occurred 5½ to 6 hours after topical application of a radioactive hydrocortisone ointment to eight sites on the flexor surface of the forearm of four human subjects. Malkinson further reported that there was no evidence of hydrocortisone absorption following application of a radioactive hydrocortisone ointment to normal skin and before and after exposure of the skin sites to an erythema-producing dose of ultraviolet light. When this ointment was applied to a total of five skin sites in three subjects immediately following stripping, gas-flow cell measurements detected evidence of C^{14} absorption at all test sites. There were levels of residual radioactivity ranging from 52 to 84 percent within the first 5 minutes after application. Radioactivity at these sites had decreased to anywhere from 16 to 37 percent of original levels after 1 hour, and to 10 to 22 percent after 4 to 6 hours. Malkinson remarked, however, that it was not surprising to him that penetration of hydrocortisone-4-C^{14} in normal skin was not detected by the gas-flow cell, because the quantitative absorption of this compound "is well within the inherent percentage of error of this device." He had found previously, from detection of radioactivity in urine extracts, that hydrocortisone-4-C^{14} is "absorbed from normal skin in small quantities approximately 1 to 2 percent of the topically applied material" (Ref. 38).

Studies conducted by Greaves demonstrated that there is some in vivo destruction of hydrocortisone (Ref. 39). Hydrocortisone that contained tritium was applied under occlusion to the skin of the abdomen, forehand, and/or scrotum of a normal male and female subject. After 12 hours, less than 0.5 percent of the radioactive hydrocortisone applied to the abdomen was detectable in the urine and occurred predominantly as 17-oxysteroids. Seventeen percent of the radioactive hydrocortisone that was applied to the scrotum was excreted as corticosteroids, with a distribution of metabolites similar to that following oral administration of hydrocortisone. Greaves feels the data suggest that hydrocortisone "When topically applied loses its side chain before reaching its site of action in the cells and so becomes physiologically inactive. The greater potency of triamcinolone and fluocinolone acetonides administered percutaneously may be in part due to the fact that their side chains cannot be cleaved."

Feldmann and Maibach performed studies in which they quantitated the effect of regional variation in normal male subjects on the percutaneous penetration of hydrocortisone (Ref. 40). They reported that absorption is increased in regions with large or numerous hair follicles and is decreased in some regions having thickened stratum corneum. These generalizations, however, do not apply to absorption through the palm of the hand and scrotum. There was significant absorption from the palm of the hand, even though it has a fairly thick stratum corneum and no hair follicles. The scrotum presented almost no barrier to hydrocortisone penetration. Feldmann and Maibach indicated that "other determining factors may be present in these regions of obvious specialization in structure and function." The Maximum C^{14} urinary excretion rate was achieved during the second 12-hour period for all areas except the foot, where the maximum rate was reached on the third and fourth days, and the back, where the maximum rate was reached on the second day. The above investigators reported the following maximum C^{14} urinary excretion rates per 24 hours, in percent of the applied dose of hydrocortisone: 0.32 percent for the ventral part of the forearm, 0.62 percent for the dorsal part of the forearm, 0.04 percent for the plantar foot arch, 0.14 percent for the lateral ankle, 0.29 percent for the palm of the hand, 0.40 percent for the back, 1.74 percent for the scalp, 1.28 percent for the axilla, 5.09 percent for the forehead, 7.84 percent for the jaw angle, and 27.7 percent for the scrotum.

Another study by Feldmann and Maibach (Ref. 41) revealed that "between 0.2 and 1.0 percent of hydrocortisone, applied to normal skin appears in the urine over a period of ten days. Stripping the skin doubles this amount and significantly alters the absorption rate curve. An occlusive dressing increases absorption ten-fold but does not basically alter the absorption rate curve. Evidence is presented suggesting that both the stratum corneum and the Malpighian/basal layers serve as skin barriers."

Percutaneous absorption studies by Feinblatt et al. in normal male children less than 2 years old revealed that an average of 21.6 percent of a hydrocortisone-4-C^{14} cream, applied topically under occlusion to the antecubital fossae, was recovered in the urine within 5 days (Ref. 35). An average of 35.6 percent was recovered under similar conditions from the urine of subjects with atopic eczema, whose ages ranged from 2 months to 18½ years. The recovery rates were highest during the first 2 days after application and declined progressively on subsequent days. The investigators concluded that when hydrocortisone is topically applied under occlusion "a significantly large amount of percutaneous absorption of hydrocortisone occurs through the skin of children. The tendency to use topical steroids indiscriminately must be condemned. When it is required, the amount of drug placed on the skin should be given consideration."

When administered orally or parenterally, hydrocortisone preparations tend to cause a lowering in circulation of eosinophiles. The following studies were performed to determine the extent to which this occurs when the drug is used topically. Thorn et al. in 1948 reported that the intramuscular administration of a single dose of 25 mg purified pituitary adrenocorticotropic hormone to normal subjects and patients with diseases not involving the adrenal cortex consistently produced a marked decrease (approximately 50 percent) in circulating eosinophils within the first 4 hours (Ref. 42).

A study reported by Smith in 1953 (Ref. 43) indicated that "there was no consistent alteration in the circulating eosinophile count after the inunction" of 6 g of a 25-mg/g hydrocortisone acetate ointment on the back, upper arms, and legs of each of eight normal adult subjects. Circulating eosinophile counts were performed the day prior to inunction and at 4, 6, and 28 hours after inunction. Similar results were obtained when the same ointment was applied to the affected areas of seven patients with generalized skin disease. Smith concluded that the data indicate "that there was either no absorption or, at any rate, insufficient absorption to produce a drop in the circulating eosinophile count. It is of course possible that the test used as a criterion of absorption and systemic effect was not sufficiently sensitive to demonstrate blood changes which might result from the absorption of very minute amounts of hydrocortisone. It is however unlikely that the small amounts which would thus escape detection could account for the therapeutic effects reported."

Gemzell, Hard, and Nilzen conducted a study reported in 1954 in which 48 subjects, some of whom were normal and some of whom had very mild mycosis of the feet, a slight dermatitis of the hands, or minor psoriasis plaques,

received a topical application of 200 mg hydrocortisone incorporated into various vehicles. The application was rubbed on the anterior surface of the body from the neck to the knees for 10 minutes (Ref. 44). In all cases the topical application of hydrocortisone was followed by an increase in the plasma levels of 17-hydroxycorticosteroids within 1 hour, but the investigators did not consider this rise to be statistically significant. Two hours after inunction, a decrease ranging from 6 to 34 percent in the circulating eosinophil count was noted. The investigators did not consider this decrease significant because among the control group there was a decrease of approximately 25 percent in the circulating eosinophil count 2 hours after inunction. They indicated, however, that "even if the figures are not statistically significant, they nevertheless suggest a general effect. It is possible that more sensitive methods than those used in this investigation would be necessary to show such an effect. A more sensitive method is not available at present."

The results from an investigation conducted by Fleischmajer and reported in 1961 "strongly suggest that external hydrocortisone treatment does not produce any major systemic effects following the use of large amounts over prolonged periods of time" (Ref. 29). Ten females and 9 males, ranging in age from 5 to 60 years, received topical applications of a 2.5-percent hydrocortisone ointment twice daily over a 3- to 20-month period. The total amount of hydrocortisone applied per subject ranged from 8,750 to 95,000 mg. Fifteen subjects were being treated for atopic dermatitis, one for atopic dermatitis in combination with ichthyosis, and three for lichen simplex chronicus. Three months after initial treatment, the circulating eosinophil count had decreased in 4 subjects, but the count remained unchanged or had increased slightly in the remaining 15 subjects. Other laboratory tests, including a white blood cell differential count, a urinary 17-ketosteroid determination, and quantitative assays of blood glucose and serum electrolytes, were periodically performed. None of these showed any distinct changes.

In the above study conducted by Gemzell, Hard, and Nilzen, five subjects received a subcutaneous injection of 0.5 mg/kg hydrocortisone. It was reported that "the plasma levels of steroids rose in one hour from 13.0 to 19.4 μg per 100 mL of plasma, then fell. The number of eosinophils decreased continuously throughout the 6-hour period and reached the low level of about 50 percent of the initial value." One subject was given 1 mg/kg hydrocortisone in oral tablet form. The investigators reported that for this subject "the plasma level of 17-hydroxycorticosteroids rose in two hours from 17.3 to 69.5 μg, and the eosinophils decreased to zero in the six-hour period" (Ref. 44). These results, according to the investigators, agreed well with previously reported findings on the use of oral hydrocortisone.

Feinblatt et al. in 1966 commented, however, that "depression of eosinophil counts has been accepted in the past as specific evidence of the circulating level of hydrocortisone-like hormones in the blood. In addition to the fact that the amount of hydrocortisone needed to depress eosinophils has not been documented, many investigators have reported on the variability and lability of eosinophil counts and the inadequacy of this method as a means of determining 17-hydroxycorticosteroid levels" (Ref. 35).

The above study by Gemzell et al. (Ref. 44) demonstrated that subcutaneous injection or oral administration of hydrocortisone increases the plasma levels of 17-hydroxycorticosteroids, attaining the maximum levels in 1 to 2 hours. Neither this study nor Fleischmajer's study discussed above (Ref. 29) demonstrated any distinct or significant change in the plasma level of 17-hydroxycorticosteroids or urinary level of 17-ketosteroids following topical application of hydrocortisone.

On the basis that a "suppression of the urinary 17-ketosteroids and an increase in the 17-hydroxycorticosteroids is the expected finding following the systemic administration of hydrocortisone," Smith attempted to show that systemic absorption of topically applied hydrocortisone does occur, by demonstrating an alteration in urinary steroids. He applied 10 g of a 25–mg/g free-alcohol form of hydrocortisone ointment to the back, arms, and thighs of eight normal male adult subjects (Ref. 45). However, Smith found that there was no consistent alteration in the urinary 17-ketosteroids or 17-hydroxycorticosteroids after inunction with the test material, nor was there any significant difference in the above urinary steroid levels following inunction with the ointment base alone. He concluded that "these results indicate that either there was no absorption or there was insufficient absorption to alter these urinary steroids."

A study conducted by Witten, Shapiro, and Silber, reported in 1955, revealed that the "inunction of relatively large body areas of normal or diseased skin with 30 g of ointment containing 750 mg hydrocortisone acetate over a 3-day period does not increase the 17,21-dihydroxy-20-ketosteroid levels in urine and blood" (Ref. 46). The study involved six normal adult males, and three females and six males with extensive or generalized skin disease (bullous erythema multiforme, allergic eczematous contact-type dermatitis, pemphigus foliaceus, and psoriasis). Determinations were made immediately following the collection of urine and blood specimens taken 12 hours after the last topical application of the above hydrocortisone ointment. It was concluded by these investigators that "the findings lend further support to the mass of clinical evidence indicating that there are no dangers to be anticipated from absorption and consequent systemic effects of therapeutic quantities of hydrocortisone applied topically in ointment form even to large areas of altered skin for long periods of time."

Scoggins and Kliman (Ref. 47) reported the case of a 22-year-old male with psoriasis of 6 years' duration which had become severe and generalized during the 11 months preceding the study period. Initially, 400 mg hydrocortisone in a cream base was applied daily for 3 days to approximately 20 percent of the body surface. After an intervening control period of at least 9 days, two applications of hydrocortisone with an occlusive dressing, which totalled 1,200 mg hydrocortisone daily, were made to 90 percent of the body surface. The investigators reported that "the smaller dose of hydrocortisone caused a decrease in eosinophil count on the 1st day of treatment and a moderate rise in plasma cortisol concentration. The absorption of small amounts of this drug was difficult to document because the methods used do not permit differentiation between exogenous and endogenous cortisol. The large dose of hydrocortisone produced unmistakable evidence of the presence of exogenous cortisol—that is, a threefold increase in plasma cortisol concentration, marked increases in the steroid content of the urine—and a prompt decrease in eosinophil count." They further reported that "when the large amount of hydrocortisone was applied, sodium excretion was almost completely suppressed, and there was a transient rise in potassium excretion." It was indicated that the amount of 17-hydroxycorticosteroids that is excreted in the urine after daily topical

administration of 1,200 mg hydrocortisone suggests that less than 10 percent of the dose was absorbed. They concluded that without an occlusive dressing, systemically significant amounts of the corticosteroids are absorbed only if the dose applied is very large.

McCorriston (Ref. 48) reported no elevation above normal levels of 17-ketosteroids, creatinine, or corticoids in a 15-year-old female during the 4-week period that the subject applied a 2.5-percent hydrocortisone acetate ointment to her face, neck, both antecubital fossae, and both wrists.

The final concern for safety, highlighted in the remaining studies, deals with prolonged use of steroid products. Questions on steroid accumulation resulting in excess levels in the body, and problems caused by steroid withdrawal are answered based on information appearing in literature over the years.

In "The Pharmacological Basis of Therapeutics," Sayers and Travis reported that administration of large doses of hydrocortisone for prolonged periods "produces changes in carbohydrate and protein metabolism that are, in general, the converse of those in adrenocortical insufficiency. Blood sugar tends to be high, liver glycogen is increased, and there is increased resistance to insulin. The catabolic action of the steroid is reflected in the wasting of tissues, reduced mass of muscle, osteoporosis (reduction in protein matrix of bone followed by calcium loss), and thinning of the skin. In certain instances, a diabetic-like state may be produced" (Ref. 49).

The report in the above study by Scoggins and Kliman involving the 22-year-old male with psoriasis indicated that there was no discernible change in glucose tolerance following the topical application of 1,200 mg hydrocortisone, under an occlusive dressing, to 90 percent of the body surface during a 1-day period. Nor was there a discernible change in glucose tolerance following the daily topical application of 400 mg hydrocortisone, without an occlusive dressing, to 20 percent of the body surface during a 3-day period (Ref. 47).

In the study by Fleischmajer, no definite changes in blood glucose levels could be found in any of the 19 subjects who received topical applications of a 2.5-percent hydrocortisone ointment twice daily over a 3- to 20-month period (Ref. 29).

Munro and Clift (Ref. 50) demonstrated "that patients with chronic skin disease using the quantity of corticosteroid ointments commonly prescribed in general practice and hospital outpatient clinics, are not significantly at risk from adrenal axis suppression." Insulin stress tests were used to determine whether adrenal axis suppression was present in 40 outpatients suffering from eczema or psoriasis and treated with topical corticosteroids for prolonged periods. Thirty-one patients (77.5 percent) had received treament for 3 to 6 years. The subjects applied one or more of the following corticosteroids topically, under occlusion by polyethylene film (50 percent of patients), polyethylene gloves, or coverings over relatively small areas of their skin: 0.1 percent betamethasone 17-valerate ointment (22 patients used this alone), 0.025 percent fluocinolone acetonide, 0.025 percent beclomethasone dipropionate, and small amounts of 1.0 percent hydrocortisone acetate ointment.

The investigators report as follows: "Of the forty patients studied thirty-seven (92.5%) had a normal response on first testing . . . . When the tests were repeated in the three cases with initial abnormal results after 2–5 months with the patients using half their previous dose of topical corticosteroid ointment, all the patients had essentially normal results (one was minimally below the normal range with a maximal level of 19.5 μg/100 mL and an increment of 12 μg/100 mL)." The three patients with abnormal results initially were using 25, 30, and 100 g betamethasone ointment weekly. The first two used polyethylene film occlusion over large areas of their bodies for a 10- and 2-year period, respectively, when their skin disorder was troublesome. The third patient was a small female for whom a weekly dose of 100 g over a 3-year period represented an especially large dose.

Corticosteroids occur naturally in the body. An excess production of corticosteroids or adrenal insufficiency can easily upset homeostatic balance and cause systemic manifestations and alarming symptoms. Possible absorption through the skin of a topically applied hydrocortisone product is an important issue when considering the safety of hydrocortisone in OTC topical antipruritic preparations. The complications of excessive corticosteroids in the body include electrolyte imbalance, hyperglycemia, glucosuria, susceptibility to superinfection due to inhibition of macrophages, and the classical picture of Cushing's syndrome. These characteristics are warnings of systemic buildup.

Numerous tests have been performed on the absorption of topically applied hydrocortisone preparations. Many are reviewed in the preceding section on human safety. Fleischmajer (Ref. 29) applied a 2.5-percent hydrocortisone acetate ointment twice daily to the skin of 19 patients with atopic dermatitis. The study extended over a 3- to 20-month period. The total dose of hydrocortisone applied ranged from 8,750 to 95,000 mg. No characteristic side effects were noted. Seven patients showed some increase in body weight, but there were no changes in eosinophil counts, in white cell differential count, in urinary 17-ketosteroid analysis, or in blood glucose and serum electrolytes values.

Feldmann and Maibach (Ref. 41) noted that following the topical application of C^{14}-hydrocortisone, only 0.2 to 1.0 percent appeared in the urine. The effect of occlusive dressing on the absorption of topically applied corticoids was studied by Feinblatt (Ref. 35). Ten mongoloid subjects with normal skin were treated with C^{14}-hydrocortisone and the treated areas were occluded with polyethylene film. Urinary recovery of hydrocortisone from these subjects averaged 21.6 percent, a 20-fold increase over subjects with nonoccluded areas. However, this difference is not major, and there are no systemic problems associated with it.

The quantity of topically applied hydrocortisone that is absorbed depends upon such factors as the dose of hydrocortisone and the size and location of the area treated (Ref. 40). As stated above, the following percentages represent the amount of C^{14}-hydrocortisone absorbed from various areas of the body: 0.32 percent from the ventral forearm, 0.62 percent from the dorsal forearm, 0.04 percent from plantar foot arch, 0.14 percent from the lateral ankle, 0.29 percent from the palm, 0.40 percent from the back, 1.74 percent from the scalp, 1.28 percent from the axilla, 7.84 percent from the angle of the jaw, and 27.7 percent from the scrotum (Ref. 40). If the ointment is applied to small areas, none of these percentages will reflect a significant increase in systemic corticoid activity. Treatment of a large area, such as the total body area, requires that attention be given to the period of use of the hydrocortisone ointment. Rare systemic effects can occur after prolonged application and when large areas of the body are treated. Only 3 actual cases have been reported during a 21-year period of use of topical hydrocortisone. The changes which occurred were temporary, and the symptoms disappeared when treatment was discontinued (Ref. 23).

Local changes may occur in the skin after long-term application of hydrocortisone, but the incidence is rare and usually results from secondary infection. A change in the type of ointment base used has often caused the

symptoms to regress or disappear (Refs. 29 and 30).

Allergic reactions to cortisone and its derivatives have been reported, but they are rare (Ref. 23). On review of the literature, the Panel found no reports on the aggravation of cutaneous bacterial, fungal, or viral infections attributable to the topical application of hydrocortisone-containing products. Based on the numerous safety studies available and on the long history of topical use, the Panel concludes that hydrocortisone and hydrocortisone acetate are generally recognized as safe for OTC topical use as antipruritics in doses up to 0.5 percent concentration.

(2) *Effectiveness.* There are studies documenting the effectiveness of hydrocortisone and hydrocortisone acetate in the dosage range recommended by the Panel for use as OTC external analgesics.

Hydrocortisone and hydrocortisone acetate are classified as external analgesics because of their effectiveness on the skin as antipruritic agents. Hydrocortisone preparations have had wide usage in the topical treatment of dermatoses and are preferred for topical use over cortisone because they are active on the skin (Ref. 51).

Hydrocortisone and hydrocortisone acetate are two of the most potent and effective agents for the treatment of many common dermatoses. Numerous controlled and uncontrolled studies provide strong documentation for their efficacy as antipruritic and anti-inflammatory agents in the 0.5 to 5 percent dosage range (Ref. 52). In recent years newer studies have investigated the topical use of concentrations in the dosage range of 0.1 to 0.25 percent.

The following table summarizes the studies that are relevant to the topical use of hydrocortisone preparations:

Controlled Studies Demonstrating Effectiveness of Topical Hydrocortisone

Investigator	Disease state	Dosage (percent)	Evaluation
Becker (Ref. 53)	Pruritus ani/vulvae	1.0	89% of patients showed improvement.
Bisley (Ref. 54)	Pruritus ani/vulvae, eczema	1.0	80% of patients had symptomatic relief.
Boffa (Ref. 55)	Eczema, psoriasis lichen planus, various dermatoses.	1.0	90% showed relief.
Carpenter et al. (Ref. 31)	Common dermatoses with secondary bacterial or fungal infections.	1.0	Average of 73.5% of patients improved in all states.
Carter et al. (Ref. 56)	Seborrheic eczema	1.0	74% of patients fast relief.
Clyman (Ref. 57)	Various dermatoses	1.0	Improvement not too significant.
Clyman (Ref. 58)	Eczema, lichen simplex chronicus, dermatosis.	0.5	Showed effective in 70% of cases.
Eskind (Ref. 59)	Contact dermatitis	0.2 to 2.5	Some improvement, especially at the high dosage.
Fisher (Ref. 60)	Lichen planus	1.0	40% effective, but no improvement with control at all.
Frank (Ref. 61)	Various pruritic dermatoses	0.25	Effective antipruritic.
Frank et al. (Ref. 62)	Various dermatoses	0.5 to 1.0	Both dosages showed effectiveness.
Goltz (Ref. 63)	Various dermatoses	1.0	61% showed fast complete improvement.
Haeger (Ref. 64)	Hypostatic eczema (stasis dermatitis).	1.0	73% improved as compared to placebo control ointment.
Heileson et al. (Ref. 65)	Various dermatoses	1.0	51% more activity than inactive control.
Heileson et al. (Ref. 66)	Eczema	1.0	59% of patients who used it improved.
Hill (Ref. 67)	Eczema	1.0	In 74% of patients strong improvement.
Howell (Ref. 68)	Various dermatoses	1.0	88% of patients improved.
Miller (Ref. 69)	Various dermatoses	1.0	76% of patients improved.
Perlstein (Ref. 70)	Nummular eczema	1.0	98% of patients relieved of pruritus and lesions.
Phillips (Ref. 71)	Various dermatoses	1.0	79.2% of patients had symptomatic improvement.
Polano (Ref. 72)	Pruritus/eczema	1.0	90% of patients showed improvement.
Portnoy (Ref. 73)	Dermatitis/eczema	1.0 to 2.5	64% of patients improved with lower dosage.
Rattner (Ref. 74)	Various dermatoses	0.5 to 1.0	1% better; both dosages effective.
Robinson et al. (Ref. 75)	Various dermatoses	0.5 to 2.5	Less than 1% concentration relatively ineffective.
Robinson et al. (Ref. 76)	Various dermatoses	0.5 to 1.0	34% of patients improved with the low dosage; 67% of patients improved with the 1% concentration.
Robinson et al. (Ref. 76)	Various dermatoses	0.5 to 2.5	Higher percentage (62 to 92%) improvement with oily base than with greaseless base.
Russell et al. (Ref. 77)	Eczema, dermatitis, lichen simplex.	1.0	Ony 38% completely relieved.
St. John's Staff (Ref. 30)	Eczema, dermatitis	1.0	65% showed relief of itching, reduction of inflammation, or complete suppression of physical signs.
Stevens et al. (Ref. 3)	Effectiveness measured by lymphocyte response.	0.5 to 1.0	Both dosage levels are active.
Turell (Ref. 78)	Pruritus ani/vulvae	1.0	32% totally cleared.
Wartzki et al. (Ref. 79)	Pruritus, eczema	1.0	64% showed good improvement.
Way (Ref. 80)	Acne	0.25	85% relieved of irritation, erythema.
Welch et al. (Ref. 81)	Various dermatoses	0.5 to 2.5	0.5% may be less effective in severe acute state otherwise equal effectiveness as the 1.0 and 2.5% ointments.
Wilson et al. (Ref. 82)	Eczema, pruritus	1.0	79% showed good to moderate improvement.
Witten et al. (Ref. 83)	Various pruritis	0.1 to 0.5	0.1% dosage helpful; the higher concentration worked well.
Zelcer (Ref. 84)	Various pruritic dermatoses	0.25	Good effect.
Zelcer (Ref. 85)	Various pruritic dermatoses	0.125	Worked in most cases.

Dosage is an important factor in the determination of therapeutic effectiveness. Hydrocortisone preparations have been marketed in a dosage range of 0.5 to 2.5 percent concentrations. It is the Panel's opinion that OTC products should contain the lowest effective dosages. Data that evaluate the effectiveness at low dosage levels are reviewed below.

Frank implemented a study to compare the effectiveness of hydrocoritsone as an antipruritic agent at concentrations of 0.1 and 0.25 percent. The hydrocortisone was incorporated into two different bases to evaluate the effects of the base media on the various pruritic dermatoses. The use of the 0.25-percent preparations resulted in an improvement in the condition in all cases, and relief from itching was almost immediate. At the 0.1-percent level, results from the test preparations could not be differentiated from those of the control preparations (Ref. 61).

A study by Isaac Zelcer further supports the effectiveness of 0.25 percent concentration of hydrocortisone preparations. In this study, 159 patients were treated with 0.25 percent hydrocortisone acetate ointment. The nature of the skin diseases varied and included eczema, contact dermatitis, atopic eczema, seborrheic eczema, dyshidrosis, lichenification, and pruritus ani and vulvae. In most cases, the treatment successfully relieved symptoms of the various skin diseases. It is important to note that a wider range of skin conditions was reviewed in this study, and that the hydrocortisone acetate ointment was, at times, used as other than an antipruritic agent. Failures occurring in this study were attributed to early discontinuance of treatment (Ref. 84).

Hydrocortisone preparations are frequently used as anti-inflammatory agents. They are prefered to cortisone for two reasons. First, local application of hydrocortisone preparations have a more constant anti-inflammatory effect. Second, hydrocortisone preparatons can be used in lower concentrations than cortisone and still be effective. It is interesting to note that despite hydrocortisone's potency, there are no reports of irritation or senstitivity due to it. Where senstitivity has occurred, it was determined that the ingredients in the base vehicle were the causative agents (Ref. 85).

A study conducted by Welch compared the effectiveness of a wide range of topical hydrocortisone concentrations. As other studies have indicated, hydrocortisone preparations are effective for many dermatoses. This study does point out one important factor. The concentrations studies were

equally effective in most cases, but in the acute phase of most dermatoses or in chronic dermatoses associated with lichenification, doses below 0.5 percent were not always effective (Ref. 81).

Hydrocortisone preparations have been used successfully in the topical treatment of many skin diseases. Hydrocortisone prepartions are safe and effective for mild contact dermatitis, transient atopic dermatitis, mild infantile eczema, uncomplicated status dermatitis, and idiopathic pruritus vulva or ani.

In a study by Witten on the treatment of infantile eczema, hydrocortisone was effective in relieving the condition (Ref.46). Interestingly enough, wide body areas were treated, and there were no problems of super-infection.

Over the past 21 years, numerous studies have reported on the effectiveness of topical hydrocortisone preparations as antipruritic and anti-inflammatory agents. The Panel believes that adequate information has been presented and reviewed to support the conclusion that hydrocortisone and hydrocortisone acetate may be used safely and effectively as OTC external analgesics in short-term therapy within the dosage range specified below.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.25 to 0.5 percent concentration of hydrocortisone or hydrocortisone acetate to affected area 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below-Category I Labeling.) In addition, the Panel recommends the following specific labeling for products containing hydrocortisone and hydrocortisone acetate as external (antipruritic) analgesic active ingreients: *Indication.* "For the temporary relief of minor skin irritations, itching, and rashes due to ecxema, dematitis, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, and jewelry, and for itchy genital and anal areas."

References

(1) OTC Volume 060106.

(2) Tonelli, G., "Acute Toxicity of Corticosteroids in the Rat," *Toxicology and Applied Pharmacology*, 8:250–258, 1966.

(3) Stevens, W., C. Colessides, and T. F. Daugherty, "A Time Study on the Effect of Cortisol on the Incorporation of thymidine–2–^{14}C Into Nucleic Acids of Mouse Lymphatic Tissue," *Endocrinology*, 78:600–604, 1966.

(4) Ingle, D. J., R. Sheppard, E. A. Oberle, and M. H. Kuizenga, "A Comparison of the Acute Effects of Corticosterone and 17-Hydroxy-corticosterone on Body Weight and the Urinary Excretion of Sodium, Chloride, Potassium, Nitrogen, and Glucose in the Normal Rat," *Endocrinology*, 39:52–57, 1946.

(5) Lahtiharju, A., T. Rasanen, and H. Tier, "Inhibition of DNA Synthesis in Various Organs of the Mouse Following a Single Corticosteroid Injection," *Growth*, 28:221–224, 1964.

(6) Ingle, D. J. and R. C. Meeks, "Comparison of Some Metabolic and Morphological Effects of Cortisone and Hrdrocortisone Given by Continued Injection to Rats," *American Journal of Physiology*, 170:77–80, 1952.

(7) Reynolds, B. L. and R. W. Buxton, "Aberrations Produced in Healing Regenerating Tissue by Exogenously Administered Testerone, Hydrocortisone, and Methandrostenolone," *The American Surgeon*, 29:859–862, 1963.

(8) Vogel, H. G., "Tensile Strength of Skin Wounds in Rats After Treatment with Corticosteroids," *Acta Endocrinologia*, 64:295–303, 1970.

(9) Pomerantz, S. H. and L. Chuang, "Effects of B–MSH, cortisol and ACHT on Tyrosinase in the Skin of Newborn Hamsters and Mice," *Endocrinology*, 87:302–310, 1970.

(10) Hall, C. E. and O. Hall, "Contrasting Effects of Stress and Cortisol Overdosage in the Rat," *American Journal of Physiology*, 196:946–948, 1958.

(11) Child, K. J., A. F. English, H. G. Gilbert, A. Hewitt, and E. A. Wollett, "Vasoconstrictor and Systemic Activities of Topical Steroids," *Archives of Dermatology*, 97:407–410, 1968.

(12) McKenzie, A. W. and R. M. Atkinson, "Topical Activities of Betamethasone Esters in *Archives of Dermatology*, 89: 741–746, 1964.

(13) Weston, W. L., M. J. Mandel, G. G. Krueger, and H. N. Claman, "Differential Suppressure Effect of Hydrocortisone on Lymphocytes and Mononuclear Macrophages in Delayed Hypersensitivity of Guinea Pigs," *Journal of Investigative Dermatology*, 59:345–348, 1972.

(14) Lykke, A. W. J., D. A. Willoughby, and J. C. Houck, "Effects of Cortisol Released Cutaneous Protease upon the Permeability of the Micro-Circulation," *Journal of Investigative Dermatology*, 48:318–325, 1967.

(15) Houck, J. C. and Y. M. Patel, "Proposed Mode of Action of Corticosteroids on the Connective Tissue," *Nature*, 206:158–160, 1965.

(16) Spector, W. G., "Substance which Affects Capillary Permeability, *Pharmacology Review*, 10:475, 1958.

(17) Houck, J. C. and Y. M. Patel, "Hormone and Drug Released Dermal Protease," *Federal Proceedings*, 25:762, 1966.

(18) Paulsen, F. and C. Rerup, "Penetration of Cortison (Hydrocortisone) through the Skin of Rats," *Acta Pharmacologica et Toxicologica*, 12:187–195, 1956.

(19) Tonelli, G., L. Thibault, and I. Ringler, "A Bio-assay for the Concomitant Assessment of the Antiphlogistic and Thymolytic Activities of Topically Applied Corticoids," *Endocrinology*, 77:625–634, 1965.

(20) Baker, B. L. and L. F. Montes, "Histochemical Changes in the Skin Following Local Application of Cortisol and Prednisolone," *Anatomical Record*, 139:133–143, 1961.

(21) Castor, C. W. and B. L. Baker, "The Local Action of Adrenocortical Steroids on Epidermis and Connective Tissue of the Skin," *Endocrinology*, 47:234–241, 1950.

(22) OTC Volume 060178.

(23) OTC Volume 060098.

(24) Adam, J. E. and G. Craig, "Striae and their Relation to Topical Steroid Therapy," *Canadian Medical Association*, 92:289–291, 1965.

(25) Sneddon, I., "Adverse Effect of Topical Fluorinated Corticosteroids in Rosacia," *British Medical Journal*, 1:671–673, 1969.

(26) Stevanovic, D. V., "Corticosteroid Induced Atrophy of the Skin with Telangiectasia," *British Journal of Dermatology*, 87:548–556, 1972.

(27) Goldman, L., H. O'Hara, and J. Baskett, "A Study of the Local Tissue Reactions in Man to Cortisone and Compound–F," *Journal of Investigative Dermatology*, 20:271–279, 1953.

(28) Goldman, L., "Histological Effects of Hydrocortisone is Skin of Man," *Annals of the New York Academy of Science*, 61:520–523, 1955.

(29) Fleischmajer, R., "The Lack of Systemic Hydrocortisone Effects After Massive and Prolonged External Applications," *Journal of Investigative Dermatology*, 36:11–16, 1961.

(30) Staff of Saint John's Hospital for Diseases of the Skin and the Institute of Dermatology, London, "The Value of Local Hydrocortisone in the Treatment of Skin Diseases," *The Practitioner*, 178:337–341, 1957.

(31) Carpenter, C. L. et al., "Combined Steroid-Antiinfective Topical Therapy in Common Dermatoses: A Double-Blind Multi-Center Study of Iodochlorhydroxyquin-Hydrocortisone in 277 Patients," *Current Therapeutic Research*, 15:650–659, 1973.

(32) Wachs, G., R. Clark, and J. Hallett, "Are Topical Steroid-related Superinfections a Myth?," *Cutis*, 12:256–257, 1973.

(33) Fanconi, G., "Hemmung des Wachstums bei Einem Saugling Durch die zu

Intrusive Anwendung Einer 1 percent Igen Hydrocortisona auf der Haut bei Generalisiertem Ekzem," *Helvetica Acta*, 17:267–268, 1962.

(34) Benson, P. F. and P. O. C. Pharoah, "Benign Intracranial Hypertension due to Adrenal Steroid Therapy," *Guy's Hospital Reports*, 109:212–218, 1960.

(35) Feinblatt, B. L., T. Aceto, G. Beckham, and E. Bruck, "Percutaneous Absorption of Hydrocortisone in Children," *American Journal of Diseases of Children*, 112:218–224, 1966.

(36) Scott, A. and F. Kalz, "The Penetration and Distribution of C^{14}-Hydrocortisone in Human Skin After Its Topical Application," *Journal of Investigative Dermatology*, 26:149–158, 1956.

(37) Malkinson, F. D., "Studies on the Percutaneous Absorption of C^{14} Labeled Steroids By Use of the Gas-Flow Cell," *Journal of Investigative Dermatology*, 31:19–28, 1958.

(38) Malkinson, F. D. and E. H. Ferguson, "Percutaneous Absorption of Hydrocortisone-4-C^{14} in Two Human Subjects," *Journal of Investigative Dermatology*, 25: 281–283, 1955.

(39) Greaves, M. S., "The In-vivo Catabolism of Cortisol by Human Skin, " *Journal of Investigative Dermatology*, 57:100–107, 1971.

(40) Feldmann, R. J. and H. I. Maibach, "Regional Variation in Percutaneous Penetration of ^{14}C Cortisol in Man," *Journal of Investigative Dermatology*, 48:181–183, 1967.

(41) Feldmann, R. J. and H. I. Maibach, "Penetration of ^{14}C Hydrocortisone Through the Normal Skin," *Archives of Dermatology*, 91:661–666, 1965.

(42) Thorn, G. W., P. H. Forsham, F. T. Garnet Prunty, and A. G. Hills, "A Test for Adrenal Cortical Insufficiency," *Journal of the American Medical Association*, 137:1005–1009, 1948.

(43) Smith, C. C., "Eosinophilic Response After Inunction of Hydrocortisone Ointment," *Archives of Dermatology*, 68:50–53, 1953.

(44) Gemzell, C. A., S. Hard, and A. Nilzen, "The Effect of Hydrocortisone Applied Locally to the Skin on the Eosinophil Count and the Plasma Level of 17-Hydrocorticosteroids," *Acta Dermato-Venereologica*, 34:327–33, 1954.

(45) Smith, G. C., "Urinary Excretions of 17-Ketosteroid and 17-hydrocorticosteroids after Inunction of Hydrocortisone Ointment," *Journal of Investigative Dermatology*, 25:67–69, 1955.

(46) Witten, V. H., A. J. Shapiro, and R. H. Silber, "Attempts to Demonstrate Absorption of Hydrocortisone by New Chemical Test Following Inunction Into Human Skin," *Proceedings of the Society for Experimental Biology and Medicine*, 88:419–421, 1955.

(47) Scoggins, R. B. and B. Kliman, "Percutaneous Absorption of Hydrocorticosteroids," *The New England Journal of Medicine*, 273:831–840, 1965.

(48) McCorriston, L. R., "Hydrocortisone (Compound F) Acetate Ointment in Eczema of Infants and Children," *Canadian Medical Association Journal*, 70:59–62, 1954.

(49) Sayers, G. and R. H. Travis, "Adrenocorticotropic Hormone; Adrenocrotical Steroids and Their Synthetic Analogs," *in* "The Pharmacological Basis of Therapeutics," 4th Ed., The MacMillan Co., New York, pp. 885–923, 1970.

(50) Munro, D. D. and D. C. Clift, "Pituitary-Adrenal Function After Prolonged Use of Topical Corticosteroids," *British Journal of Dermatology*, 88:381–385, 1973.

(51) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., MacMillan Publishing Co., Inc., New York, pp. 1490–1491, 1975.

(52) OTC Volume 060100.

(53) Becker, G. L., "Recent Advances in the Local Treatment of Perianal Skin Lesions," *American Journal of Surgery*, 88:289–292, 1954.

(54) Bisley, B. L., "Efficacy of Two Topical Hydrocortisone Preparations with Antibacterial," *General Practitioner*, 191:101–102, 1965.

(55) Boffa, P. S., "Topical Corticosteroid Therapy in Low Dosage," *General Practitioner*, 199:105–108, 1967.

(56) Carter, V. H. AND R. O. Noojin, "The Evaluation of Betamethasone-17-valerate as a Topical Agent," *Current Therapeutic Research*, 9:253–255, 1967.

(57) Clyman, S. G., "Comparative Study of Dermatological Ointments: Effectiveness of Tarsteroid-Neomycin Compared with Hydrocortisone Alone," *Industrial Medicine and Surgery*, 27:531–532, 1958.

(58) Clyman, S. G., "Comparative Effects of Hydrocortisone and Hydrocortisone Coal Tar Extract Creams in Cases of Atopic Dermatitis, *"Postgraduate Medicine*, 21:309–313, 1957.

(59) Eskind, I. B. "Treatment of Rhus Dermatitis with Topical Hydrocortisone," *Archives of Dermatology*, 69:410–413, 1954.

(60) Fisher, A. A., "The Topical Use of Hydrocortisone Ointment for Certain Oral Conditions," *New York State Journal of Medicine*, 55:2494–2496, 1955.

(61) Frank, L., "A Study of the Antipruritic Effects of Topical Steroids," *American Medical Association Archives of Dermatology*, 77:443–434, 1958.

(62) Frank, L., C. Stritzler, and J. Kaufman, "Clinial Evaluation of Five-Tenths Per Cent Hydrocortisone Ointment," *Archives of Dermatology*, 71:637, 1955.

(63) Goltz, R. W., "Topical Hydrocortisone in the Treatment of Skin Diseases," *Minnesota Medicine*, 38:404–407, 1955.

(64) Haeger, K., "Betamethasone-17-valerate in Topical Treatment of Hypostatic Leg Eczema," *Angiology*, 20:27–32, 1969.

(65) Heilesen, B., A. Kristjansen, and F. Regmann, "Hydrocortisone in the Therapy of Cutaneous Disease," *Archives of Dermatology*, 70:360–362, 1954.

(66) Heilesen, B., A. A. Kristjansen, and F. Regmann, "Hydrocortisone Ointment in the Treatment of Children with Atopic Dermatitis," *Acta Allergologica*, 8:314–322, 1955.

(67) Hill, L. W., "Hydrocortisone Ointment in the Treatment of Infantile Eczema," *The New England Journal of Medicine*, 252:1038–1039, 1955.

(68) Howell, C. M., "An Evaluation of the Treatment of 259 Cases of Inflammatory Dermatoses with Hydrocortisone Free Alcohol Ointment," *Journal of Allergy*, 27:477–479, 1956.

(69) Miller, C. S., "Clinical Value of Hydrocortisone-Oxytetracycline Topical Ointment," *New York State Journal of Medicine*, 56:2098–2099, 1956.

(70) Perlstein, S. M., "Treatment of Nummular Eczema," *Medical Times*, 86:1238–1239, 1958.

(71) Phillips, F. J., "Steroid Ointments in General Dermatological Practice II," *Medical Times*, 91:999–1003, 1963.

(72) Polano, M. K., "The External Use of Hydrocortisone in Skin Diseases," *Acta Dermatovenereologica*, 36:283–290, 1956.

(73) Portnoy, B., "A Comparison Between 92-Fluorohydrocortisone and Hydrocortisone in the Topical Treatment of Certain Dermatoses," *British Journal of Dermatology*, 68:303–306, 1956.

(74) Rattner, H., "The Status of Corticosteroid Theraphy in Dermatology," *California Medicine*, 83:331–335, 1955.

(75) Robinson, H. M. and R. C. V. Robinson, "Treatment of Dermatoses with Local Applications of Hydrocortisone Acetate," *Journal of the American Medical Association*, 155:1213–1216, 1954.

(76) Robinson, H. M., R. C. V. Robinson, and J. F. Strahan, "Indications for Local Hydrocortisone Therapy," *Medical Times*, 83:227–237, 1955.

(77) Russell, B., J. S. Pegum, N. A. Thorne, and R. V. Grange, "A Valuation of Hydrocortisone Ointment," *Lancet*, 1:1038–1043, 1955.

(78) Turell, R., Hydrocortisone Therapy In Control of Anogenital Pruritus," *Journal of the American Medical Association*, 158:173–175, 1955.

(79) Wartzki, I. M. and B. R. Entwisle, "Topical Hydrocortisone Therapy in Diseases of the Skin: A Clinical Evaluation," *Medical Journal of Australia*, 1:318–325, 1956.

(80) Way, S. C., "Topical Hydrocortisone Therapy in Acne Rosacia and Acne Vulgaris," *New York State Journal of Medicine*, 57:3463–3465, 1957.

(81) Welsh, A. L. and M. Ede, "Further Observations on Hydrocortisone Ointments: Their Rational Use in Dermatology," *Ohio State Medical Journal*, 51:350–352, 1955.

(82) Wilson, H. T. and J. H. Edward, "A Comparison of Glycyrrheinic Acid Hydrocortisone Ointment," *British Journal of Dermatology*, 70:452–457, 1958.

(83) Witten, V. H., M. B. Sulzberger, E. H. Zimmerman, and A. J. Sharpiro, "A Therapeutic Assay of Topically Applied 92-Fluorhydrocortisone Acetate in Selected Dermatoses," *Journal of Investigative Dermatology*, 24:1–4, 1955.

(84) Zelcher, I., "La Hidrocortisona en el Tratamiento Local de las Enfermedades de la Peil [Hydrocortisone in the Local Treatment of Diseases of the Skin]," *La Semana Midica*, pp. 1206–1211, December, 1954, in OTC Volume 060161.

(85) Zelcer, I., "Cortisona e hidrocortisona local; Estudio comparativo de su activadad en dermatologia (Local cortisone and hydrocortisone; Study comparing their activity in dermatology)," *Orientacion Midica*, pp. 1568–1569, December, 1954, in OTC Volume 060161.

o. *Juniper tar.* The Panel concludes that juniper tar is safe and effective for use as an OTC external analgesic as

specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Juniper tar, also known as oil of cade, Haarlem oil, bili-drops, Holland balsam, silver drops, and silver balsam (Ref. 1), is a dark brown, viscous liquid with a smoky odor and an acrid, slightly aromatic bitter taste. It is a volatile oil derived from the wood of *Juniperus oxycedrus Linne.* It is composed of cadinene along with varying concentrations of phenols, cresols, acetic acid, hydrocarbons, resins, and phenolic bodies. Juniper tar is very slightly soluble in water. One volume is soluble in 9 volumes of alcohol and in 3 volumes of ether. It is also soluble in chloroform, alcohol, glacial acetic acid, turpentine, and petroleum ether. Juniper tar is acid in reaction (Refs. 1 and 2).

The cadinenes are sesquiterpenes occurring in essential oils. Nine possible isomers exist. They are capable of forming dihydrochlorides (Ref. 3).

(1) *Safety.* Clinical use has confirmed that juniper tar is safe in the dosage range used as an OTC external analgesic.

Data on oral toxicity are not available in standard texts. From juniper tar's chemical composition, the Panel concludes that it is unsafe for oral ingestion. Oral ingestion may cause injurious effects on the kidneys (Ref. 4).

(2) *Effectiveness.* Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that juniper tar is effective for use as an OTC external analgesic.

Juniper tar is used chiefly in topical therapy of cutaneous lesions. It is markedly keratolytic. It is effective as an antipruritic for the treatment of psoriasis, eczema, and various dermatoses, largely due to the fact that it consists of a mixture of phenolic derivatives. Juniper tar is indicated for the temporary relief of discomfort of minor skin irritations and itching (Ref. 1). Juniper tar is only used externally.

Juniper tar has been effectively used in concentrations ranging from 1 to 5 percent (Ref. 5).

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 1 to 5 percent concentration of juniper tar to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

4. *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, p. 1384, 1955.

(2) OTC Volume 060038.

(3) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 691, 1976.

(4) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 647, 1973.

(5) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, p. 721, 1975.

p. *Lidocaine.* The Panel concludes that lidocaine is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Lidocaine is an amide type of topical anesthetic and differs from tetracaine, benzocaine, and butamben, which are esters of aminobenzoic acid. Lidocaine is 2-(diethylamino)-2',6'-acetoxylidide (Ref. 1). It can be considered as an acetamide with one hydrogen atom on the amino group of the amide portion of the compound replaced by a dimethyl aniline group and one hydrogen atom on the terminal carbon atom replaced by a nitrogen atom with two ethyl groups. It is a tertiary amine and is a base that forms salts with acids (Ref. 2).

Lidocaine was synthesized by Lofgren in 1946 in Sweden. Lidocaine base is a white to slightly yellow crystalline powder having a characteristic aromatic odor. It is practically insoluble in water, very soluble in alcohol and chloroform, freely soluble in ether, and dissolves in oils. Lidocaine is more lipophilic than procaine. Lidocaine base melts at between 66° and 69° C. Lidocaine base for use as a topical external analgesic is incorporated in water-miscible ointment bases composed of polyethylene glycol and propylene glycol (Ref. 3).

Lidocaine is highly stable in vitro. It endures 8 hours of boiling with 30 percent hydrochloric acid or lengthy heating with alcohol and potassium hydroxide (Ref. 2). However, it is readily metabolized in the body. Up to 11 percent of the usual doses used for regional anesthetic block in man are recoverable in the urine within 4 hours (Ref. 4).

(1) *Safety.* Clinical use has confirmed that lidocaine is safe in the dosage range used as an OTC external analgesic (Refs. 5, 6, 7, and 8). Lidocaine base is poorly soluble in water but is readily absorbed when applied over extensive denuded areas of skin. If sufficient quantities are absorbed, plasma levels may be attained that result in systemic pharmacological reactions characteristic of the "caine" type drugs which may terminate fatally (Ref. 9). Reactions due to systemic absorption affect the central nervous and the cardiovascular system. Stimulation of the cortex occurs first, followed by depression of both the cerebral cortex and lower centers (Ref. 10). Slow onset of a reaction first causes stimulation followed by depression leading to drowsiness, nervousness, dizziness, blurred vision, nausea, tremors, convulsions, and finally respiratory arrest. When the onset is rapid, central nervous system depression occurs, leading primarily to unconsciousness which may be followed by respiratory arrest (Ref. 9). Myocardial depression and cardiac arrest can occur simultaneously. The fall in blood pressure and intercostal paralysis indicates a potential hazard resulting from high plasma levels (Ref. 11).

Lidocaine is used intravenously in small quantities by physicians for its useful antiarrhythmic activity attributed to an increase of the electrical stimulation threshold of the ventricle during diastole. The antiarrhythmic action is similar to that of procainamide and quinidine but, because of its short duration of action, lidocaine must be given by continuous intravenous infusion if the action is to be sustained. The antiarrhythmic action usually develops within a few minutes and lasts 10 to 20 minutes, following a single intravenous injection of 50 to 100 mg. When it is used intravenously at the rate of 10 to 45 μg/kg of body weight per minute, the antiarhythmic action begins in 10 to 20 minutes. Blood levels of 1.0 to 2.5 μg/mL are required to suppress ventricular arrhythmias. These blood levels may be attained by an intravenous priming dose or by continuous infusion of the drug. Blood levels exceeding 5 μg/mL may prove toxic and cause convulsions and cardiac depression. Constant electrocardiograph monitoring is used to avoid overdosage and toxicity. Manufacturers of lidocaine indicate that its specific indication is to manage ventricular arrhythmias occurring during cardiac manipulation such as cardiac surgery. It is used for life-threatening arrhythmias, particularly those of ventricular origin, which occur with acute myocardial infarction (Refs. 12 and 13).

Approximately 90 percent of a dose of lidocaine is rapidly metabolized by the enzymes in the microsomes of the liver,

and the metabolites are excreted along with 10 percent of the unchanged drug into the urine. Lidocaine is metabolized by several metabolic pathways in the liver. The enzymes involved are oxidases and amidases. Several metabolites have recently been found that cause convulsions. These findings may account for delayed reactions due to cumulative effects. Lidocaine is not hydrolyzed by the plasma cholinesterases as are tetracaine, procaine, and other esters of aminobenzoic acid (Refs. 4 and 10).

Neither lidocaine base nor its salts is irritating to intact or abraded skin (Ref. 14). Despite statements made to the contrary, lidocaine can produce sensitization after repeated applications, as do the other "caine" type drugs. However, the incidence of sensitization is extremely low (Ref. 9). The medical literature reports that the amide type of the "caine" local anesthetics is devoid of sensitizing potential (Ref. 10), but such a statement cannot be supported on either a theoretical or a factual basis. Most soluble drugs can act as haptenes and form antigens that stimulate production of immune bodies of the IgE type that cause allergic reactions in susceptible individuals. Anaphylaxis has been reported after application of lidocaine to the mucous membranes and infiltration. One case of an anaphylactic reaction occurred following application to the skin (Ref. 16). The report does not state whether the quantity, which was said to be minute, was injected intradermally or applied by a patch or scratch test. In another case (Ref. 16), a female patient who alleged she was allergic to lidocaine was tested for lidocaine allergy by instilling one drop into the conjunctival sac. The patient developed immediate syncope, circulatory collapse, and then severe shock. Upon treatment with vasopressor agents, antihistamines, and steroids, she recovered after 2 hours.

(2) *Effectiveness.* There are studies documenting the effectiveness of lidocaine as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that lidocaine is effective for use as an OTC external analgesic (Ref. 7).

Lidocaine is widely and effectively used as a topical anesthetic on the mucous membranes in concentrations ranging from 1.0 to 4.0 percent (Ref. 15). Lidocaine is approximately twice as potent and toxic as procaine on a weight basis (Ref. 9). The onset of anesthesia is rapid after injection, requiring less than one minute. The onset of action when the ingredient is used on the skin has not been reported. The Panel concludes that this is variable and difficult to establish, because it will depend upon the degree of penetration and the type of lesion. The base is poorly soluble in water but soluble in lipid substances, glycols, and similar types of solvents. The base penetrates the intact skin and exerts an analgesic and antipruritic action in the skin (Ref. 14).

Lidocaine base is an effective topical anesthetic on the skin and mucous membranes. When properly formulated to ensure its stability and continuous contact with a cutaneous or mucous surface, it provides prolonged analgesia and anesthesia. When incorporated into a vehicle that is sufficiently alkaline to release bioactive quantities of the free base, it penetrates both intact and damaged skin (Ref. 14). Percutaneous absorption occurs, but when lidocaine is applied to limited areas of the skin, blood levels are insignificant and systemic reactions do not occur (Ref. 11). The Panel stresses, however, that no preparation should be applied over a wide area. Lidocaine, like other topical anesthetics of the "caine" type, relieves pain entirely within the skin or in the mucous membranes. The quantity circulating in the blood does not provide analgesia or anesthesia to parts of the body distal to the site of application or in structures beneath skin, such as the muscles, tendons, or joints. Lidocaine blocks transmission at nerve endings by stabilizing the neuronal membrane as do other topical anesthetics of the "caine" type (Ref. 2). Dalili and Adriani (Ref. 14) found that a 1-percent solution of the lidocaine hydrochloride did not block the effects of electrical stimulation on receptors eliciting sensation of burning and itch. When the skin was burned with ultraviolet light, the application of the solution of lidocaine hydrochloride exaggerated, rather than relieved, the pain. They were able to obtain blockade of the sensation of pain and itch using a saturated solution of lidocaine base in a solution composed of 40 percent alcohol, 10 percent glycerin, and water. Anesthesia, which began to diminish after 4 hours had elapsed, persisted as long as the film of the preparation remained in contact with the skin.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 4 percent concentration of lidocaine to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not use in large quantities, particularly over raw surfaces or blistered areas."

References

(1) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 717, 1976.

(2) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(3) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 667, 1973.

(4) Adriani, J. and M. Naraghi, "Pharmacologic Basis of Regional Pain Relief," *Annual Review of Pharmacology and Toxicology*, 17:223–242, 1977.

(5) OTC Volume 060020.

(6) OTC Volume 060043.

(7) OTC Volume 060049.

(8) OTC Volume 060071.

(9) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Practitioner*, 25:82–86, 1962.

(10) Covino, B. G., "Local Anesthesia," *New England Medical Journal*, 286:975–983, 1972.

(11) Adriani, J. and D. Campbell, "Fatalities Following Topical Application of Local Anesthetics to Mucous Membranes," *Journal of the American Medical Association*, 162:527–530, 1956.

(12) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 696–697, 1975.

(13) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 13–18, 1977.

(14) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia*, 50:834–841, 1971.

(15) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 277–279, 1977.

(16) Adriani, J., Personal communication.

q. *Lidocaine hydrochloride.* The Panel concludes that lidocaine hydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Lidocaine hydrochloride is the salt of lidocaine base, a tertiary amine. The chemistry of lidocaine base has been described elsewhere in this document. (See part III. paragraph B.1.p. above—Lidocaine.) Lidocaine hydrochloride is a white crystalline powder with a slightly bitter taste. It melts at between 74° and 79° C. It is very soluble in water, alcohol, and chloroform, but is insoluble in ether (Ref. 1). Lidocaine hydrochloride is very stable in vitro and

withstands boiling in 30 percent hydrochloric acid for 8 hours or more. Aqueous solutions are acid in reaction, the pH ranging from 5 to 6.4 (Ref. 2). The salt is highly ionized and not lipophilic. When injected into the tissues, it is converted to the free base due to the buffering mechanisms present in the tissues. The free base is the physiologically active form. The nitrogen atom on the cation of lidocaine hydrochloride is converted from a tertiary one to a quaternary (Ref. 3).

(1) *Safety.* Clinical use has confirmed that lidocaine hydrochloride is safe in the dosage range used as an OTC external analgesic.

The general properties and chemistry of lidocaine have been described elsewhere in this document. (See part III. paragraph B.1.p. above—Lidocaine.) Lidocaine hydrochloride is very soluble in water. It is twice as potent and twice as toxic as procaine. It is readily absorbed from open lesions when the stratum corneum has been removed and deeper layers of the skin exposed. Absorption is followed by significantly perceptible blood levels that result in systematic toxicity if lidocaine hydrochloride is applied to extensive areas. Human toxicity varies with individual tolerance, age, sex, health, and tissue vascularity. Convulsions and cardiac depression may occur if the drug is applied over extensive abraded areas (Refs. 4 and 5). However, systemic toxicity has not been demonstrated when lidocaine hydrochloride has been applied over small areas of the body and on intact skin (Refs. 4 and 6). The potential for sensitization exists, as with any other drug, but is not greater than those of other topical anesthetics, and may possibly be less (Refs. 1 and 5). Primary contact irritancy is low, and rashes and other cutaneous lesions have not been reported. As with other nitrogenous local anesthetics, lidocaine is dispensed as the hydrochloride because of its greater stability and ease of handling.

(2) *Effectiveness.* There are studies documenting the effectiveness of lidocaine hydrochloride as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that lidocaine hydrochloride is effective for use as an OTC external analgesic (Ref. 7).

Lidocaine hydrochloride is very slowly absorbed from the intact skin. The hydrochloride is acidic and is highly ionized; it is not strongly lipophilic and does not readily penetrate the cutaneous epithelial barrier. It is active when it gains access to the deeper cutaneous structures and to the nerve endings, being converted to the base by the buffering mechanisms of tissue fluids in the deeper layers of the skin (Ref. 8).

It stabilizes the axonal membrane and prevents conduction in the nerve fibers connecting with receptors for pain and other stimuli in the skin. Dalili and Adriani (Ref. 6) found that solutions of lidocaine hydrochloride in concentrations up to 4 percent did not obtund the sensation of burning and itch produced by electrical stimulation of the intact skin. However, lidocaine base, which is the physiologically active form, was effective. Additional data on effectiveness is presented in the section on lidocaine (base). (See part III. paragraph B.1.p. above—Lidocaine.)

Lidocaine hydrochloride is effective on damaged skin in concentrations of 0.5 to 4 percent. Claims for effectiveness on intact skin cannot be made for the hydrochloride. Therefore, the Panel does not recommend a dose for use on the intact skin.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 4.0 percent concentration of lidocaine hydrochloride to affected area of broken skin not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not use in large quantities, particularly over raw surfaces or blistered areas."

References

(1) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 666–669, 1973.

(2) Stecher, P. G., "The Merck Index," 7th Ed., Merck and Co., Rahway, NJ, p. 608, 1960.

(3) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(4) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Practitioner,* 25:82–86, 1962.

(5) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, p. 277, 1977.

(6) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics,* 12:913–919, 1971.

(7) OTC Volume 060049.

(8) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia,* 50:834–841, 1971.

r. *Menthol.* The Panel concludes that menthol is safe and effective for use as an OTC external analgesic as specified in the dosage section below. In concentrations of 1.0 percent or less, the ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below. In concentrations exceeding 1.25 percent up to 16 percent, menthol stimulates cutaneous sensory receptors and should bear the labeling for topical counterirritants set forth below.

Menthol is a secondary alcohol extracted from peppermint oil or made synthetically. Chemically it is hexahydrothymol. Natural menthol is known as peppermint camphor. It may be levorotatory (*l*-menthol) or racemic (*d,l*-menthol). Menthol is slightly soluble in water but soluble in alcohol, ether, chloroform, and mineral oil (Refs. 1 and 2). Menthol may be fatal if ingested in large quantities. Doses of 1 g/kg may be fatal (Ref. 2).

(1) *Safety.* Clinical use has confirmed that menthol is safe in the dosage range used as an OTC external analgesic.

Menthol can cause sensitization in certain individuals. Symptoms include urticaria, erythema, and other cutaneous lesions. However, the sensitization index is low. Menthol has caused asphixia in infants when applied locally for the treatment of coryza (runny nose).

Menthol was used internally as a carminative. Being the active ingredient of peppermint oil, it has found wide acceptance in candy, chewing gum, and cigarettes (Refs. 3 and 4). Menthol has had extensive use in inhalant preparations for the nose and throat. Inhalers containing menthol are commonly used for the relief of nasal congestion, headache, and neuralgia (Ref. 4).

Toxic effects from excessive ingestion of mentholated products can include nausea, abdominal pain, vomiting, and symptoms of central nervous system depression, such as dizziness, staggering gait, flushed face, sleepiness, slow respiration, and coma. The fatal dose of menthol in man is about 2 g (Refs. 5 and 6). Menthol is excreted in the bile and urine as a glucuronide (Ref. 7).

Rakieten et al. studied the effects of menthol vapor on the upper respiratory tract of rats. The rats were exposed to different menthol vapor concentrations over a period of several months. Vapor concentrations of 0.087, 0.148, and 0.295 part per million (ppm) showed no toxic effects, and no significant changes in skeletal muscle, skin, brain, or internal

organs. Animals did show indications of lung irritation when they were exposed to the highest menthol concentrations of 0.259±0.166 ppm (Ref. 8).

When a 20-percent oil solution of menthol is vigorously applied to the skin, an intense and lasting cooling sensation is felt. This is followed by numbness with a slight smarting sensation and hyperemia. Irritation beyond the rubefacient stage does not occur. Repeated topical application of mentholated products has been reported to give rise to hypersensitivity reactions (Refs. 7 and 9).

In young children, nose drops containing menthol may cause spasm of the glottis. Cases of dangerous asphyxiation have been reported in infants following local application of menthol (Ref. 7). However, clinical experience over many years of use of nose drops containing essential oils, including menthol, have shown no untoward effects (Ref. 10).

Marketing experience with counterirritant products containing menthol attests to the safety of such products. Based upon marketing data supplied by the manufacturers of 7 products, it can be conservatively estimated that more than 32,000,000 dosage units of these products alone were sold in 1972. Customer complaints of 1 per 310,000 were reported by one major manufacturer, while a second reported 1 per 950,000. No complaints of a serious nature were received (Refs. 11 through 17).

It is the opinion of the Panel that although the actual number of adverse effects attributed to the external use of menthol is relatively low, care should be taken to ensure that safety is maintained through adequate packaging, labeling, and application.

(2) *Effectiveness.* There are studies documenting the effectiveness of menthol as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that menthol is effective for use as an OTC external analgesic.

Menthol is used as an antipruritic (Ref. 1) in a concentration range of 0.1 to 1.0 percent. In a higher concentration, it also possesses counterirritant properties; in some cases it merely substitutes one sensation for another. When applied to the skin, menthol stimulates the nerves for perception of cold, while depressing those which perceive pain. Counterirritant concentrations of menthol applied topically produce a preliminary feeling of coolness that is soon followed by a sensation of warmth (Ref. 2). The sensation of cold is not due to cooling of the skin, for the vessels of the treated part are dilated, and a thermometer reading indicates a higher skin temperature than in the other parts of the body (Ref. 18).

The effectiveness of menthol used alone as a counterirritant has been mentioned in many standard texts (Refs. 19 through 22). The irritant (counterirritant) action of menthol varies significantly with the vehicle employed and the method of application. Topical application of a 1-percent solution of menthol in an acetone-alcohol vehicle is often followed by a prompt and persistent feeling of warmth. Other studies have shown that menthol used in combination is also effective (Ref. 17). White and Sage showed that application of a cream containing 15 percent methyl salicylate and 10 percent menthol effectively reduced muscular pain induced by exercise. The counterirritant applied produced skin hyperemia accompanied by the sensation of heat (Ref. 17).

Menthol is usually combined with other ingredients with antipruritic or analgesic properties, such as camphor. Menthol penetrates the intact as well as the damaged skin.

Menthol has been effectively used as a topical analgesic in concentrations ranging from 0.1 to 1.0 percent and as a topical counterirritant in concentrations exceeding 1.25 percent up to 16 percent.

(3) *Dosage*—(i) *For use as a topical analgesic, anesthetic, and antipruritic: For adults and children 2 years of age and older:* Apply a 0.1 to 1.0 percent concentration of menthol to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(ii) *For use as a counterirritant: For adults and children 2 years of age and older:* Apply a concentration of menthol exceeding 1.25 percent up to 16 percent to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* Based upon the dosage, the Panel recommends the applicable Category I labeling for products containing topical analgesic, anesthetic, antipruritic, or counterirritant active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) "The United States Pharmacopeia," 19th Rev. United States Pharmacopeial Convention, Inc., Rockville, MD., p. 302, 1975.

(2) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 697–698, 1973.

(3) Claus, E., V. Tyler, and L. Brady, "Pharamacognosy," 6th Ed., Lea and Febiger, Philadelphia, pp. 211–212, 1970.

(4) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, p. 721, 1975.

(5) Arena, J. M., "Poisoning: Chemistry, Symptoms, Treatments," Charles C. Thomas Publishing Co., Springfield, IL, pp 236–245, 1963.

(6) Deickman, W. B. and H. W. Gerarde, "Symptomatology and Therapy of Toxicological Emergencies," Academic Press, New York, p. 251, 1964.

(7) Todd, R. G., "Martindale, The Extra Pharmacopeia," 26th Ed., The Pharmaceutical Press, London, p. 374, 1972.

(8) Rakieten, N., M. L. Rakieten, and M. Boyd, "Effects of Menthol Vapor on the Intact Animal With Special Reference to the Upper Respiratory Tract," *Journal of the American Pharmaceutical Association, Scientific Edition,* 43:390–392, 1954.

(9) Rudzki, E. and D. Kleniewska, "Kontaktallergie auf einige Lokaltherapeutika und Konservierungsmittel," *Dermatologica,* 143:36–42, 1971.

(10) Adriani, J. and D. Campbell, "Fatalities Following Topical Application of Local Anesthetics to Mucous Membrances," *Journal of the American Medical Association,* 162:527–530, 1956.

(11) OTC Volume 060022.

(12) OTC Volume 060023.

(13) OTC Volume 060029.

(14) OTC Volume 060035.

(15) OTC Volume 060050.

(16) OTC Volume 060051.

(17) OTC Volume 060056.

(18) Grollman, A. and E. F. Grollman, "Pharamcology and Therapeutics," 4th Ed., Lea and Febiger, Philadelphia, p. 734, 1960.

(19) DiPalma, J. R., "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill Book Co., New York, p. 530, 1971.

(20) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, p. 722, 1975.

(21) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, p. 795, 1955.

(22) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 757, 1976.

s. *Methapyrilene hydrochloride.* The Panel concludes that methapyrilene hydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Methapyrilene is an analogue of tripelennamine and of pyrilamine. Chemically, it is *N,N*-dimethyl-*N'*-2-pyridinyl-*N'*-(2-thienylmethyl)-1,2-ethanediamine (Ref. 1). Its structure in many respects resembles that of the nitrogenous topical anesthetics, but there are sufficient modifications from

the classic configuration characteristic of the "caine" type drugs to decrease its potency as a topical anesthetic and to lessen its toxicity systemically (Refs. 2 and 3).

Methapyrilene is a base that forms salts with acids. The two most common salts used clinically are the hydrochloride and the fumarate. The hydrochloride is used topically. It is a white crystalline powder with a faint odor. One g dissolves in 0.5 mL water, 5 ml alcohol, or 3 ml chloroform. It melts at between 161° and 165° C. Pharmacologically, methapyrilene belongs to the class of antihistamine drugs, being similar in its actions and uses to other antihistaminic drugs (Refs. 4 and 5). Methapyrilene hydrochloride was introduced into clinical medicine by Feinberg and Bernstein (Ref. 6).

(1) *Safety.* Clinical use has confirmed that methapyrilene hydrochloride is safe in the dosage range used an an OTC external analgesic.

Methapyrilene hydrochloride is safe and effective as an antipruritic ingredient when applied to damaged skin (Ref. 7). The acute toxicity of methapyrilene hydrochloride is low. The intravenous median lethal dose in mice is 19 mg/kg, and orally, 182 mg/kg. It is somewhat less toxic in mice than tripelennamine but more toxic than diphenhydramine hydrochloride in comparative doses (Ref. 8). The Panel is aware of instances of poisoning following oral ingestion of toxic doses of methapyrilene hydrochloride due to accidental overdosage or deliberate ingestion of massive quantities for suicidal intent. One fatality occurred in a 1-year-old girl who developed hyperpyrexia, cerebral edema, and nephrosis followed by uremia (Ref. 9). When taken orally, methapyrilene causes drowsiness, the most frequent side effect (Ref. 10). Overdosage by any route may produce central nervous system stimulation, followed by depression. Anxiety, hyperative reflexes, and voluntary muscle spasms have been reported following ingestion of toxic doses. Nausea, vomiting, cyanosis, and unconsciousness precede death, following accidental ingestion of an overdose of the drug (Ref. 11). Clinical use and wide marketing experience indicate that even though methapyrilene is absorbed through the skin, side effects do not occur when the ingredient is applied to the skin. The quantity absorbed is not sufficient to cause adverse systemic reactions.

(2) *Effectiveness.* There are studies documenting the effectiveness of methapyrilene hydrochloride as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that methapyrilene hydrochloride is effective for use as an OTC external analgesic.

Methapyrilene hydrochloride, like other antihistaminic drugs, specifically blocks or diminishes the effects of histamine on smooth muscle and on the exocrine glands (Ref. 12). Methapyrilene hydrochloride inhibits the spasmogenic action of histamine on smooth muscle in the bronchioles, gastrointestinal tract, and uterus. Methapyrilene hydrochloride prevents histamine from increasing the permeability of the capillary endothelium, and inhibits the vasodilating action of histamine on the capillaries (Ref. 13). In therapeutic doses, methapyrilene hydrochloride does not inhibit the stimulating action of histamine on gastric secretion. The antiallergic reaction of methapyrilene hydrochloride is due to its antagonistic effect on histamine (Ref. 12). It binds at receptor sites on cells where histamine ordinarily binds, thereby preventing histamine from acting on a cell. Therapeutic doses have no significant effect on blood pressure, heart, and gastrointestinal tract. Methapyrilene hydrochloride protects the body from the effects of exogenous and endogenous histamine (Ref. 13). In comparison to other drugs used in the management of allergic disorders, such as epinephrine or aminophylline, methapyrilene hydrochloride does not overcome the various physiologic responses induced by histamine by an opposing pharmacologic action. Methapyrilene hydrochloride provides symptomatic relief in allergic disorders by protecting the cells from the effects of the free histamine released by pathologic conditions. Any effect that methapyrilene hydrochloride exerts topically is due mostly to its antagonistic effect on histamine. Histamine may be released in the skin and subcutaneous structures due to the action of an antigen-antibody response, and from trauma due to mechanical, chemical, or other causes. It is generally conceded that the receptors occupied by the antihistamine cannot react with free histamine (Ref. 13).

Methapyrilene hydrochloride has a weak anticholinergic and topical anesthetic effect. The anticholinergic effect is of no consequence in considering topical use (Ref. 14). Methapyrilene hydrochloride acts in the same manner as topical anesthetics and does not penetrate the epithelial barrier when the ingredient is applied to the intact skin. Methapyrilene hydrochloride is used orally and topically for symptomatic treatment of pruritus due to urticaria, hay fever, and other allergic disorders caused by histamine release. It is also reported to be useful in some disorders not directly related to histamine release. Sedation is not a problem when the ingredient is used topically on localized areas of the skin, as attested by long marketing experience and clinical usage (Ref. 15). Methapyrilene hydrochloride possesses a feeble topical anesthetic effect. Some of its antipruritic action may be due to its anesthetic action rather than to its antihistaminic effect (Refs. 12 and 13).

Methapyrilene has been used effectively as a topical antipruritic on skin in concentrations of 1 to 2 percent (Ref. 15).

The increasing problem of acquired sensitivity to antihistaminic drugs is presented by Ellis and Bundick (Ref. 16). These authors indicate that the antipruritic action of topical antihistaminic drugs is most useful for 1 to 2 weeks to prevent continued trauma or scratching, and thereby permit permanent healing. However, these drugs frequently lose efficacy after 3 or 4 weeks. Methapyrilene hydrochloride is no exception. Sensitivity often develops after this period of use. The Panel does not recommend use of methapyrilene hydrochloride for longer than 7 days except under the advice and supervision of a physician.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 1 to 1 percent concentration of methapyrilene hydrochloride to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 777, 1976.

(2) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(3) Adriani, J. and D. Campbell, "Fatalities Following Topical Application of Local Anesthetics to Mucous Membrances," *Journal of the American Medical Association,* 162:527–530, 1956.

(4) "AMA Drug Evaluations—1971," 1st Ed., American Medical Association, Chicago, p. 103, 1971.

(5) "AMA Drug Evaluations—1971," 1st Ed., American Medical Association, Chicago, pp. 657–674, 1971.

(6) Feinberg, S. and T. Bernstein, "Histamine Antagonists," *Journal of*

Laboratory and Clinical Medicine, 32:1370–1373, 1947.

(7) Sollmann, T., "A Manual of Pharmacology and Its Applications to Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, p. 559, 1957.

(8) Lee, H. M., W. G. Dinwiddie, and K. K. Chen, "The Antihistamine Action of N-(2-Pyridyl)-N-(2-Thenyl)-N',N'-Dimethylethylenediamine Hydrochloride," *Journal of Pharmacology and Experimental Therapeutics*, 90:83–87, 1947.

(9) Wyngaarden, J. B. and M. H. Seevers, "The Toxic Effects of Antihistamine Drugs," *Journal of the American Medical Association*, 145:277–282, 1951.

(10) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 673–675, 1977.

(11) Fattek, A. and J. B. Dudley, "Fatal Poisoning Involving Methapyrilene," *Journal of the American Medical Association*, 219:756–757, 1972.

(12) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., MacMillan Publishing Co., Inc., New York, p. 608, 1975.

(13) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 147, 723, 1973.

(14) Adriani, J. and M. Naraghi, "Pharmacologic Principles of Regional Pain Relief," *Annual Review of Pharmacology and Toxicology*, 17:223–242, 1977.

(15) OTC Volume 060141.

(16) Ellis, F. A. and W. R. Bundick, "Appraisal of Topical Use of Antihistamines," *Journal of the American Medical Association*, 150:773–776, 1950.

t. *Methyl nicotinate.* The Panel concludes that methyl nicotinate is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient stimulates cutaneous sensory receptors and should bear the labeling for topical counterirritants set forth below.

Methyl nicotinate is the methyl ester of nicotinic acid prepared synthetically by passing hydrochloric acid gas into a hot methanol solution of nicotinic acid. The drug occurs as colorless crystals with a melting point of 39° C and is soluble in water, alcohol, and benzene (Ref. 1).

(1) *Safety.* Clinical use has confirmed that methyl nicotinate is safe in the dosage range used as an OTC external analgesic.

Nicotinic esters administered parenterally or rectally to test animals provided evidence of very low toxicity (Ref. 2). The oral LD_{50} for mice was 310 mg/kg (Ref. 3).

When applied over large skin surfaces of a susceptible person, various concentrations of nicotinate counterirritants may produce generalized vascular dilatation as evidenced by a fall in blood pressure, change in pulse rate, and syncopy (Ref. 3).

Marketing data reveals that 3 manufacturers of counterirritant products containing methyl nicotinate sold more then 2,700,000 units in 1972. In all, they received 16 customer complaints, all of them minor (Refs. 2, 3, and 4).

(2) *Effectiveness.* There are studies documenting the effectiveness of methyl nicotinate as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that methyl nicotinate is effective for use as an OTC external analgesic.

Although nicotinic acid is inactive in topical applications, its esters possess a marked power of diffusion and readily penetrate the cutaneous barrier (Ref. 5). Vasodilation results from very low concentrations. The rate of absorption differed among various vehicles, but duration of reaction showed an inverse relationship to the rate of absorption (Ref. 6). The rate of absorption is accelerated by increased ambient temperatures. Alteration of concentrations between 0.25 and 1.0 percent does not change the rate of absorption, but does increase the intensity of the reaction.

Fulton and associates studied the mechanism of action of methyl nicotinate and other rubefacients. They used the cheek pouch of the hamster and observed for response of microcirculation. Vasodilation was produced consistently by ethyl, methyl, *n*-hexyl, and tetrahydrofurfuryl esters of nicotinic acid applied topically to the walls of arterioles in concentrations ranging from 1 to 100 percent (Ref. 7).

Application to human subjects produced erthema with skin temperature elevation corresponding to the degree of erythema produced (Ref. 8).

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.25 to 1.0 percent concentration of methyl nicotinate to the affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical counterirritant active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 795, 1975.

(2) OTC Volume 060029.

(3) OTC Volume 060077.

(4) OTC Volume 060033.

(5) Stoughton, R. B., W. E. Clendenning, and D. Kruse, "Percutaneous Absorption of Nicotinic Acid and Derivatives," *Journal of Investigative Dermatology*, 35:337–340, 1960.

(6) Fountain, R. B., B. S. Baker, J. W. Hadgraft, and I. S. Sarkany, "The Rate of Absorption and Duration of Action of Four Different Solutions of Methyl Nicotinate, "*British Journal of Dermatology*, 81:202–206, March, 1969.

(7) Fulton, G. P., E. M. Farber, and A. P. Moreci, "The Mechanism of Action of Rubefacients," *Journal of Investigative Dermatology*, 33:317–325, 1959.

(8) Peterson, J. B., E. M. Farber, and G. P. Fulton, "Responses of the Skin to Rubefacients," *Journal of Investigative Dermatology*, 35:57–64, 1960.

u. *Methyl salicylate.* The Panel concludes that methyl salicylate is safe and effective for use as an OTC external analgesic as specified in the dosage section discussed below. The ingredient stimulates cutaneous sensory receptors and should bear the labeling for topical counterirritants set forth below. There are no data to confirm any claims that methyl salicylate depresses cutaneous sensory receptors in the same way as the topical analgesics. Therefore the Panel has not considered methyl salicylate as a topic analgesic.

Methyl salicylate is the methyl ester of salicylic acid. Before the discovery of methods for synthesizing methyl salicylate, it was produced by steam distillation from natural sources. The natural source products are known as gaultheria oil, betula oil, sweet birch oil, teaberry oil, and wintergreen oil. These products when pure are as effective as the synthetic product. Today, these names are considered synonymous with methyl salicylate, which is prepared synthetically by esterification of salicylic acid with methanol.

Methyl salicylate is a volatile liquid having a density of 1.18 g/mL. One mL of methyl salicylate has a salicylate content equivalent to 1.4 g aspirin. It is a colorless, yellowish, or reddish, oily liquid and is miscible with alcohol, ether, and chloroform. It is only slightly soluble in water and not highly volatile (Ref. 1).

Methyl salicylate boils at between 220° to 224° C. At low concentrations, methyl salicylate is used as an organoleptic agent for both its condimental flavor and pleasing aroma. Methyl salicylate acts as a counterirritant for the temporary relief of deep-seated pain (Refs. 2 through 6). Methyl salicylate penetrates intact skin after topical application. Some available data suggest that the amounts absorbed percutaneously act systemically and are sufficient to have significant analgesic activity (Refs. 7 through 10).

(1) *Safety.* Clinical use has confirmed that methyl salicylate is safe in the

dosage range used as an OTC external analgesic.

The Panel has given much consideration to the toxicity of methyl salicylate. The American Medical Association has linked methyl salicylate's candy-like odor (wintergreen, teaberry flavors) to children's ingestion of toxic quantities of drug products containing therapeutic amounts of methyl salicylate (Ref. 11). But a review of the data on poisoning from the National Clearinghouse of Poison Control Centers (Bethesda, Maryland) for the period of 1970 to 1972 concerning oral ingestion of methyl salicylate primarily in ointment formulations indicates that there were no deaths and a lack of cases manifesting severe symptoms. Recent regulations require the use of child-resistant containers for liquid preparations containing more than 5 percent methyl salicylate (16 CFR 1700.14(a)(3)). These containers cause some inconvenience for arthritic and rheumatic patients, but they provide an important safeguard for small children, who are the most common victims of accidental poisoning caused by toxic household medicinal substances.

Except for the fact that it can cause severe local irritations, ingested methyl salicylate is not notably different in its toxic actions from other salicylates. Metabolic acidosis may be a more prominent complication with the methyl ester than with other derivatives of salicylic acid (Ref. 12). The average lethal dose of methyl salicylate is estimated to be 10 mL for children and 30 mL for adults (Refs. 13 and 14). But the ingestion of as little as 4 mL (4.7 g) methyl salicylate has caused death in children (Ref. 15). For comparative purposes, it should be noted that 4 mL (4.7 g) methyl salicylate is equivalent in salicylate content to 4.3 g salicylic acid, 4.96 g sodium salicylate, or 5.6 aspirin, and that death has ensued following the ingestion of 3 g salicylic acid and 4 g sodium salicylate (Ref. 16). The toxic dose of aspirin is estimated to range from 75 to 150 mg/kg. This is in the range of 5.3 to 10.5 g for a 154–1b adult.

The Panel has carefully considered the benefit-to-risk potential of topically adminstered methyl salicylate in arriving at its conclusion concerning safety and effectiveness, and has recommended appropriate precautionary labeling elsewhere in this document. (See part III. paragraph B.1. below—Category I Labeling.) There is adequate evidence that ingestion of more than small condimental amounts of methyl salicylate is hazardous, but little to suggest that these toxicity hazards restrict the rational topical use of the drug as a counterirritant.

Methyl salicylate has a high degree of safety for topical use. The manufacturers of 10 counterirritant OTC drug products provided marketing data on thier sales through 1972. Their data show that in 1972 they marketed more than 35,000,000 individual packages containing methyl salicylate. No customer complaints of a serious nature were received by these manufacturers. Minor complaints were about 1 out of 500,000 (Refs. 17 through 26).

(2) *Effectiveness.* There are studies documenting the effectiveness of methyl salicylate as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that methyl salicylate is effective for use as an OTC external analgesic.

Using a single-blind technique, Brusch (Ref. 27) compared a topical lotion containing methyl salicylate with placebo lotion on a test group of 203 arthritic patients. Both the placebo and the test lotion producted improved comfort levels. However, significantly greater improvement resulted from the use of the counterirritant lotion.

In a double-blind study, the effect of a counter-irritant lotion containing methyl salicylate was compared with a placebo in 62 individuals suffering from moderately painful arthritis. The methyl salicylate-containing lotion was significantly superior to the placebo in reducing the arthritic pain (Ref. 27).

Chronic muscle pain is a component of arthritic pain. Sustained hypertonicity of skeletal muscles results in chronic muscle pain. The resting muscle action potential can be determined by use of the electromyograph and can be used to measure the degree of muscle tone. Application of a topical ointment containing methyl salicylate to painful arthritic joints of a test group of 30 individuals produced a significant decrease in the muscle action potential in the adjacent muscles, whereas the application of a placebo produced no significant change (Ref. 28).

Counterirritant methyl salicylate products are used extensively in the management of muscle pain. A test group of 40 healthy individuals performed fatiguing exercise which produced muscle soreness in both forearms. Forty-eight hours later, the muscle action potential was determined on each individual's forearm, followed by the application of a placebo to one forearm and the application of a counterirritant ointment containing methyl salicylate to the other. Postmedication muscle action potentials showed a significant decrease of hypertonicity in the treated forearms and little change in the placebo-treated control forearms (Ref. 29).

Methyl salicylate is one of the most widely used single ingredients considered by the Panel. It is not only a component of a large number of OTC products for self-medication, but is also the most widely used ingredient in "locker-room" atheletic rubs.

In addition to the numerous proprietary products containing methyl salicytate, a considerable number of nonproprietary formulas may be found published in the older official compendia of the United States and Great Britain. The Extra Pharmacopoeia (Ref. 30) lists nine such formulas, four ointments and five liniments. The methyl salicylate content in these ointments ranges from 12.5 to 50.0 percent by weight, and from 25 to approximately 65 percent by volume in the five liniments. A concentration of 100 percent, undiluted methyl salicylate had been used for many years as a counterirritant for relieving pain of sore muscles and sprains, and for the symptomatic treatment of painful rheumatoid arthritis, rheumatic fever, and the like (Ref. 31). In considering the benefit-to-risk ration, however, the Panel believes that using concentrations of methyl salicylate exceeding 60 percent by weight (50 percent by volume) increases the hazards without significantly increasing the therapeutic benefits. Therefore, the 60-percent maximum concentration is chosen by the Panel in the interest of safety. Concentrations of less than 10 percent are not effective irritants.

Methyl salicylate has been effectively used in concentrations ranging from 10 to 60 percent.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 10 to 60 percent concentration of methyl salicylate to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical counterirritant active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Sollmann, T., "A Manual of Pharmacology and Its Application to Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, pp. 743–744, 1957.

(2) Krantz, J. C., Jr. and C. J. Carr, "Pharmacological Principles of Medical Practice," 6th Ed., The Williams and Wilkins Co., Baltimore, p. 200, 1965.

(3) Swinyard, E. A., "Demulcents, Emollients, Protectives and Adsorbents, Antiperspirants and Deodorants, Absorbable Hemostatics, Astringents, Irritants, Sclerosing Agents, Caustics, Keratolytics, Antiseborrheics, Melanizing and Demelanizing Agents, Mucolytics, and Certain Enzymes," *in* "The Pharmacological Basis of Therapeutics," 4th Ed., Edited by Goodman, L. S. and A. Gilman, The MacMillan Co., New York, p. 993, 1970.

(4) Crossland, J., "Lewis's Pharmacology," 4th Ed., E. and S. Livingstone, London, pp. 562–563, 1970.

(5) Fulton, G. P., E. M. Farber, and A. P. Moreci, "The Mechanism of Action of Rubefacients," *The Journal of Investigative Dermatology*, 33:317–325, 1959.

(6) DiPalma, J. R., "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill Book Co., New York, p. 1036, 1971.

(7) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 749–750, 1973.

(8) Swinyard, E. A., "Demulcents, Emollients, Protectives and Adsorbents, Antiperspirants and Deodorants, Absorbable Hemostatics, Astringents, Irritants, Sclerosing Agents, Caustics, Keratolytics, Antiseborrheics, Melanizing and Demelanizing Agents, Mucolytics, and Certain Enzymes," *in* "The Pharmacological Basis of Therapeutics," 4th Ed., Edited by Goodman, L. S. and A. Gilman, The MacMillan Co., New York, pp. 987–1001, 1970.

(9) Crossland, J., "Lewis's Pharmacology," 4th Ed., The Williams and Wilkins Co., Baltimore, p. 560, 1970.

(10) Beutner, R., B. Calesnick, E. Powell, and L. Bortin, "On the Absorption and Excretion of Methylsalicylate Administered by Inunction," *Journal of Laboratory and Clinical Medicine*, 28:1655–1663, 1943.

(11) Anon., "Candy Medication and Accidental Poisoning," *Journal of the American Medical Association*, 158:44–45, 1955.

(12) Davison, C., E. F. Zimmerman, and P. K. Smith, "On the Metabolism and Toxicity of Methyl Salicylate," *Journal of Pharmacology and Experimental Therapeutics*, 132:207–211, 1961.

(13) Deichman, W. B. and H. W. Gerarde, "Toxicology of Drugs and Chemicals," Academic Press, New York, p. 662, 1969.

(14) Wilson, C. O., O. Gisvold, and R. F. Doerge, "Textbook of Organic Medicinal and Pharmaceutical Chemistry," 5th Ed., J. B. Lippincott Co., Philadelphia, p. 675, 1966.

(15) "The Year Book of Drug Therapy—1969," Edited by Beckman, H., Year Book Medical Publishers, Chicago, p. 268, 1969.

(16) Thienes, C. H. and T. J. Haley, "Clinical Toxicology," 5th Ed., Lea and Febiger, Philadelphia, p. 80, 1972.

(17) OTC Volume 060022.

(18) OTC Volume 060023.

(19) OTC Volume 060029.

(20) OTC Volume 060030.

(21) OTC Volume 060031.

(22) OTC Volume 060040.

(23) OTC Volume 060050.

(24) OTC Volume 060051.

(25) OTC Volume 060056.

(26) OTC Volume 060077.

(27) OTC Volume 060036.

(28) White, J. R. and J. M. Sage, "Effects of a Counterirritant on Muscular Distress in Patients with Arthritis," *Physical Therapy*, 51:36–42, 1971.

(29) White, J. R. and J. M. Sage, "Topical Analgesic on Induced Muscular Pain," *Physical Therapy*, 50:166–172, 1970.

(30) Todd, R. G., "Martindale, The Extra Pharmacopeia," 25th Ed., The Pharmaceutical Press, London, pp. 1262–1263, 1972.

(31) Lyght, C. E., "The Merck Manual of Diagnosis and Therapy," 11th Ed., Merck and Co., Rahway, NJ, p. 1545, 1966.

v. *Phenol.* The Panel concludes that phenol is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Phenol is hydroxybenzene. Phenol was discovered in 1834 in coal tar by Ringe who named it "carbolic acid." It was also once called phenic acid (Ref. 1). Phenol is a primary alcohol of the aromatic series and as such exerts a topical anesthetic action (Ref. 2). Although it may be obtained from coal tar, most of it is now prepared synthetically. The antimicrobial efficacy of phenol was first demonstrated by Lister in 1857. Now it has limited clinical use. It is used most often as a topical analgesic and for cauterization (Ref. 3). Compounds less toxic than phenol are more effective antimicrobial agents (Ref. 1). Phenol consists of colorless to light-pink, needle-shaped crystals interlaced or separated, or as a white to light-pink crystalline mass (Ref. 4). It possesses a distinctive aromatic odor. It gradually darkens on exposure to light and air. Phenol is liquefied by warming or by the addition of 10 percent water. It is caustic if applied directly to tissues (Ref. 1). A concentrated solution of phenol and water has a strength of approximately 6 percent. Phenol is soluble in alcohol, glycerin, chloroform, ether, and fixed and volatile oils (Ref. 4). It is sparingly soluble in mineral oil. One g dissolves in about 5 mL of water. Solutions of phenol are oxidized and turn brown due to the formation of quinones (Ref. 1). With sodium hydroxide, phenol forms a salt that is ionized and highly alkaline. Phenol boils at about 182° C. It congeals at temperatures lower than 39° C. Phenol combines with camphor to form a substance known as camphor-phenol (Ref. 5). Whether this is a definite chemical complex or a solution of phenol in camphor has not been established. The mixture releases phenol slowly in small quantities. The presence of moisture hastens the process (Ref. 1).

(1) *Safety.* Clinical use has confirmed that phenol is safe in the dosage range used as an OTC external analgesic.

Concentrations greater than 2 percent in aqueous solutions are irritating and may cause sloughing and necrosis (Refs. 3 and 6). When applied in pure form to the skin, phenol causes an area of blanching. A feeling of numbness develops. Later the area undergoes necrosis and sloughing (Ref. 1).

After oral ingestion or absorption, phenol is oxidized and conjugated with sulfuric, glucuronic and other acids by the liver and excreted into the urine. Only small quantities of free phenol are excreted into the urine. Phenol is lipophilic and is readily absorbed through the intact and damaged skin and passes into the systemic circulation (Ref. 7). Absorption through the skin depends upon the area exposed rather than on the concentration (Refs. 3 and 8). Concentrated solutions are toxic and cause death if ingested orally (Ref. 8). Phenol has been used for suicidal purposes. Cases of accidental poisoning have been common. The symptons of toxicity usually develop rapidly and death has occurred within 2 or 3 minutes after ingestion. Coma and collapse are the main signs of toxicity from large doses. After ingestion of small amounts, the most common symptoms are nausea, vomiting, collapse, pallor, cold sweats, and feeble pulse. Stupor ensues, deepening into a comatose state with insensibility. Respirations are often rapid and shallow, irregular, and sometimes paroxysmal. Death results from respiratory arrest. Paralysis of both sensation and motion may occur. In some cases, violent clonic or epileptiform convulsions have occurred. The urine is generally scanty, albuminous, and greenish or black in color. The diagnosis is usually not difficult to make, since the odor of phenol can be detected on the breath and in the smoky urine. White, corrugated spots are present on the mucous membranes of the mouth and throat due to the caustic action of the phenol. The estimated fatal dose of phenol is approximately 15 g. However, death has been reported following the ingestion of as little as 1.5 g. Recovery has followed the ingestion of as much as 30 g. Death usually occurs from respiratory failure, although in some instances fatal cardiac failure has been reported. The degree of toxicity depends upon the amount of phenol ingested; its concentration is not an important consideration (Refs. 1 and 8).

Some question exists concerning the carcinogenic potential of phenol (Ref. 9). How important this finding may be in

regard to the use of phenol on the human skin is unknown.

This issue was addressed in the tentative final order on OTC Topical Antimicrobial Products, published in the Federal Register of January 6, 1978 (43 FR 1210), as follows:

The Commissioner recognizes that the accepted protocol for determining the potential for the carcinogenicity or cocarcinogenicity (tumor promotion) of any drug is the National Cancer Institute (NCI) standard bioassay program. Phenol has been included in this program, but the results are not yet available. The Commissioner will carefully review the results of the NCI study and will determine at that time whether any regulatory action is appropriate.

Chronic ingestion of phenol in small quantities may produce a dark discoloration of the tissues, particularly cartilage.

(2) *Effectiveness.* There are studies documenting the effectiveness of phenol as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that phenol is effective for use as an OTC external analgesic.

Phenol penetrates the sensory nerve endings and exerts its analgesic and anesthetic effect in a manner that is not clearly understood (Refs. 6 and 7). It is a polar substance and is thought to act in the same manner as the "caine" type of topical anesthetics (Ref. 10). The hydrocarbon pole is lipophilic and orients into the lipid phase of the axon. The hydroxyl group is hydrophilic and orients into the water phase (Ref. 11). Phenol is acidic and forms salts with alkalies. When combined with the nitrogenous basic topical anesthetics, it may nullify their effects by lowering the pH (Ref. 12). Its absorption from the skin does not depend upon the pH of the medium. A feeling of warmth and tingling ensues following the application of 5 percent phenol to the unabraded skin. Complete topical anesthesia eventuall develops and the area becomes irritated. In many cases, phenol can be very irritating, even caustic, to the skin and can cause necrosis in concentrations of more than 2 percent in water. It possesses topical anesthetic activity and acts as an antipruritic when aded to dermatologic preparations in concentrations of 0.5 to 2.0 percent (Refs. 2 and 10). The blockade produced in concentrations of less than 2 percent is reversible. Aqueous solutions stronger than 2 percent are too irritating for topical application to the skin. A 4-percent solution in glycerin is sometimes used and is said not to have caustic properties. When camphor is added to phenol, a liquid forms. This reduces the severity of the topical reaction and the absorption of phenol, apparently due to its camphor-holding property (Ref. 5). Phenol is employed topically as a keratolytic, neurolytic, and a destructive agent in concentrations of 10 percent to 40 percent (Ref. 1).

Phenol is analgesic and anesthetic to the mucous membranes. A 5-percent solution of phenol and water has definite topical anesthetic action, but sloughing occurs in about 10 percent of the cases (Ref. 13).

A 5-percent solution of phenol in 95 percent alcohol is an efficient topical anesthetic. Complete anesthesia results in 53 percent and partial anesthesia in 47 percent. However, slough or superficial necrosis resulted in 22 percent of cases studied.

Dressings or compresses saturated with solutions of phenol, even though dilute, may cause sloughing, and are not recommended. Preparations containing 1 to 2 percent phenol should be applied only to the smallest area needing treatment and should not be bandaged to prevent severe skin irritation.

When phenol is combined with other topical anesthetics of the nitrogenous type that are active in the basic form on the skin, conversion of the nitrogenous base form of the anesthetic to the acid form by the phenol may nullify their action and not necessarily produce an additive effect or summation. The antimicrobial activity of phenol is due to its ability to coagulate proteins.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 2.0 percent concentration of phenol to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not apply this product to extensive areas of the body or under compresses or bandages."

References

(1) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, pp. 1037–1038, 1955.

(2) Adriani, J. and M. Naraghi, "Pharmacologic Principles of Regional Pain Relief," *Annual Review of Pharmacology and Toxicology*, 17:223–242, 1977.

(3) "AMA Drug Evaluations," 3d Ed., Publishing Sciences Group, Inc., Littleton, MA, pp. 892–893, 1977.

(4) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 940, 1976.

(5) OTC Volume 060053.

(6) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 900–901, 1973.

(7) Freeman, M. V., J. H. Draize, and E. Alvarez, "Cutaneous Absorption of Phenol," *Journal of Laboratory and Clinical Medicine*, 38:262–266, 1951.

(8) Deichman, W. B., "Local and Systemic Effects Following Skin Contact with Phenol-A Review of the Literature," *Journal of Industrial Hygiene and Toxicology*, 31:146–154, 1949.

(9) Boutwell, R. K. and D. K. Bosch, "The Tumor-Producing Action of Phenol and Related Compounds for Mouse Skin," *Cancer Research*, 19:413–424, 1959.

(10) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(11) Adriani, J., "Local Anesthetics," *in* "The Pharmacology of Anesthetic Drugs," 5th Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 131–145, 1970.

(12) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia*, 50:834–841, 1971.

(13) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., MacMillan Publishing Co., Inc., New York, pp. 990–991, 1975.

w. *Phenolate sodium.* The Panel concludes that phenolate sodium is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Phenolate sodium, also known as sodium phenoxide, sodium phenate, sodium carbolate, and phenol sodium, is the sodium salt of phenol (carbolic acid) (Ref. 1). Ordinarily, phenol exists in the enol form, that is, a benzene ring with a hydroxyl group. Phenol has high resonant energy and can revert to the keto form (Ref. 2). The keto form is less stable than the enol form. The sodium salt is formed with the keto form. One hydrogen atom on position 2 is replaced by the metallic ion. Phenols are more acidic than other alcohols or water but are weaker acids than carboxylic and carbonic acids. The dissociation constant of phenol is 1.3×10^{10} compared to 4.3×10^{7} for carbonic acid. Phenol reacts with sodium hydroxide to form a water-soluble salt, but it will not interact with sodium carbonate to form the salt.

Phenolate sodium is a white to reddish deliquescent substance composed of rods or granules. If exposed to air, it is readily decomposed by carbon dioxide to phenol and sodium carbonate. It must be stored in tightly

closed containers Phenolate sodium is strongly alkaline and caustic. It is soluble in water and alcohol. Aqueous solutions are strongly alkaline and caustic. Phenolate sodium releases 81 percent phenol on decomposition or acidification. The therapeutic and toxic effects of phenolate sodium are due to the phenol released (Refs. 1, 2, and 3).

(1) *Safety.* Clinical use has confirmed that phenolate sodium is safe in the dosage range used as an OTC external analgesic.

The safety considerations for phenolate sodium are the same as those for phenol because phenolate sodium releases phenol, and its toxic effects are due to the phenol (Ref. 1). Phenolate sodium may augment the caustic effects of phenol if concentrated solutions are ingested orally or applied topically. This is due to the presence of sodium hydroxide, from which phenolate sodium is formed. Phenolate sodium precipitates proteins and can, therefore, exert an antimicrobial effect as does phenol. The Panel has not considered the antimicrobial effects of phenol or phenolate sodium. Phenolate sodium, in doses of 0.1 to 0.3 g, was formerly used to treat diarrhea.

(2) *Effectiveness.* There are studies documenting the effectiveness of phenolate sodium as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that phenolate sodium is effective for use as an OTC external analgesic.

Aqueous solutions of phenolate sodium are alkaline and caustic, but dilute solutions can be used to obtain the same analgesic, anesthetic, and antipruritic effect as phenol (Ref. 1). Because solutions containing phenolate sodium are alkaline, the effects of certain ingredients that are active physiologically in the form of a base, as is the case with nitrogenous topical anesthetics, is assured. The released phenol and alkali may enhance the effects of the latter compounds and maintain an alkaline medium. Aqueous solutions of phenolate sodium have been used as a topical analgesic applied in the form of bandages. It has also been used combined with linseed oil in a ratio of 1:5 phenolate sodium-linseed oil. Phenolate sodium is not used as the sole ingredient in any of the products submitted to the Panel for consideration but has been submitted in combination with other external analgesic ingredients.

Phenolate sodium has been used effectively as an external analgesic on the skin in concentrations of 0.25 to 2.0 percent.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 2.0 percent concentration of phenolate sodium to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Stecher, P. G., "The Merck Index," 7th Ed., Merck and Co., Rahway, NJ, p. 958, 1960.

(2) Noller, C. R., "Chemistry of Organic Compounds," W. B. Saunders Co., Philadelphia, pp. 489–490, 1951.

(3) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 1118, 1976.

x. *Pramoxine hydrochloride.* The Panel concludes that pramoxine hydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Pramoxine, also known as pramocaine and proxazocain, is a tertiary amine that combines with acids to form salts. It interacts with hydrochloric acid to form the hydrochloride, which is the form used in OTC products (Ref. 2). The drug first became available in 1952.

Pramoxine is 4[3-(*p*-butoxyphenoxy)]-propyl morpholine and differs from the usual type of nitrogen-containing topical anesthetics because its chemical structure departs from that of the "caine" type drugs. Unlike them, it is neither an ester nor an amide. Pramoxine base is a liquid that boils at 183° to 184° C (Ref. 1). Pramoxine hydrochloride is a white crystalline powder that melts at 181° to 183° C. It is freely soluble in water and alcohol, and is insoluble in ether. Data on the lipophilic nature of the base are not available.

(1) *Safety.* Clinical use has confirmed that pramoxine hydrochloride is safe in the dosage range used as an OTC external analgesic.

The systemic toxicity of pramoxine hydrochloride is of a low order (Ref. 2). The intravenous LD_{50} in rats is 79.5 mg/kg. The compound appears to be relatively nontoxic when studied in laboratory animals. The intravenous administration of 5 mg/kg to anesthetized rats, cats, dogs, and monkeys produced only transient mild depression of the blood pressure. Other studies using rats, mice, and guinea pigs involving both intraperitoneal and subcutaneous routes reveal few toxic effects unless extremely large doses are used (up to 942 mg/kg) (Ref. 3). The orally ingested lethal dose for man is not known. Only one report of alleged toxicity was received by the manufacturer from August 1954 to January 1973. A child ingested approximately 10 grams of the product orally without any adverse effects or sequellae (Ref. 3). Pramoxine hydrochloride, despite its low order of toxicity, is not suitable for injection and can irritate tissues and delicate mucous membranes. It should not be used in the eye, nose, or for bronchoscopy or gastroscopy. Systemic absorption does not cause the characteristic reactions, such as convulsions, cardiac depression, etc., ascribed to the "caine" type drugs. Although pramoxine hydrochloride has a local irritating effect on certain mucous membranes and produces burning if applied to the eye, it is not irritating to the skin. Sensitization may occur, but it is no more common than with other topical anesthetics in other chemical groups. Chronic toxicity studies reveal no alteration in the heart, liver, or kidney (Ref. 3).

(2) *Effectiveness.* There are studies documenting the effectiveness of pramoxine hydrochloride as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that pramoxine hydrochloride is effective for use as an OTC external analgesic.

Like other topical anesthetics, pramoxine hydrochloride acts by stabilizing the neuronal membrane of the nerve ending with which it comes into contact, thus blocking painful sensations due to burns, cuts, and abrasions (Ref. 4). Its onset of action on mucous membranes requires several minutes. It is ionized and does not penetrate the intact skin unless it is converted to the base (Ref. 5). It causes analgesia on the skin (Ref. 3) but the sensation of numbness is not obtained unless deeper layers of the skin are exposed. Pramoxine hydrochloride obtunds the sensation of itch and is an effective antipruritic agent on damaged skin. Dalili and Adriani (Ref. 5) found that 1 percent ointment, when applied to intact skin and skin that had been burned with ultraviolet light, did not obtund the sensation of burning and itching elicited by electrical stimulation.

Pramoxine hydrochloride has been effectively used on damaged skin in concentrations ranging from 0.5 to 1.0 percent (Ref. 3).

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 1.0 percent concentration of pramoxine hydrochloride to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Windholz, M., "The Merck Index," 9th Ed., Merck and Co, Rahway, NJ, p. 997, 1976.

(2) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 951, 1973.

(3) OTC Volume 060045.

(4) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 390–391, 1976.

(5) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics*, 12:913–919, 1971.

y. *Resorcinol.* The Panel concludes that resorcinol is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Resorcinol, also known as resorcin, is metadihydroxybenzene, an aromatic alcohol, and, therefore, it is a phenolic type compound (Ref. 1). Resorcinol was first prepared by Hlasiwetz and Barth in 1864. It may be prepared by fusing benzene disulfonic acid with sodium hydroxide. Resorcinol is chemically allied to pyrocatechol, which is the *ortho*-dihydroxybenzene, and hydroquinone, which is *para*-dihydroxybenzene. Resorcinol occurs as white, or nearly white, needle-shaped crystals or as a powder. It has a faint, characteristic aromatic odor. When initially applied to the tip of the tongue, it imparts a sweetish taste that is promptly followed by a bitter taste. Resorcinol melts at between 109° and 111° C. A 1:20 concentration of an aqueous solution is acidic. One g of resorcinol dissolves in 1 mL of water and approximately 1 mL of alcohol. It is freely soluble in glycerin and ether but only slightly soluble in chloroform. Resorcinol powder acquires a pink tint on exposure to light and air. An aqueous solution of resorcinol first turns pink, then red, and finally brown on exposure to light and air, due to oxidation to quinones. The change is hastened by alkalies. Oxidizing agents produce a red or violet color. A liquid or soft mass results from the trituration with camphor, menthol, phenol, chloral hydrate, acetanilid, antipyrine, and other substances. Resorcinol has been obtained from sagapenum, asafetida, ammoniac, etc. The present-day compound is prepared synthetically as described above (Ref. 2).

Resorcinol can be acetylated to form the acetyl monoacetate. The action of resorcinol monoacetate is similar to that of resorcinol because of the gradual liberation of the latter due to a slow hydrolytic reaction that occurs. The effects, therefore, are milder and longer lasting than those of the unacetylated derivative (Ref. 1).

(1) *Safety.* Clinical use has confirmed that resorcinol is safe in the dosage range used as an OTC external analgesic.

Resorcinol resembles phenol in its physiologic properties. However, it is less toxic than phenol (Refs. 3 and 4). Topically, resorcinol is a protein precipitant (Ref. 5). Because of this action, it possesses an antimicrobial action. Resorcinol will darken white, blonde, or gray hair (Ref. 1). After oral ingestion, resorcinol causes depression of the central nervous system and an elevation in blood pressure.

In concentrations of 1 to 6 percent, resorcinol is not a primary irritant. But concentations exceeding 10 percent may cause severe skin irritation (Ref. 6). Resorcinol is readily absorbed from the intact and damaged skin. As is the case with phenol, absorption of resorcinol does not depend upon the pH of the medium in which it is incorporated. In concentrations above 6 percent, it causes skin irritation manifested by hyperemia, itching, edema, corrosion, and loss of superficial layers of the skin (Ref. 2). Topical exposure to high concentrations causes systemic absorption resulting in enlargement of regional lymph nodes.

Poisoning can occur from the ingestion of resorcinol. Manifestations are restlessness, cyanosis, convulsions, tachycardia, and dyspnea. Death is caused by respiratory failure. If resorcinol is absorbed in large quantities when it is applied topically, it causes methemoglobinemia (Ref. 2).

The minimum lethal dose of resorcinol is 400 to 500 mg/kg subcutaneously in guinea pigs, 340 to 360 mg/kg in mice subcutaneously, and 400 to 500 mg/kg in rats subcutaneously. In dogs, the median lethal dose intravenously is 700 to 1,000 mg/kg. The oral median lethal dose in rabbits is 750 mg/kg, and in rats and guinea pigs it is 370 mg/kg (Ref. 2).

Although resorcinol is much less toxic than phenol, cases of poisoning have been reported, with some fatalities. Cunningham (Ref. 7) reviewed the literature and found eight cases of poisoning, mostly in children. Six of the eight cases were fatal. In addition, he reviewed a case in which a 7-week-old child developed severe hemolytic anemia. He concluded that the use of resorcinol, even in low concentrations in weak lotions or ointments, on the skin of babies and young children was dangerous. Absorption may be intense and lethal quantities absorbed if applied to extensive areas of the damaged skin. Bull and Fraser (Ref. 8) reported three cases of myxedema associated with varicose ulcers to which resorcinol ointment had been applied. They concluded that when resorcinol was absorbed through the ulcer it acted as an antithyroid agent. Pascher (Ref. 9) cities two cases of resorcinol toxicity in young adults with pustular acne. A 40-percent concentation was applied from 1 to 4 hours over 33 and 22 days, respectively. The urine was violet-black. Both patients recovered.

Resorcinol has keratolytic properties and causes exfoliation of the skin (Ref. 2).

Resorcinol can act as a paptene and produce sensitization, although the Panel finds that the incidence of allergic reactions following its use is low (Refs. 10, 11, and 12). One product submitted for review has been on the market for 78 years without any report of substantial toxicity (Ref. 10).

(2) *Effectiveness.* There are studies documenting the effectiveness of resorcinol as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that resorcinol is effective for use as an OTC external analgesic.

Because resorcinol is an aromatic alcohol and resembles phenol in many of its qualities, it would be expected to demonstrate the antipruritic effects that phenol does (Ref. 1).

Resorcinol has bactericidal and fungicidal activity. Because resorcinol is a phenol, it belongs to the hydroxy group of topical anesthetics and acts in the same manner as other hydroxy compounds (Refs. 1, and 3 through 5). Resorcinol produces no significant degree of anesthesia when applied in concentrations of less than 6 percent to

the intact skin but is effective as an antipruritic (Refs. 1, and 3 through 5).

Resorcinol was formerly used as an intestinal antiseptic in enteritis, but it is doubtful that it was effective in these situations. It has been used in concentrations ranging from 2 to 5 percent as a gastric lavage or as a wash in nasal cararrh, otitis externa, chronic colitis, leukoplakia, and other inflammations of the mucous membranes (Ref. 2). The Panel merely mentions these uses and does not condone the use of resorcinol for these purposes.

Resorcinol is an antipruritic in solutions of 0.5 to 3.0 percent (Ref. 3).

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 3.0 percent concentration of resorcinol to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not apply this product to large areas of the body."

References

(1) Osol, A., "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 1017–1018, 1973.

(2) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, pp. 1184–1185, 1955.

(3) Grollman, A., "Pharmacology and Therapeutics," 6th Ed., Lea and Febiger, Philadelphia, p. 816, 1965.

(4) Krantz, J. C. and C. J. Carr, "The Pharmacologic Principles of Medical Practice," 7th Ed., The Williams and Wilkins Co., Baltimore, p. 775, 1969.

(5) Goodman, L. S. and A. Gilman, "The Pharmacologic Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, p. 991, 1975.

(6) Boyd, E. M., "Dermatomucosal Agents," *in* "Drill's Pharmacology in Medicine," 4th Ed., Edited by DiPalma, J. R., McGraw-Hill Book Co., New York, p. 1036, 1971.

(7) Cunningham, A. A., "Resorcin Poisoning," *Archives of Disease in Childhood,* 31:173–176, 1956.

(8) Bull, G. M. and R. Fraser, "Myxedema from Resorcinol Ointment Applied to Leg Ulcers," *Lancet,* 258(1):851–855, 1950.

(9) Pascher, F., "Systemic Reactions to Topically Applied Drugs," *Bulletin of the New York Academy of Medicine,* 49:613–617, 1973.

(10) OTC Volume 060038.

(11) OTC Volume 060060.

(12) OTC Volume 060123.

z. *Tetracaine.* The Panel concludes that tetracaine is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Tetracaine is one of the numerous soluble aminobenzoic acid esters possessing local anesthetic activity. Tetracaine is closely allied to procaine in chemical structure (Ref. 1). It has also been known as amethocaine, pantocaine, decicaine, certacaine, and anethcaine (Ref. 2). It has been available since 1932 for spinal nerve blocks, epidural nerve blocks, and topical anesthesia. In the structure of tetracaine, a butyl group is substituted for one of the hydrogen atoms of the amino group on the benzene ring of procaine. The two ethyl groups on the nitrogen atom of the amino ethanol portion of the procaine molecule are replaced by methyl groups. The molecule of tetracaine conforms to the general configuration characteristics of the "caine" type drugs that have an aromatic nucleus, an ester linkage, an intervening dimethylene chain, and a tertiary nitrogen atom. Shortening the ethyl groups to methyl groups and replacing the hydrogen atom on the amino group with a butyl radical increases the potency and toxicity of tetracaine about 10 times compared to that of procaine (Refs. 1 and 3). Tetracaine manifests topical anesthetic activity both on the mucous membranes and on the skin. The duration of action is approximately 2 to 2.5 times that of procaine because the protein-binding activity and the lipid solubility of tetracaine are increased over those of procaine by the alteration in structural configuration and by the increase in molecular weight (Ref. 3).

Tetracaine is a tertiary amine and, therefore, is a base. It forms salts with various acids including hydrochloric acid. It is generally used as a salt on broken and abraded skin, and as the base on intact skin (Ref. 4). One g of the base dissolves in approximately 1,000 mL of water. Tetracaine base is much more soluble in organic solvents than in water. One g of the base dissolves in 5 mL alcohol, 2 mL chloroform, and 2 mL ether. Tetracaine is less stable than its salts. It is readily soluble in oils and oleaginous bases. The base may be incorporated into water-soluble creams for topical use. It is not as readily released when applied topically from petrolatum bases as it is from water-soluble bases (Ref. 5).

Aqueous solutions of the base decompose rapidly. Tetracaine hydrochloride occurs as fine white crystalline odorless powder and has a slightly bitter taste that is followed by a sense of numbness. Solutions of the base are alkaline.

Tetracaine salt solutions can be sterilized by boiling for short periods of time. The shelf life is limited to less than 1 year. The shelf life of ointments and other preparations containing the base is not known (Ref. 3).

(1) *Safety.* Clinical use has confirmed that tetracaine is safe in the dosage range used as an OTC external analgesic.

Although tetracaine is sparingly soluble in water, sufficient quantities can be absorbed from extensive areas of damaged, abraded, or excoriated skin in quantities that produce adverse systemic effects (Ref. 3). High plasma levels of tetracaine will produce convulsions and cardiac depression, as do other local anesthetics of the "caine" type. Adriani and Campbell (Ref. 5) have indicated that the cardiovascular reactions may occur without central excitation and cause syncope and cardiac arrest. This type of reaction often occurs abruptly without warning and is usually fatal (Ref. 6). Tetracaine is 10 times more toxic than procaine when administered intravenously in animals. Its relative toxicity is equal to that of procaine since 1 mg is equal to 10 mg procaine in potency and toxicity. Due to tetracaine's potency, dosage is more difficult to control and overdosage occurs more readily than with less potent drugs. The intraperitoneal LD_{50} in mice is 70 mg/kg. Data on animal toxicity are not in agreement because of different methods of studying toxicity by different investigators. Rapid intravenous injection into animals irrespective of species causes convulsions and circulatory system depression (Ref. 7).

Differences in results obtained by different investigators are merely quantitative; qualitatively the responses are the same. Tetracaine manifests a greater degree of myocardial depression than do other drugs of the "caine" type when the plasma concentrations reach toxic levels (Ref. 6). Tetracaine is hydrolyzed by pseudocholinesterase in the blood, as are procaine and other esters of aminobenzoic acid, but the rate of hydrolysis is approximately one-fifth the rate of procaine (Ref. 3). This slower rate of detoxification contributes to the greater degree of toxicity it manifests compared with other drugs of the "caine" type. Tetracaine has no well-defined chronic toxicity. Adverse reactions from repeated use have not

been reported. The action perineurally is reversible and no histological changes have been demonstrated in nerve tissues. The toxic dose in humans is not known. The maximum limit of dosage perineurally or by infiltration is considered to be between 75 to 100 mg in healthy adults. Topically on the mucous membranes of the pharynx, the maximum dose ranges between 25 and 40 mg (Refs. 3 and 6). The toxic dose, when applied externally on the skin, is not known. Tetracaine manifests no appreciable degree of irritancy when the ingredient is injected or applied topically. It may cause the cytotoxic type of reaction after repeated applications (Refs. 3 and 6).

Tetracaine base is safe when applied to limited areas of damaged skin. It is also safe when applied to intact skin because absorption and penetration occur slowly (Ref. 8). Significant amounts of the base are readily absorbed from damaged skin or denuded areas of skin, particularly if such areas are extensive or exceed 25 percent of the total body surface (Ref. 6). Sufficient quantities may be absorbed from damaged skin to produce systemic adverse reactions. Although this has not been reported following the use of tetracaine, it has occurred with others of the "caine" type topical anesthetics. Since tetracaine can act as a haptene, it is capable of producing allergic type reactions mediated by immunoglobulin E (Ref. 3). The sensitizing potential of tetracaine on the skin is no greater than it is with other topical anesthetics. Because tetracaine is a derivative of aminobenzoic acid, the possibility of cross-sensitization is frequently mentioned, but documentation and data substantiating this contention are sparse and not convincing. Cross-sensitization with other derivatives of aminobenzoic acid may occur; but if it does, it is rare (Ref. 3). Tetracaine base penetrates the intact skin (Refs. 4 and 8). Quantities absorbed vary with the area of application. Plasma levels are very low but are detectable by microchemical methods. The Panel does not consider this to be a significant factor in toxic reactions to the drug if the areas of application are limited (Ref. 5). Absorption occurs readily from raw and denuded areas, such as second and third degree burns, and from abraded skin or lesions where considerable area of skin has been injured and an extensive exposed raw surface is present (Ref. 6).

(2) *Effectiveness.* There are studies documenting the effectiveness of tetracaine as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that tetracaine is effective for use as an OTC external analgesic.

Tetracaine penetrates the intact and damaged skin and produces analgesic and antipruritic effects (Refs. 4 and 8). It is absorbed from abraded areas and produces analgesia and anesthesia.

The unionized tetracaine base penetrates and stabilizes the axonal membrane and blocks pain and other receptors in the skin. Tetracaine is much more lipid soluble than procaine and has 10 times the protein-binding capacity of procaine (Ref. 3). Therefore tetracaine has a longer latent period and lasts two to four times longer than procaine. As is the case with other topical anesthetics, the duration of action is variable and depends upon the relative vascularity at the site of application (Ref. 6). Tetracaine base and tetracaine salts are effective topically on the mucous membranes (Ref. 10).

Adriani and Dalili (Refs. 4 and 9) found that tetracaine base was effective in relieving the sensation of burning and itching resulting from electrical stimulation of the skin when a saturated solution in 40 percent alcohol, 10 percent glycerin, and 50 percent water is used. A 2-percent tetracaine hydrochloride solution was totally without effect under similar conditions. Topical preparation to be used on the intact skin for relieving pain, burning, or pruritus should be composed of the base incorporated in a medium which allows a thin film to be present in a moist state continuously over the afflicted areas.

Tetracaine base has been effectively used on intact and damaged skin in concentrations of 1 to 2 percent (Ref. 7).

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 1 to 2 percent concentration of tetracaine to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not use in large quantities, particularly on raw surfaces or blistered areas."

References

(1) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(2) Swinyward, G. A., "Demulcents, Emollients, Protectives and Adsorbents, Antiperspirants and Deodorants, Absorbable Hemostatics, Astringents, Irritants, Sclerosing Agents, Caustics, Keratolytics, Antiseborrheics, Melanizing and Demelanizing Agents, Mucolytics, and Certain Enzymes," *in* "The Pharmacological Basis of Therapeutics," 4th Ed., Edited by Goodman, L. S. and A. Gilman, The MacMillan Co., New York, pp. 987–1001, 1970.

(3) Adriani, J. and M. Naraghi, "Pharmacologic Principles of Regional Pain Relief," *Annual Review of Pharmacology and Toxicology*, 17:223–242, 1977.

(4) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers, "*Anesthesia and Analgesia*, 50:834–841, 1971.

(5) Adriani, J. and D. Campbell, "Fatalities Following Topical Application of Local Anesthetics to Mucous Membranes," *Journal of the American Medical Association*, 162:527–530, 1956.

(6) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Practitioner*, 25:82–86, 1962.

(7) OTC Volume 060047.

(8) Monash, S., "Topical Anesthesia of the Unbroken Skin," *Archives of Dermatology*, 76:752–756, 1957.

(9) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itch, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics*, 12:913–919, 1971.

(10) Andrews, G. C., "Diseases of the Skin," 6th Ed., W. B. Saunders Co., New York, pp. 107–108, 111, 1971.

aa. *Tetracaine hydrochloride.* The Panel concludes that tetracaine hydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Tetracaine hydrochloride is the salt of the tertiary amine, tetracaine, which has been described above. Tetracaine hydrochloride consists of a white crystalline powder that is oderless and hygroscopic. Tetracaine hydrochloride is soluble, 1 part in 7 parts of water, unlike the base, which is poorly soluble. Tetracaine hydrochloride has a slightly bitter taste that is followed by a sense of numbness. Tetracaine hydrochloride melts at between 147° and 150° C. (Refs. 1 and 2). Tetracaine hydrochloride hydrolyzes slowly and loses its anesthetic activity with time. The shelf life of the powder in sealed ampules is less than 1 year. The hydrochloride is the most widely used salt. Solutions of the salt are more stable than the base and, because they are converted to the base when they are injected or applied topically to the mucous membrances by the buffering mechanisms of the tissues, they are physiologically active and widely used clinically. The salt is not

converted to the base when the salt is applied to the intact skin. For this reason it penetrates very slowly and is without effect (Refs. 3 through 5). Aquesous solutions have a pH of 5 to 6.

(1) *Safety.* Clinical use has confirmed that tetracaine hydrochloride is safe in the dosage range used as an OTC external analgesic.

Tetracaine hydrochloride is 10 times more potent and toxic than procaine (Ref. 1). It may be absorbed in large quantities from abraded and denuded areas because it is water soluble. Tetracaine hydrochloride produces convulsions and cardiac depression similar to those produced by other local anesthetics (Ref. 6). Reactions of this type from topical application to minor skin lesions have not been reported and are unknown. Tetracaine hydrochloride manifests no appreciable degree of irritancy. Sensitizing potential is low but, like all other anesthetics of its type, it will cause allergic reactions. Tetracaine hydrochloride can act as a haptene and cause allergic reactions mediated by IgE immune globulins (Ref. 7). Repeated application can cause the cytotoxic type of sensitization mediated by the T cell lymph system. Topical reactions are characterized by rashes, eczema, etc. (Ref. 8).

(2) *Effectiveness.* There are studies documenting the effectiveness of tetracaine hydrochloride as an OTC external analgesic. Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that tetracaine hydrochloride is effective for use an an OTC external analgesic.

Tetracaine hydrochloride is highly ionized and does not readily penetrate lipid barriers of the cell membrane. Tetracaine hydrochloride is very slowly absorbed from the intact skin and, therefore, exerts no significant therapeutic effect (Refs. 5 and 9). Tetracaine hydrochloride is readily absorbed from abraded skin and open cutaneous lesions. It is effective when it comes into contact with the tissue fluids because it is converted to the base, which is the active form that penetrates the neuronal membrane and blocks conduction of nervous impulses. Absorption from damaged skin occurs readily and systemic reaction can occur if the ingredient is applied over extensive areas of the body (Ref. 6).

Tetracaine hydrochloride has been effectively used on damaged skin in concentrations ranging from 1 to 2 percent.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 1 to 2 percent concentration of tetracaine hydrochloride to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervsion of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not use in large quantities, particularly on raw surfaces or blistered areas."

References

(1) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(2) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, pp. 995–996, 1975.

(3) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 99–106, 1973.

(4) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 1183, 1976.

(5) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia*, 50:834–841, 1971.

(6) Adriani, J., "Absorption and Systemic Toxicity of Local Anesthetics," *General Practitioner*, 25:82–86, 1962.

(7) Adriani, J. and M. Naraghi, "Pharmacologic Principles of Regional Pain Relief," *Annual Review of Pharmacology and Toxicology*, 17:223–242, 1977.

(8) OTC Volume 060047.

(9) Monash, S., "Topical Anesthesia of the Unbroken Skin," *Archives of Dermatology*, 76:752–756, 1957.

bb. *Tripelennamine hydrochloride.* The Panel concludes that tripelennamine hydrochloride is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient depresses cutaneous sensory receptors and should bear the labeling for topical analgesics, anesthetics, and antipruritics set forth below.

Tripelennamine hydrochloride is 1,2-ethanediamine, *N,N*-dimethyl-*N'*-(phenylmethyl)-*N'*-2-pyridinyl-, monohydrochloride. It may be prepared by the interaction of 2-amino pyridine, 2-dimethylamino ethylchloride, and benzyl chloride. tripelennamine is a derivative of ethylenediamine. It is a base that interacts with acids to form salts. In this respect, it behaves similarly to the nitrogenous type of topical anesthetics. The two salts most commonly used are the hydrochloride and the citrate, which are both white crystalline powders. The citrate is more palatable than the hydrochloride when taken orally. One g of the hydrochloride dissolves in 0.77 mL water, in 6 mL alcohol, in 6 mL chloroform, and is pratically insoluble in benzene, ether, and ethyl acetate. The citrate melts at approximately 106° to 110° C. The hydrochloride melts at 192° to 193.5° C. An aqueous solution of the hydrochloride containing 25 mg/mL has a pH of 6.71 (Refs. 1, 2, and 3).

Tripelennamine hydrochloride slowly darkens on exposure to light. Tripelennamine belongs to the pharmacologic class of antagonists known as the antihistamines. Mirrored in its structure is the configuration common to the topical anesthetic drugs of the "caine" type. However, there is sufficient modification in its structure to attenuate the toxicity characteristic of the "caine" type of topical anesthetics (Refs 4 and 5). In addition to its antihistaminic and topical anesthetic activity, tripelennamine hydrochloride has a weak anticholinergic action (Ref. 6).

(1) *Safety.* Clinical use has confirmed that tripelennamine hydrochloride is safe in the dosage range used as an OTC external analgesic.

Prolonged daily use of tripelennamine causes no untoward effects in the majority of patients on whom it is used topically. No changes in kidney or liver function have been found after prolonged and continued oral use. In a series of 800 patients, only 5.5 percent could not tolerate the drug when administered orally, and required that it be discontinued (Ref. 2).

Adverse effects include drowsiness, dry mouth, nausea, excitement, headache, polyuria, heartburn, loss of potency, diplopia, chilliness, dizziness, sweating, and dysuria. The dry mouth is due to its anticholinergic effect. Performance tests were conducted after a dose of 100 mg tripelennamine administered orally by McKay and Ferguson (Ref. 7), using a complex coordination test and also a rapid calculation test. Results showed impairment of the calculation test but not of the coordination test. Drowsiness proved to be the most sensitive criterion of adverse drug action. Diphenhydramine has a greater tendency to cause drowsiness than tripelennamine but tripelennamine is more spasmogenic on the gastrointestinal and genitourinary tract than diphenhydramine. The incidence of untoward effects using doses ranging from 200 to 300 mg daily is about the same for diphenhydramine as for tripelennamine, but when larger doses are used, the latter is less toxic. Towers and Giuffra (Ref. 8) reported a case of a 39-year-old woman who had taken 6.35 g

over a 4-week interval, 1.35 g of which had been ingested in 48 hours. She complained of dyspnea, pectoral pain, and a burning of the tongue. Cyanosis, rigidity of the entire body, stupor, and circulatory collapse developed. She recovered within 24 hours but had amnesia for 4 days following the episode.

Agranulocytosis has been reported following ingestion of tripelennamine. Tripelennamine hydrochloride was one of the drugs taken by three patients who developed hemolytic anemia following the use of antihistamines over long periods of time (Ref. 9). Other cases of agranulocytosis have been reported. A case of pancytopenia (aplastic anemia) likewise has been reported. A case of purpura has been described (Ref. 10). Gross hematuria and dysuria were frequently described in the early use of the drug. A 32-year-old man who had received 50 mg tripelennamine four times daily for 2 days in the course of treatment for chronic ethmoiditis and prostatitis developed hematuria and dysuria. Impotence has been observed in two patients taking tripelennamine hydrochloride. No cases of systemic toxicity following topical use on the skin have been called to the Panel's attention. Tripelennamine salts and the base are absorbed from damaged skin but not in sufficient quantities to produce systemic adverse effects, unless they are applied to areas exceeding 25 percent of the body surface.

Tripelennamine has a low degree of irritancy and a low sensitizing potential in either base or salt form. The development of acute urticaria, atopic dermatitis, and eczematous contact dermatitis has been reported after topical application in patients who did not have these cutaneous manifestations before topical use. Ellis and Bundick (Ref. 11) found 10 instances of sensitivity to tripelennamine in 141 cases reported. As has been mentioned, the antihistamines are capable of acting as haptenes and producing sensitization mediated by immunoglobulin E (IgE) as well as local cytotoxic reactions due to activity of the T lymphocytic cell system.

The increasing incidence of acquired sensitivity to the antihistaminic creams is discussed by Ellis and Bundick (Ref. 11). These authors indicate that the antipruritic action of topical antihistamine drugs is most useful for 1 to 2 weeks to prevent the continued trauma of scratching and permanent healing. However, loss of efficacy is frequent after uses of 3 to 4 weeks. Sensitivity often develops after this period of use. The Panel does not recommend topical use of tripelennamine or its salts for longer than 7 days except under the advice and supervision of a physician.

(2) *Effectiveness.* There are studies documenting the effectiveness of tripelennamine hydrochloride as an OTC external analgesic.

Tripelennamine was one of the first effective antihistaminic drugs to be adopted for general clinical use in the United States (Ref. 12). Tripelennamine hydrochloride, diphenhydramine hydrochloride, and pyrilamine maleate were found to be the most effective of 13 antihistaminic drugs tested by Sternberg and associated (Ref. 13) for the ability to nullify the effect of histamine in raising wheals in the skin of man in clinical studies.

Tripelennamine hydrochloride is used for the symptomatic treatment of urticaria, hay fever, and other allergic disorders (Ref. 2). It has been reported to be useful in alleviating a variety of cutaneous disorders related indirectly, or not at all, to histamine release (Ref. 2). Tripelennamine prevents the attachment of histamine to the H_1 type receptor on cells. Tripelennamine is effective as an antagonist when histamine is circulating and diffusing extracellularly but is not effective when the histamine is released intracellularly by an antigen-antibody or other type reaction (Ref. 2). In these cases tripelennamine is not protective when used prophylactically or as an antagonist.

Tripelennamine applied by iontophoresis inhibits the wheal formation produced by the intracutaneous injection of histamine or ragweed extract in sensitive persons. The application must be made before injection of the drug. Once the receptor sites are occupied by the histamine, the antihistamine is not effective until the histamine is displaced from the cell (Ref. 2). The antihistamine must be introduced prior to the histamine release. Intracutaneous injections of histamine immediately following the application of 0.5 percent tripelennamine hydrochloride cream to the skin produce the usual reaction; but 5 minutes after the cream is applied, the response is almost completely inhibited. Development of tolerance to continued use of 50 mg tripelennamine hydrochloride three times daily by mouth was observed by Dannenberg and Feinberg (Ref. 14). The response to an intracutaneous dose of histamine was inhibited during the first week. During the second week it produced a minimal effect; and during the third and fourth weeks, it produced a definite wheal (Ref. 15).

Tripelennammine and its salts do not affect or inhibit in any way the antigen-antibody reaction, but they do counteract the local and systemic effects of histamine released by the interaction (Ref. 2). There is considerable evidence that the oral administration of tripelennamine relieves urticaria and other cutaneous reactions, including cases of ivy poisoning and bee stings (Ref. 2). There is evidence that topical creams containing 2 to 3 percent tripelennamine hydrochloride are effective in temporarily relieving the pruritus of poison ivy eruptions. However, it exerts no curative effects. The pruritus of chicken pox has been relieved by oral administration.

Mucosal anesthesia is produced in the oropharynx and rectum by 0.5 to 2.0 percent aqueous solutions of tripelennamine hydrochloride. Solutions of tripelennamine up to 4 percent have been used topically for anesthesia of the mucous membranes in certain dental procedures. The Panel considers this topical anesthetic effect to be significant and partly, if not completely, responsible for its topical antipruritic effect.

As is the case with topical anesthetics, the base of tripelennamine penetrates the intact skin more effectively than do the salts (Refs. 4 and 5). Tripelennamine hydrochloride is absorbed from the damaged skin but there is doubt that quantities sufficient to produce adverse reactions are absorbed from topical applications in localized areas or from lesions causing localized pruritus.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 2.0 percent concentrations of tripelennamine hydrochloride to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 1220–1221, 1973.

(2) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, pp. 1452–1457, 1955.

(3) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 1249, 1976.

(4) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d

Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(5) Adriani, J. and M. Naraghi, "Pharmacologic Principles of Regional Pain Relief," *Annual Review of Pharmacology and Toxicology*, 17:223–242, 1977.

(6) OTC Volume 060045.

(7) McKay, R. A. and I, K. W. Ferguson, "Influence of Certain Anti-Motion Sickness Drugs on Psychomotor and Mental Performance," *Journal of Aviation Medicine*, 22:194–195, 1951.

(8) Towers, P. A. and L. J. Giuffra, "An Unusual Reaction Following the Use of Pyribenzamine," *New York State Journal of Medicine*, 50:214–215, 1950.

(9) Crumbley, J. J., "Anemia Following Use of Antihistaminic Drugs," *Journal of the American Medical Association*, 143:726–728, 1950.

(10) Uvitsky, I. H., "Purpura Simplex due to Antihistaminic Drugs," *Journal of Allergy*, 22:544–546, 1951.

(11) Ellis, F. A. and W. R. Bundick, "Appraisal of Topical Use of Antihistamines," *Journal of the American Medical Association*, 150:773–776, 1950.

(12) OTC Volume 060068.

(13) Sternberg, T. H., D. J. Perry, and P. LeVan, "Antihistaminic Drugs," *Journal of the American Medical Association*, 142:969–973, 1950.

(14) Dannenberg, T. B. and S. M. Feinberg, "The Development of Tolerance to Antihistamines," *The Journal of Allergy*, 22:330–339, 1951.

(15) OTC Volume 060037.

cc. *Turpentine oil.* The Panel concludes that turpentine oil is safe and effective for use as an OTC external analgesic as specified in the dosage section below. The ingredient stimulates cutaneous sensory receptors and should bear the labeling for topical counterirritants set forth below.

Turpentine oil is commonly misnamed "Turpentine." Turpentine oil for medicinal use must be of better quality than commercial turpentine oil, that is, it should be rectified turpentine oil (Ref. 1).

Turpentine oil is a volatile oil prepared by steam distillation of turpentine oleoresin collected from *Pinus palustrus* and other species of Pinus (Pinaceae) (Ref. 2). It is a colorless liquid having a characteristic odor and taste. Turpentine oil boils at 155° C. It is practically insoluble in water, but is miscible with alcohol, chloroform, and ether. Its chief chemical components are *alpha*- (64 percent) and *beta*-pinene (33 percent) and varying amounts of carene (Refs. 3 and 4).

According to Pirila et al., most oils of turpentine contain large amounts of 2-pinene. However, the 3-carene content varies depending on the country of origin (Ref. 5).

(1) *Safety.* Clinical use has confirmed that turpentine oil is safe in the dosage range used as an OTC external analgesic.

Oral LD_{50} in rats is 1,800 mg/kg (Ref. 6). Several human fatalities from the ingestion of turpentine oil have been reported over the past century, but none from inhalation or topical application. The mean lethal dose orally for adults is approximately 150 mL (Ref. 7). Turpentine oil is absorbed from the intestinal tract and the lungs, and through the intact skin. It is excreted primarily by the kidney (Ref. 8).

Several official formulations contain turpentine oil. These include 25 percent in White Liniment, "British Pharmaceutical Codex" (Ref. 9), 25 percent in Turpentine Liniment, "United States Pharmacopeia" (Ref. 10) and 65 percent in Turpentine Liniment, "British Pharmacopeia" (Ref. 10).

Turpentine oil is both a primary irritant and a sensitizer. As an irritant, it usually acts by defatting the skin, causing dryness and fissuring. It is often used as a cleanser for removing paints and waxes. It is one of the commonest causes of hand eczema.

Turpentine oil is easily oxidized. The oxidized form is more irritating and sensitizing than the fresh product. Cross-sensitization may occur between turpentine and ragweed oleoresin, chrysanthemum, pyrethrum, and various balsams such as those of pine, spruce, and Peru (Ref. 11).

In poisoning due to oral ingestion, turpentine oil may cause hematuria, albuminuria, and coma. The urine has an odor resembling violets. A dose of 140 mL (15 mL in children) may be fatal. The application of liniments containing turpentine oil to the intact skin may cause vesicular eruption, hives, and vomiting in susceptible persons.

Four thousand patients were patch tested in five European clinics with turpentine oil. Positive reactions occurred in 5.2 percent of the males and 6.5 percent of the females tested (Ref. 12).

In a modified repeated-insult patch test, 50 percent turpentine oil caused severe sensitization of the skin (Ref. 13). Patch testing with 10 percent turpentine oil in arachis oil produced positive reactions in 4.3 percent of 1,205 individuals with dermatitis or eczema (Ref. 12).

In a study by Baer, Ramsey, and Biondi (Ref. 14), 540 subjects were patch tested with a solution of 10 percent turpentine oil in olive oil. The intensity of the reaction was rated on a scale of from 1 to 4. Of the 540 subjects tested, 12.2 percent had a positive reaction. Twenty-nine subjects had a rating of 1; 21 subjects had a rating of 2; 16 subjects had a rating of 3, and no subjects had a rating of 4 (most intense reaction).

Roe and Field (Ref. 15) conducted studies in which turpentine oil was applied dorsally to the skin of mice after pretreatment with 1,10-dimethyl-1,2-benzanthracene (DMBA). DMBA induces the formation of skin tumors, but generally speaking, not all are carcinomas. After one treatment with DMBA, no further challenge was given for 3 weeks. Two groups of 300 mice were so treated with one group used as a control. The other group was challenged at weekly intervals with 0.25 mL undiluted oil of turpentine applied dorsally to the skin for 33 weeks. Weak tumor promotion occurred with turpentine oil. A total of 10 papillomas was observed in the test group compared with 1 papilloma that appeared outside the treated area in the control group.

Turpentine oil has been used as an ingredient in counterirritant products with a long history of safety. One manufacturer reports sales of more than 40,000,000 bottles of liniment over a period of 80 years with no reports of customer problems (Ref. 16). Another manufacturer of a liniment containing turpentine oil has been manufacturing and distributing this product since 1913 and reported the manufacture and sale of more than 9,000,000 ounces in 1972. Only two customer complaints alleging injury (minor skin reaction or burn) were received in 1972 (Ref. 17).

The cited clinical studies (Refs. 12 through 14) were performed upon individuals with known histories of dermatological problems. The Panel recognizes the irritant, sensitizing, and tumorigenic potential of turpentine oil, but considers the marketing experience and lack of significant adverse reactions to illustrate the safety of turpentine oil as used in currently marketed OTC drug products.

(2) *Effectiveness.* Due to the ingredient's wide use and clinical acceptance and on the basis of published reports in the literature, the Panel concludes that turpentine oil is effective for use as an OTC external analgesic.

No scientifically controlled studies concerning the use of turpentine oil alone for the treatment of rheumatism, arthritis, and muscular aches and pains were found. However, the use of turpentine oil for self-medication is almost an American folk tradition, and full-strength turpentine oil has been employed with impunity as a topical counterirritant.

Turpentine oil has been effectively used in concentrations ranging from 6 to 50 percent.

(3) *Dosage—For adults and children 2 years of age and older:* Apply a 6 to 50 percent concentration of turpentine oil to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical counterirritant active ingredients. (See part III. paragraph B.1. below—Category I Labeling.)

References

(1) Sollmann, T., "A Manual of Pharmacology and its Application to Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, pp. 166–169, 1957.

(2) Todd, R. G., "Martindale, The Extra Pharmacopeia," 25th Ed., The Pharmaceutical Press, London, pp. 1467–1468, 1967.

(3) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 1259, 1976.

(4) Claus, E., V. Tyler, and L. Brady, "Pharmacognosy," 6th Ed., Lea and Febiger, Philadelphia, p. 166, 1970.

(5) Pirila, V., O. Kilpio, A. Olkkonen, L. Pirila, and E. Siltanen, "On the Chemical Nature of Exzematogens in Oil of Turpentine," *Dermatologica*, 139:183–194, 1969.

(6) Sperling, F., H. K. U. Ewenike, and T. Farber, "Changes in LD_{50} of Parathion and Heptachlor Following Turpentine Pretreatment, *Environmental Research*, 5:164–171, 1972.

(7) Gleason, M. M., R. E. Gosselin, H. C. Hodge, and R. P. Smith, "Clinical Toxicology of Commercial Products," 4th Ed., The Williams and Wilkins Co., Baltimore, pp. 315–316, 1976.

(8) Arena, J. M., "Poisoning: Chemistry, Symptoms, Treatments," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 173–174, 597, 1970.

(9) Osol, A. "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, pp. 1450–1451, 1975.

(10) Osol, A., "The Dispensatory of the United States," 22d Ed., J. B. Lippincott Co., Philadelphia, p. 781, 1940.

(11) Fisher, A. A., "Contact Dermatitis," 2d Ed., Lea and Febiger, Philadelphia, pp. 49–50, 1973.

(12) Bandmann, H. J., C. C. Calnan, E. Cronin, S. Fregert, N. Hjorth, B. Magnusson, H. Maibach, K. E. Malten, C. L. Meneghini, V. Pirila, and D. S. Wilkinson, "Dermatitis from Applied Medicaments," *Archieves of Dermatology*, 106:335–337, 1972.

(13) Klingman, A. M., "The Identification of Contact Allergens by Human Assay," *Journal of Investigative Dermatology*, 47:393–409, 1966.

(14) Baer, R. L., D. L. Ramsey, and E. Biondi, "The Most Common Contact Allergens," *Archives of Dermatology*, 108:74–78, 1973.

(15) Roe, F. I. C. and W. H. Field, "Chronic Toxicity of Essential Oils and Certain Other Products of Natural Origin," *Food and Cosmetic Toxicology*, 3:311–324, 1965.

(16) OTC Volume 060009.

(17) OTC Volume 060040.

Category I Labeling

The Panel was not in agreement with regard to the labeling indications for counterirritant and hydrocortisone products. The Panel, however, was in complete agreement regarding labeling warnings and the labeling indication for analgesic, anesthetic, or antipruritic products. Accordingly, this section consists of a majority report and a minority report for counterirritant and hydrocortisone products. The minority report reflects the opinion of one Panel member.

The majority of the Panel recommends the following Category I labeling for external analgesic active ingredients to be generally recognized as safe and effective and not misbranded as well as the specific labeling discussed in the individual ingredient statements:

a. *Indications.* (1) *For products containing analgesic, anesthetic, or antipruritic external analgesic active ingredients except for hydrocortisone and hydrocortisone acetate:* "For the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bits, and minor skin irritations."

(2) *For products containing counterirritant external analgesic active ingredients:* "For the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains."

(3) *For products containing hydrocortisone and hydrocortisone acetate:* "For the temporary relief of minor skin irritations, itching, and rashes due to eczema, dermatitis, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, and jewelry, and for itchy genital and anal areas."

b. *Warnings.* (1) *For products containing any external analgesic active ingredient and hydrocortisone and hydorcortisone acetate:* (i) "For external use only."

(ii) "Avoid contact with the eyes."

(iii) "Discontinue use if condition worsens or if symptoms persist for more than 7 days and consult a physician."

(iv) "Do not use on children under 2 years of age except under the advice and supervision of a physician."

(2) *For products containing counterirritant external analgesic active ingredients:* (i) "Do not apply to wounds or damaged skin."

(ii) "Do not bandage."

c. *Minority report for Category I labeling indications.* The minority of the Panel disagrees with the labeling for Category I indications for topical counterirritant active ingredients and for hydrocortisone and hydrocortisone acetate as topical antipruritic active ingredients recommended by the majority of the Panel. The minority of the Panel recommends that the following Category I indications for the labeling of these active ingredients be generally recognized as safe and effective. A justification for the disagreement with the indications recommended by the majority of the Panel follows each minority recommendation.

(1) *For products containing counterirritant external analgesic active ingredients:* "For the temporary relief of minor aches and pains of muscles and joints."

Because OTC drugs are intended to be used only for the temporary relief of symptoms, the labeling should not indicate or imply that the preparation is for the treatment of a specific disease entity as is the case in the indications recommended by the majority of the Panel, i.e., "For the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains." Such indications in the labeling are not amenable to self-diagnosis and self-treatment, and require medical diagnosis and supervision for safe use. Examples of such claims are "arthritis," "neuralgia," and "lumbago."

In addition, the labeling recommended by the majority of the Panel includes claims for bruises, simple backache, strains, and sprains. The majority of the Panel states that "the Panel used the terms in the above list of indications because it believes these terms would be understood by the general population," and that "these are not necessarily terms which would be used by physicians in specific diagnoses." The minority of the Panel disagrees with this assumption because it is contradictory. The terms listed are in fact used by physicians in diagnosing disease processes. The use of dissimilar medical terminology, i.e., the terminology used by physicians and the terminology assumed to be understood by the general population, to designate identical disease conditions would cause consumer confusion and could lead to deception and unsafe use. The use of disease-oriented labeling for symptom-oriented indications may lead to misuse by the consumer. These terms, therefore, are not acceptable for the following reasons:

(i) *Arthritis.* Arthritis is a clinical entity that designates an inflammation of a joint or joints of an arthritic process, and may be of many types and of multivaried etiology. Therefore, it cannot be categorized by one all-inclusive term. Arthritis may be due to trauma, infection, or degenerative changes in the joints. It may be of unknown etiology, such as rheumatoid or osteoarthritis, or it may be a manifestation of a systemic disease, such as rheumatic fever, gout, serum sickness, etc. Self-diagnosis and self-treatment could lead to a delay in proper treatment by a physician and an aggravation of a disease process even to the point of irreversibility. Therefore, the indication for use in arthritis is unacceptable for OTC labeling. However, the labeling recommended by the minority of the Panel, i.e., "For the temporary relief of minor aches and pains of muscles and joints," does not restrict access to a counterirritant analgesic ingredient by a consumer seeking temporary relief of arthritis pain.

(ii) *Neuralgia.* Neuralgia is defined as nerve pain, generally severe, that is throbbing or static in character. It is a medical term designating a clinical entity. Its etiology is unknown, and no histopathologic changes are noted in the afflicted nerve or nerve root. The term is often erroneously used to designate neuritis, which is a medical term that designates a group of clinical conditions of multivaried etiologies that are more aptly described by symptom-oriented labeling than by disease-oriented labeling. Usually, the pain is felt along the course of, or the area of, distribution of the terminal fibers of a nerve. There are various types of neuralgia, designated at times as degenerative, epileptiform (tic douloureux), geniculate, hallucinatory, idiopathic, etc. Neuralgia is generally central in origin. Application of a medicament peripherally would, in many cases, not relieve the symptoms. The term "neuralgia" appearing on OTC labeling again would encourage a consumer to attempt self-diagnosis and self-treatment of a pain which ordinarily is not minor, and is often recurrent and intractable. In certain types of neuralgia, pain can be "triggered" by stimulation of areas referred to as "trigger zones." Counterirritants are stimulants of cutaneous receptors and, if applied to these areas, could aggravate or prolong such types of pain.

(iii) *Lumbago.* Lumbago is a medical term that is defined as an inflammation of the tendinous attachments of the muscles of the lumbar region causing severe pain and rigidity. Pain is felt in the lumbar area. It is also referred to as osphyitis or lumbodynia. Pain along the vertebral column in the lumbar area may be due to many other causes besides tendinous inflammation, such as arthritis of the vertebrae, radiculitis, cord tumor, ruptured intervertebral disks, etc. Pain in the lumbar area may be referred from pelvic viscera, such as the sigmoid colon, uterus, the bladder, prostate, and other intra-abdominal structures. Such a pain may be an early manifestation of disease in these organs. The diagnosis of lumbago, therefore, can only be made by physicians who have the expertise to differentiate lumbago from other clinical entities whose symptoms may simulate the syndrome. The indication "For the temporary relief of minor aches and pains of muscles and joints" does not restrict access by the consumer to an OTC product for the temporary relief of the symptoms associated with lumbago.

(iv) *Bruises.* A bruise is an injury to the skin without breaking its continuity, followed by a discoloration due to the formation of a hematoma and extravasation of blood at the site of the trauma. It is usually caused by blunt traumas. It is usually superficial but may at times be deep. Superficial bruises occur in the skin and are not necessarily painful. "Deep" bruises involve the subcutaneous tissue and even muscles. Deep bruises may be accompanied by edema and hematomas in subcutaneous structures beneath the discoloration. The term "bruise" is, at times, used interchangeably with the term contusion. Areas of discoloration of the skin due to extravasation of blood, referred to as ecchymosis, may occur spontaneously and be due to vascular injury or deficiencies or abnormalities of clotting mechanisms. Since counterirritants are vasodilators and can act both locally and centrally as vasodilators, their use on a bruise may actually be contraindicated because they may aggravate the condition.

(v) *Sprains.* A sprain is an injury to a joint with possible rupture of some of the ligaments or tendons, but without dislocation or fracture. The word "sprain" should not be included in the indication of the labeling of an OTC product intended for counterirritation for the relief of minor aches and pains of muscles, joints, and tendons. It would encourage self-diagnosis and self-treatment by the consumer. The differential diagnosis between a fracture and a sprain is not easily made. A fracture is often overlooked and called a sprain. Furthermore, both fractures and sprains require immobilization and are best treated in this manner. The application of a counterirritant to the injured area would temporarily relieve the symptoms and cause the subject to continue activity and possibly further aggravate the injury.

(vi) *Strains.* A strain is a term used to designate overuse of a part of the body, generally a muscle. It is vague, not specific, and can mean different things to different persons and therefore be misleading to a lay consumer. Besides, it encourages self-diagnosis and self-treatment. An ache or a pain developing in a joint or muscle could be a warning of an incipient, serious disease process. Overuse of a muscle or joint does not ordinarily cause pain if there has been no trauma. If overuse does cause pain, such a pain or ache is self-limiting and disappears after rest; furthermore, the label indication for "the temporary relief of pain of muscles and joints" does not preclude the availability of the product for use in "sprains."

(vii) *Simple backache.* "Simple backache" is an undesirable term that is vague and nonspecific and that can have different meanings to different persons. Backache is a general term that neither describes the exact nature or location nor gives any clue as to the severity of the ache, whether it is deep or superficial, or whether it involves the sacrum or lumbar vertebrae or both. Placing the adjective "simple" before the term is misleading. There is no such thing as "simple stomach ache"; likewise, the adjective "simple" applied to backache is misleading. Backache may, like lumbago, mean many things and be due to a variety of causes. Use of the terms "backache" or "simple backache" would encourage self-diagnosis and self-treatment by a consumer.

(2) *For products containing hydrocortisone and hydrocortisone acetate as topical antipruritic active ingredients:* "For the temporary relief of minor skin irritations and itching."

Because OTC products containing hydrocortisone preparations are intended to be used to relieve symptoms, labeling that includes a list of clinical entities or pathologic states encourages self-diagnosis and self-medication. Such clinical entities require diagnosis and treatment by a physician. Therefore, the indications on the labeling recommended by the majority are unacceptable and would not protect the consumer, i.e., "For the temporary relief of minor skin irritations, itching, and rashes due to eczema, dermatitis, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, and jewelry, and for itchy genital and anal areas." Rashes due to

"eczema, dermatitis, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, and jewelry" are unacceptable additions for the following reasons:

(i) *Eczema.* The term "eczema" refers to an inflammation of the skin and also describes a clinical entity that has multivaried etiologies. There are many manifestations of eczema, and the disease entity varies in severity and distribution. In addition, it simulates cutaneous lesions due to specific causes, such as lesions due to psoriasis, and other multivaried dermatologic diseases. Its use in the indication section of the labeling for hydrocortisone and hydrocortisone acetate preparations would encourage the consumer to self-diagnose and self-treat. The diagnosis of eczema must be made and the treatment directed by a physician. Eczema is not necessarily a transient and self-limiting affliction of brief duration, but one which can be acute, progressive, and sometimes protracted. It may recur, after receding temporarily, after the application of a steroid. The term, therefore, should be deleted from the labeling proposed by the majority of the Panel.

(ii) *Dermatitis.* Dermatitis is a general medical term used to designate an inflammatory condition of the skin. Dermatitis also may have multivaried etiologies. It may be due to an infection, to some exogenous or endogenous agent that produces primary direct irritation, or irritation due to local sensitization of an immunogenetic type (contact allergic dermatitis).

The term "dermatitis" is objectionable for the same general reasons given above for the term "eczema."

The minority of the Panel could also enumerate in detail similar objections for the inclusion of the terms "poison ivy," "poison oak," "poison sumac," "soaps," "detergents," and "jewelry" as it has for "eczema."

The majority of the Panel includes in the labeling of hydrocortisone and hydrocortisone acetate "itchy genital and anal areas." The term "anal areas" indicates that the preparation may be applied at a mucocutaneous junction. The absorption of topical preparations from the skin differs from the absorption from mucous membranes, such as are found at mucocutaneous junctions. The same is the case if the itching involves femal genitalia, such as the vulva. The majority of the Panel does not specify the area of involvement. The pharmacokinetics of the absorption of externally applied topical analgesics differs from the absorption of internally applied topical analgesics. Steroids are readily absorbed from the mucous membranes, and greater blood levels may be obtained than from the application of steroids to the skin. Furthermore, lesions at these anatomic sites do not come under the purview of this Panel.

Hydrocortisone and related steroids relieve the symptoms of, or temporarily arrest the progress of, many systemic and skin diseases whose etiologies are unknown. Therefore, the Panel minority does not consider indication labeling that is disease-oriented appropriate for hydrocortisone and hydrocortisone acetate.

The labeling for hydrocortisone as recommended by the minority of the Panel, "For the temporary relief of minor skin irritations and itching," in no way restricts a manufacturer from making available a product for the temporary relief of the symptoms of the various clinical entities that have been listed in the indications on the labeling recommended by the majority of the Panel.

In summary, the minority of the Panel emphasizes that external analgesics may relieve the pain and itching due to various physical conditions and cutaneous lesions. A comprehensive list of the sites of various kinds of lesions or the sites of pain or discomfort would be lengthy. Such a list would not only confuse and mislead the consumer but would also imply that the product treats the physical condition, lesion, or disease instead of temporarily relieving the pain (symptom) and discomfort associated with the physical condition, lesion, or disease, and would encourage self-diagnosis and self-treatment.

The minority of the Panel also emphasizes that the recognition of a dual medical terminology, i.e., a terminology that is assumed will be understood by the consumer and a terminology that is properly used in diagnoses by physicians, is irrational and unrealistic. The use of a terminology that is assumed will be understood by the consumer is inappropriate for OTC labeling, which should contain only symptom-oriented indications and not disease-oriented indications.

The minority of the Panel concurs with the conclusion of the Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Products published in the **Federal Register** of July 8, 1977 [42 FR 35346] that the use of only a partial list of claims, such as "arthritis," "neuralgia," "lumbago," "eczema," "dermatitis," etc., in the labeling of a product would mislead the user into believing the preparations treat these particular disease conditions as distinguished from other disease conditions. Therefore, the minority of the Panel urges the following: that the disease conditions and cutaneous lesions in the indications for topical counterirritant active ingredients, and for hydrocortisone and hydrocortisone acetate as topical antipruritic active ingredients, recommended by the majority of the Panel be deleted; and that the Category I indications recommended by the minority of the Panel be adopted by FDA.

2. *Category II conditions under which external analgesic active ingredients are not generally recognized as safe and effective or are misbranded.* The Panel recommends that the Category II conditions be eliminated from external analgesic drug products effective 6 months after the date of publication of the final monograph in the **Federal Register.**

Category II Active Ingredients

The Panel has classified the following external analgesic active ingredient as not generally recognized as safe and effective:

Chloral hydrate. The Panel concludes that chloral hydrate is safe but not effective for use as an OTC external analgesic.

Chloral hydrate was discovered in 1832 by Liebig, but it was not used in medicine as a hypnotic until 1869 (Ref. 1). The terms "chloral" and "chloral hydrate" are often used interchangeably but there is a difference between them, because chemically and physically they are two distinct compounds. Chloral is trichloracetaldehyde, while chloral hydrate is chloral that has interacted with one molecule of water. This causes a modification in structure and converts it to a dihydric alcohol. The water interacts with the aldehyde group of chloral. Thus, in chloral hydrate, the unhalogenated carbon has two hydroxyl groups. In addition, another molecule combines with the hydrate as water of crystallization. Its impiric formula, therefore, is $CCl_3CH(OH)_2 \cdot H_2O$ rather than $CCl_3C(OH)_2$. Chloral is a liquid, while the chloral hydrate is a crystalline powder composed of white crystals. Chloral hydrate has an aromatic, penetrating, and slightly acrid odor. It is slightly bitter and has a caustic taste. When exposed to air or when warmed, it slowly volatilizes to chloral. The crystals have a low melting point of 57°C. The resulting liquid boils at 98° C. Heating causes dissociation of chloral hydrate to chloral and water. Both chloral and chloral hydrate are freely soluble in water. One g of chloral hydrate dissolves in 0.25 ml water, 1.3 ml alcohol, 2 ml chloroform, and 1.5 ml ether. It is also soluble in glycerin, acetone, and various glycols. It is very soluble in vegetable oils and freely soluble in turpentine (Ref. 1 and 2).

Aqueous solutions of chloral hydrate are not stable and are quickly decomposed by light, heat, or air to hydorchloric acid, trichloroacetic acid,

and formic acid. Under ordinary conditions of storage, chloral hydrate solutions decompose very slowly. Aqueous solutions of chloral hydrate may develop molds. Therefore, such solutions should not be kept for long periods of time without a preservative. Chloral hydrate is incompatible with iodides, cyanides, permanganates, boraxate, borax, and alkalis, such as the hydroxides. It is also incompatible with carbonates, bicarbonates, lead acetate, camphor, quinine, theobromide, sodium phosphate, urea, urethane and phenacetin (Refs. 1 and 2).

Chloral combines with alcohol to form chloral alcoholate, which systemically is less effective as a hypnotic and sedative than chloral. Chloral condenses with numerous compounds to form derivatives from which chloral is released when they are used therapeutically. Among these are chloral ammonia, chloral antipyrine, chloral formaldehyde, etc. Chloral combines with sugars to form chloralose, which is used as an anesthetic in laboratory animals. In aqueous solutions, chloral and chloral hydrate are incompatible with alkalis that cause decomposition with the formation of chloroform and a formate. This reaction occurs also when chloral hydrate is combined with sodium derivatives of barbiturates that are alkaline (Ref. 3).

(1) *Safety.* Chloral hydrate is a hypnotic and sedative when ingested orally. Some clinicians consider it to be one of the best sedatives available, even though it is not used as extensively as it was before the introduction of barbiturates and other sedatives. It is used chiefly for insominia, but also in patients undergoing morphine or alcohol withdrawal, or in patients with delirium tremens. As is the case with most hypnotics, it is a poor analgesic and will not control pain in oridnary therapeutic doses. Systemically, it depresses the central nervous system, dulling both sensory and motor functions of the brain. Poisoning, after oral ingestion, is characterized by deep coma. The clinical findings in chloral hydrate poisoning are an initial delirium stage, followed by a deepening sleep, and then coma. The pupils first contract and then dilate. The respiratory rate and minute volume exchange decrease, and respiratory arrest follows. The pulse weakens, decreasing at first, but later may become rapid and irregular. The body temperature falls, the muscles relax, and sensibility and reflex action are diminished or completely abolished. In most cases, the immediate cause of death is respiratory failure but a simultaneous cardiac arrest seems to occur in others.

The Panel concludes that an elaborate and detailed discussion of the animal and human toxicology of chloral hydrate is superfluous because the drug has been widely used for many years, its pharmacologic internal effects have been extensively studied, and its safety established. When taken internally, chloral and chloral hydrate are reduced to trichloroethanol, which is conjugated with glucuronic acid in the liver in the detoxification process. The oral dose ranges from 0.5 to 1.0 g every 4 to 6 hours. Because the therapeutic does is relatively large, the Panel doubts that toxic doses would be absorbed from the skin in adults.

Chloral hydrate is somewhat irritating to the skin and mucous membranes. It is not caustic, nor is it a vesicant. Its alleged irritating effect accounts for its past used as a rubefacient (counterirritant) in liniments. One compound is a complex known as camphorated chloral, which results when camphor and chloral interact. How much of the counterirritating effect is due to camphor cannot be stated. Patients ingesting chloral hydrate for systemic use often experience gastric distress, nausea, and vomiting, particularly when the drug is taken on an empty stomach or in concentrated form. This irritating effect is transient and is greater on the mucous membranes than on the skin.

Systemically, chloral hydrate has a potential for causing dependency. In many respects, dependent individuals have the same manifestations as those who are dependent on alcohol. Withdrawal symptoms occur that are difficult to distinguish from the alcohol abstinence syndrome (delirium tremens). Chloral hydrate is a restricted substance subject to the control of the Drug Enforcement Agency for systemic use. Occasionally, chloral hydrate will produce skin lesions, but the local sensitizing and allergenic potential of the skin following topical applications is low. Allergic reactions are uncommon. Prolonged use by the oral route may cause hepatitis, similar to that observed with chloroform. This has not been reported from its topical use on the skin.

(2) *Effectiveness.* The Panel concludes that chloral hydrate is not effective for use as an OTC external analgesic.

The systemic effects of chloral hydrate and its derivatives are undisputed, but its topical analgesic effectiveness is questionable. Although it was used years ago as a topical analgesic, it is no longer recommended in official compendia for this purpose. There is no evidence to indicate that it has a topical anesthetic action even though it is an alcohol. This may be due to its being a dihydric alcohol, which is not as effective as a monohydric alcohol in topical anesthetic action. Chloral hydrate does not block nerve conduction as do the topical anesthetics. However, it has been used in some preparations for topical application as a counterirritant. Chloral hydrate is alleged to be irritating to the skin and mucous membranes, which accounts for its past use as a rubefacient (counterirritant) in liniments. The topical irritation applies to the mucous membranes also. However, it is questionable whether it is as effective and stable as other available compounds (Ref. 1).

After careful review of the data available for chloral hydrate, the Panel concludes that the ingredient is not effective as an external analgesic.

(3) *Evaluation.* The Panel concludes that chloral hydrate is not effective for use as an OTC external analgesic because it does not block nerve conduction as do the topical anesthetics.

References

(1) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 271–272, 1973.

(2) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 260, 1976.

(3) Adriani, J., "Halogenated Compounds," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 325–327, 1975.

Category II Labeling

The Panel concludes that the use of certain labeling claims related to the safety or effectiveness of the product is unsupported by scientific data and in some instances by sound theoretical reasoning. The Panel was not in agreement with regard to Category II claims requiring the diagnosis and care of a physician. It was, however, in complete agreement regarding all other Category II claims. Accordingly, this section consists of a majority and a minority report identified below on claims requiring the diagnosis of a physician. The minority report reflects the opinion of one member of the Panel.

The Panel considers the following claims to be misleading or unsupported by scientific data:

a. *Claims related to product performance.* The Panel has considered the following claims related to the performance of a product and considers them to be confusing, meaningless, and misleading to the consumer, and has therefore classified them as Category II: "fast," "swift," "sudden," "immediate," "prompt," "poignant," "bright," "fast cooling pain relief," "relief of cuts,

scratches, abrasions, wounds, etc.," "rubs out pain fast," "diminishes swelling," and "stops pain."

b. *Claims requiring the diagnosis and care of a physician*—(1) *Majority recommendation.* These claims are not amenable to self-diagnosis and self-treatment and require medical diagnosis and supervision for safe use. Examples of such claims are "rheumatic . . . aches," "bursitis," and "rheumatism."

c. *Minority recommendation.* These claims are not amenable to self-diagnosis and self-treatment and require medical diagnosis and supervision for safe use. Examples of such claims are "rheumatic . . . aches," "arthritis," "bursitis," "neuralgia," "bruises," "simple neuralgia," "sprains," "lumbago backache," "rheumatism," and "rashes due to poison ivy, poison oak, poison sumac, eczema, dermatitis, soaps, detergents, cosmetics, and jewelry, and itchy genital and anal areas."

d. *Pharmacologic activities not considered by this Panel and considered by other Panels.* Some claims on the labeling of external analgesic products refer to pharmacologic activities of drugs that were not considered by the Panel. These claims contain pharmacologic activities that do not pertain to the pharmacologic activities of ingredients used as topical analgesics, topical anesthetics, topical antipruritics, or topical counterirritants. Examples of these claims are "fungistatic for athlete's foot," "kills germs," "antiseptic," "discourages infection," "helps prevent infection," and "first aid."

e. *Claims containing anatomical areas specifically considered as deferred to other Advisory Review Panels.* Some Advisory Review Panels have been charged with the evaluation of ingredients for OTC use on specific anatomical areas, e.g., the Advisory Review Panel on OTC Hemorrhoidal Products. Claims referring to such anatomical areas have been deferred because they will be considered by the appropriate Advisory Review Panel. These include such claims as "pain due to hemorrhoids," "relief of athlete's foot," "piles," "diaper rash," and "denture irritation."

3. *Category III conditions for which the available data are insufficient to permit final classification at this time.* The Panel recommends that a period of 3 years be permitted for the completion of studies to support the movement of the following Category III conditions to Category I: effectiveness for the ingredients aspirin, glycol salicylate, salicylamide, triethanolamine salicylate, and thymol, and the claim for relief of deep seated pain for any ingredient. The Panel recommends that a period of 2 years be permitted for the completion of studies to support the movement of all other Category III conditions to Category I.

Category III Active Ingredients

Aspirin
Camphorated metacresol
Chlorobutanol
Cyclomethycaine sulfate
Eucalyptus oil
Eugenol
Glycol salicylate
Hexylresorcinol
Salicylamide
Thymol
Triethanolamine salicylate

a. *Aspirin.* The Panel concludes that aspirin is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetic, and antipruritics.

Aspirin is the acetyl ester of salicylic acid (acetylsalicylic acid) (Ref. 1). Acetylsalicylic acid had been synthesized some years before it was introduced into medicine by Dreser in 1899. It was first known as acetyl spiricum, from which the name aspirin is derived. Originally it was obtained from a plant source, *Spiraea ulmaria.*

Aspirin is an ester of salicylic acid. The acetic acid interacts with the hydroxyl group on the 2 position of salicylic acid. Aspirin is a powder consisting of white, tubular, or needle-like crystals. It is odorless and somewhat bitter tasting. Aspirin melts at approximately 135° C. In moist air it slowly hydrolyzes to salicylic and acetic acids and acquires the odor of acetic acid. The decomposition may be retarded somewhat by glycerin (Ref. 2). One g dissolves in approximately 300 ml water, 5 ml alcohol, 17 ml chloroform, and 10 to 15 ml ether. Two polymorphic forms have been described. One form is prepared in a slow crystallization process at room temperature from a saturated solution of aspirin in 95 percent alcohol. This form melts at between 143° and 144° C. The other is obtained simply from evaporation of hexane solution. It melts at between 123° and 125° C. Tablets prepared from the product derived from the slow crystallization technique have a slower rate of dissolution than tablets prepared from the hexane solution. Some evidence suggests that both forms of aspirin crystals are converted to the less soluble form during dissolution. Study of aspirin in aqueous media has led to the suggestion that a phase change occurs on the surface of the crystals (Ref. 1).

Aspirin readily undergoes hydrolysis in aqueous solutions with the liberation of salicylic and acetic acids. In pure water, complete decomposition takes place in 100 days. Acids hasten the rapidity of hydrolysis. The alkalis present in solutions of alkaline acetate and citrate dissolve aspirin, but the resulting solutions hydrolyze rapidly to form salts of acetic and salicylic acids. Half the aspirin decomposes in about 4 days. The decomposition may be retarded somewhat by glycerin and sugar. Liquefaction occurs when aspirin is saturated with phenyl salicylate, acetanilid, phenacetin, aminopyrine, antipyrine, and many other organic products. Partial hydrolysis occurs in mixtures of aspirin and hydroscopic substances or salts containing water of hydration. Even some talcs adversely affect the stability of aspirin (Ref. 3).

(1) *Safety.* Clinical use has confirmed that aspirin is safe in the dosage range used as an OTC external analgesic. When aspirin is applied topically to the skin, it is neither an irritant nor a counterirritant. Aspirin is both an ester and a weak acid. The acid id poorly ionized to the acetylsalicylate ion and the hydrogen ion in aqueous solution. Following oral ingestion it is absorbed from the stomach in the nonionized form. It is more highly ionized in the small intestines, and is absorbed as acetylsalicylate ion. Peak serum levels are reached in 1 to 2 hours after oral ingestion. Half or more of the aspirin circulating in the blood is bound to plasma proteins, especially albumin. The drug is very rapidly distributed to all highly perfused, watery body tissues. Since it has a short half-life, it is excreted very rapidly, largely in the urine. Most of it is excreted within a few hours, although traces continue to be excreted for several days. However, larger doses of aspirin do not follow first-order kinetics, and the higher the dose, the longer the half-life (Ref. 4). In febrile patients, a portion of the drug excreted is eliminated unchanged, but most of it is converted to salicyluric acid. Smaller amounts are eliminated as salicylic acid. It also conjugates with glucuronic acid in the liver to form glucuronates which are excreted in the urine. Some is eliminated as gentisic acid (Ref. 5).

Aspirin is not highly toxic, notwithstanding the voluminous literature on poisoning by the drug. Much of the poisoning is accidental and occurs in children. Poisoning in adults is uncommon. When the widespread use of aspirin is taken into consideration, the

total number of cases of poisoning that have occurred is small when extrapolated to the number of doses used.

A single dose of 10 to 30 g aspirin may be fatal, although survival has been reported when much larger doses have been ingested. Deaths from smaller doses have been reported. Impaired renal function interferes with excretion and accentuates toxicity. A total of 12 g ingested during 24 hours usually produces symptoms of salicylism, such as tinnitus, vertigo, impaired hearing, and headache. More severe manifestations include hyperpnea, fever, metabolic acidosis, and, less regularly, dimness of vision, sweating, thirst, vomiting, diarrhea, skin rashes, tachycardia, restlessness, and delirium. Salicylism may resemble diabetic and renal disorders. Central nervous system depression, stupor, coma, cardiovascular collapse, convulsions, and respiratory failure may be part of the clinical picture of salicylism. Fatal cases show diffuse changes in endothelial tissues with petechial hemorrhages and congestion throughout the viscera (Ref. 5).

The esters and other derivatives of salicylic acid may have an adverse effect upon the clotting mechanism. Aspirin is known to inhibit prothrombin formation, prolong prothrombin time, and interfere with the action of platelets on the clotting mechanisms. Even slight traces circulating in the blood can exert an adverse effect on the activity of platelets that lasts several days. Although salicylates are absorbed from the skin and detectable blood levels result from this absoption, the Panel believes that a special warning regarding possible adverse effects of topically applied esters of salicylic acid is not necessary (Refs. 5 and 6).

One of the untoward effects following oral administration of undissolved aspirin is gastrointestinal bleeding. The extent of blood loss is dose related. The effect that reportedly occurs in 70 percent of patients taking repeated doses of aspirin has been studied by determining the fecal blood loss in healthy human volunteers injected with radioactive chromium-51 tagged red blood cells. The radioactivity of the stools provided a measure for blood loss. During the drug-free control period, the average daily blood loss in one group of volunteers was 0.3 mL per individual. With doses of aspirin of 2.6 g daily, the average loss was increased to 2.3 mL per individual. When doses of 4.5 g aspirin were administered daily, losses increased to 6 mL per individual (Ref. 7).

Because the administration of aspirin in these subjects caused an increase in bleeding time from an average of 2.6 minutes during the control period to an average of 4.5 minutes when aspirin was given to them, the question of whether gastrointestinal bleeding is due to the local effect on the stomach mucosa or to a systemic effect related to the prolonged bleeding time has been the subject of considerable debate.

When aspirin as a sodium salt is injected intravenously, gastric intestinal bleeding does not occur, implying that bleeding is due to a local effect. Bleeding time is prolonged to approximately the same degree whether aspirin is given orally or parenterally. The importance of recognizing this untoward effect of aspirin in patients with hemostatic abnormalities and clotting defects has been stressed and documented in many reports. Although the prolongation of bleeding time has been ascribed by some clinicians to a defective vascular response, others attribute it to a decrease in blood platelet aggregation. Following injury to a capillary, endogenous adenosine diphosphate is released from platelets, causing an irreversible aggregation which results in the formation of a plug in a capillary that is primarily responsible for the arrest of bleeding. Aspirin apparently inhibits the release of endogenous adenosine diphosphate and thereby prolongs bleeding time. As little as 5 gr aspirin can produce this type of abnormal platelet response, and the abnormality persists anywhere from 4 to 7 days, corresponding to the lifespan of the platelets. Because aspirin is absorbed in appreciable amounts through the skin and circulates in the blood, the effect it may have upon coagulation is important in patients whose clotting mechanism is disturbed (Ref. 8).

Idiosyncrasy to aspirin is rare. But aspirin may cause hypersensitivity reactions. These reactions are of two types: a nonimmunogenic reaction characterized by the triad of hypersensitivity, nasal polyps, and asthma; and an immunogenic reaction that occurs in atopic individuals. The nonatopic reaction is probably related to the inhibition of prostaglandin synthesis. As is the case with any other drug, aspirin can act as a haptene and produce an immunogenic type of sensitization. Sensitization is most frequently observed in high risk allergic atopic individuals, particularly in asthmatics and individuals with nasal polyps (Refs. 9 and 10). The manifestations of an allergic response are urticaria, erythema, desquamated bullous or purpural skin lesions, angioneuronic edema, laryngeal stridor, asthma, and peripheral vascular collapse. Absorption of aspirin from damaged skin may produce a systemic allergic response. These reactions are often serious and can be fatal. Direct application of aspirin to the skin may produce irritation in susceptible individuals, but this is uncommon. Large doses of aspirin reduce plasma prothrombin levels in subjects with nonbleeding problems and hence increase prothrombin time, but this effect is clinically significant only when anticoagulants are administered.

The Panel concludes from the ingredient's extensive oral use and long marketing history that aspirin is safe when used topically, and that even though it is readily absorbed through the skin, the risk-to-benefit ratio is low. Aspirin has a relatively low incidence of serious toxic effects associated with short-term use for the majority of the target population. Toxic reactions due to the application of overdoses to the skin are unknown. However, the Panel emphasizes that this does not mean that aspirin circulating in the blood after percutaneous absorption has no adverse effects.

(2) *Effectiveness.* Aspirin is the most widely used OTC internal analgesic ingredient in the United States (Ref. 11). In view of its immense popularity in this country, it has been extensively discussed in the medical and scientific literature. Aspirin is useful to relieve mild to moderate pain, not only when the pain is localized but also when it is generalized. Thousands of articles have been written concerning the safety and effectiveness of aspirin since the first pharmacologic data were reported in the literature in 1899.

Aspirin possesses no direct topical anesthetic activity and does not block the neuronal membrances as do the topical anesthetics such as benzocaine, tetracaine, lidocaine, etc. Therefore, it exerts no anesthetic, analgesic, or antipruritic effect on the skin. Some degree of percutaneous absorption of salicylate esters occurs through the intact skin (Refs. 12 and 13), but no significant cutaneous analgesic or anesthetic activity has been demonstrated. Kionka (Ref. 14) states that, of all salicylates, aspirin is the best absorbed percutaneously from various types of solution, and that the percutaneous absorption of aspirin is increased 30 percent when 2 percent camphor is present. In another statement attributed to Fantus (Ref. 14), it is said that absorption of salicylates through the skin is increased if the solution contains 20 percent alcohol. Blood levels of salicylates have been

demonstrated after cutaneous application using tracer elements in animals. Excretion of salicylates and metabolites into the urine has been demonstrated after percutaneous absorption. Comparisons of blood levels following topical application to those following oral ingestion of therapeutic doses have not been made. Claims have been made that localized areas of myalgia and other painful muscular skeletal disorders are relieved by the applciation of esters of salicylic acid to the affected part. Data to support the contention that this is due to a local action of the ingredient are lacking.

The Panel concludes from available data that the action of salicylates is systemic and that any analgesic effect resulting from topical application is due to the blood-borne drug distributed systemically in the same manner it would be after oral absorption. The exact mechanism by which salicylates produce their analgesic effects is not known, but it is generally conceded that they act in part by exerting an anti-inflammatory effect and in part by a central depressant effect. Systemic salicylates also exert a peripheral anti-inflammatory action. Some workers have attempted to explain the action of salicylates on the basis of their effects on the water balance of tissues. In addition, there is considerable evidence that aspirin interferes with the synthesis of prostaglandins and exerts its analgesic effect in this manner. Although the Panel accepts the fact that aspirin may have a dual effect, that is, one acting centrally and one peripherally, it does not support the assumption that the drug penetrates the skin and passes into and exerts its effect on the structures beneath and skin. The Panel finds no evidence to support the fact that salicylates, including aspirin, produce an antipruritic or analgesic effect within the skin. The Panel does not disagree that the blood-borne drug may exert an effect on the musculo-skeletal structures and relieve pain if the drug is absorbed in sufficient quantities to produce effective plasma levels. However, the Panel has insufficient evidence to support this contention.

Although 5 to 6 percent concentrations of aspirin have been used topically in OTC preparations, there is insufficient evidence to support the contention that such concentrations are effective.

(3) *Proposed dosage—For adults and children 2 years of age and older:* Apply a 5 to 6 percent concentration of aspirin to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not use this product if you are allergic to aspirin."

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for OTC external analgesics. (See part III. paragraph C. below—Data Required for Evaluation.)

References

(1) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 160–164, 1973.

(2) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, p. 15, 1955.

(3) Gold, G. and J. A. Campbell, "Effect of Selected U.S.P. Talcs on Acetylsalicylic Acid Stability in Tablets," *Journal of Pharmaceutical Sciences,* 53:52–54, 1964.

(4) Levine, R. R., "Pharmacology: Drug Actions and Reactions," Little, Brown, and Co., Boston, pp. 211–218, 1973.

(5) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, pp. 326–339, 1975.

(6) Quick, A. J., "The Story of Salicylates in Bleeding Problems in Clinical Medicine," W. B. Saunders Co., Philadelphia, pp. 14–33, 1970.

(7) Leonards, J. R. and G. Levy, "Soluble Buffered Aspirin Sought to Eliminate Blood Loss in the Stomach," *Journal of the American Medical Association,* 209:17–19, 1969.

(8) O'Brien, J. R., "Aspirin and Platelet Aggregation, *Lancet,* 1:204–205, 1968.

(9) Speer, F., "Aspirin Allergy: A Clinical Study," *Southern Medical Journal,* 68:314–318, 1975.

(10) Fein, B. T., "Aspirin Shock Associated with Asthma and Nasal Polyps," *Annals of Allergy,* 29:598–601, 1971.

(11) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 99–106, 1973.

(12) Beutner, R., et al., "On the Absorption and Excretion of Methylsalicylate Administered by Inunction," *Journal of Laboratory and Clinical Medicine,* 28:1655–63, 1943.

(13) Greiner, H., "Klinischer Erfahrungsbericht uber ein neues perkutan wirkendes Antirheumatikum," *Medizinische Welt,* 48: 2667–9, 1968.

(14) OTC Volume 060008.

b. *Camphorated metacresol.* The Panel concludes that there are insufficient data available to permit final classification of the safety and effectiveness of camphorated metacresol for use as an OTC external analgesic. During the testing period provided to demonstrate safety and effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetics, and antipruritics.

Camphorated metacresol is either a "complex" formed by the interaction of camphor with metacresol or a solution of the cresol in camphor. Whether a definite chemical complex forms or whether the cresol dissolves in the camphor has not been established. It is claimed (Ref. 1) that cresol is released in small quantities from the complex to exert its therapeutic effect. The amount of camphor that combines with the cresol is approximately 66 percent on a weight-for-weight basis. The amount of metacresol is approximately 22 percent on a weight-for-weight basis. Camphorated metacresol has been on the market since 1930. No other data on the chemical and physical properties of the combination of the two ingredients were supplied to the Panel (Ref. 1).

Phenol combines with camphor to form a complex. This results in a marked decrease in the caustic action of phenol. Because metacresol is a phenol, it has been assumed that with camphor it also forms a similar complex that results in a decrease in caustic action. No data have been supplied, nor has the Panel found any data in the medical literature to support these assumptions. The assumption of the supposed effectiveness of camphorated metacresol is based on the fact that a phenol-camphor complex is effective, and is not based on any laboratory or clinical data (Ref. 1). The three forms of cresols are ortho, para, and metacresol. Of these, the metacresol is less toxic than phenol (Ref. 2).

(1) *Safety.* Data on the clinical use as an OTC external analgesic are insufficient to conform that camphorated metacresol is safe.

There were two reports of adverse reactions (Ref. 1). Both were caused by accidental swallowing of the liquid. One report concerned a child who reportedly swallowed ½ ounce metacresol. The child developed convulsions shortly after ingestion. The patient rapidly improved after several hours and was discharged from the hospital the day after the incident occurred. The second case involved a woman who, as a hospital patient, swallowed an undetermined amount of the preparation. A tablespoonful of epsom salts dissolved in water was administered orally and the stomach was pumped. The patient recovered. The woman suffered no post-ingestion sequelae. Other than these two reports, there have been no indications that this compound has caused any harm to

humans. These were cases that resulted from accidental use or misuse of the product. No fatalities have been reported (Ref. 1). The Panel stresses that it found no other data concerning this product in the textbooks and medical literature that were reviewed.

Data on animal and human toxicity was not provided in a submission to the Panel. It has been claimed that camphorated metacresol causes no irritancy to the skin. However, this claim is based on uncontrolled patch tests in rats.

When this cresol complex is applied topically, the index of its caustic effects on the skin is alleged to depend on the amount of free cresol released from the camphor complex. For instance, in a ratio of 3:1 camphor-metacresol, a 25-percent cresol preparation releases approximately 2 percent free metacresol. This, it is claimed, is a noncaustic level on the skin. Data substantiating this statement are lacking. At the ratio of 3:2 camphor-metacresol (40 percent cresol), the free metacresol level rises to 8 percent and at a 1:1 ratio of camphor-metacresol, the level of free cresol increases above 16 percent.

In combination with camphor, cresols are released slowly if there is no water present. Water causes the cresol to be released more rapidly and in quantities greater than those mentioned above. Since tissues are composed of water, the Panel is deeply concerned that application of this preparation to the skin, particularly if open lesions are present, may cause caustic quantities of cresol to be released.

Based on the lack of sufficient data on systemic and topical toxicity in animals and in man, the Panel concludes that camphorated metacresol must be classified as Category III at this time.

(2) *Effectiveness.* The Panel concludes that the data are insufficient to classify camphorated metacresol as effective for use as an OTC external analgesic.

The panel has found no information documenting the effectiveness of camphorated metacresol as a topical analgesic, anesthetic, or antipruritic in textbooks and other literature that was reviewed.

The cresols, like the phenols which are aromatic alcohols, are topical anesthetics in low concentrations (Ref. 3). It would be expected that analgesic, anesthetic, and antipruritic effects can occur with camphorated metacresol, but there are not controlled studies to substantiate such a finding. Conclusions drawn from data obtained from the use of electrical stimulation indicate that camphorated metacresol possesses pain-reducing properties. These data are inadequate and insufficient for the Panel to make a judgment (Ref. 1). The germicidal activity of the cresols averages three or more times that of phenol (Ref. 1). The Panel has not considered the antimicrobial claims for this ingredient. Based on the insufficiency of data, the Panel concludes that camphorated metacresol must be classified as Category III as a topical analgesic, anesthetic, or antipruritic for OTC use.

(3) *Proposed dosage—For adult and children 2 years of age and older:* Apply a 0.1 to 3.0 percent concentration of camphor with metacresol, at a ratio of 66 percent camphor to 22 percent metacresol, to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate safety and effectiveness will be required in accordance with the guidelines set forth below for OTC external analgesics. (See part III. paragraph C. below—Data Required for Evaluation.)

References

(1) OTC Volume 060152.

(2) Osol, a. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, pp. 400–401, 1955.

(3) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(c) *Chlorobutanol.* The Panel concludes that chlorobutanol is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetics, and antipruritics.

Chlorobutanol is 1,1,1-trichloro-2-methyl-2-propanol. It is a halogenated tertiary alcohol also known as acetone-chloroform, chloretone, chlorbutyl, methaform, acetiform, and chlorobutasol. Chlorobutanol is made by condensing acetone with chloroform in the presence of an alkali. The hydrogen atom from chloroform shifts to the ketonic oxygen atom of acetone to form a hydroxyl group and the tri-chlorinated carbon residue becomes attached to the middle carbon of the acetone molecule.

Chlorobutanol is a crystalline substance existing in two forms. One is the anhydrous form. The other is a hemihydrate. In the hemihydrate, two molecules of chlorobutanol share one molecule of water. Both the hemihydrate and the anhydrous form have a camphor-like odor and taste. Both forms of chlorobutanol sublime readily. The anhydrous form melts at 97° C. The hemihydrate form melts at 78° C. Both forms are easily soluble in water and very soluble in alcohol. One g of the anhydrous form dissolves in 1 mL alcohol and 10 mL glycerol. It is also soluble in chloroform, ether, acetone, glacial acetic acid, and various oils. The anhydrous form dissolves in liquid petrolatum to form a clear liquid solution. The hemihydrate does not form a clear solution. Chlorobutanol produces a soft mass when it is triturated with menthol, phenol, antipyrine, and certain other substances. Alkali causes chlorobutanol to break down to carbon dioxide, acetone, and other byproducts. Chlorobutanol condenses with chloral hydrate to form a stable compound that is a distinct chemical entity.

(1) *Safety.* Clinical use has confirmed that chlorobutanol is safe in the dosage range used as an OTC external analgesic.

Chlorobutanol possesses a low degree of systemic and local toxicity. Toxic doses ingested orally cause unconsciousness, coma, and death due to respiratory failure. Its systemic toxicity resembles that of chloral hydrate. Continued oral use of chlorobutanol induces tolerance. Chronic toxicity has not been demonstrated. Chlorobutanol is an old drug, having first been used systemically in 1894 by Abel as a hyponotic and as an antispasmodic of smooth muscle. Chlorobutanol is not irritating to the skin and is safe for topical application. Sensitization can occur but is uncommon (Refs. 1, 2, and 3).

(2) *Effectiveness.* Chlorobutanol is a hydroxy type of compound and has weak topical anesthetic properties on the mucous membranes. Its effectiveness topically on the skin has not been demonstrated by controlled studies. Chlorobutanol has been used systemically as a hypnotic and as an antispasmodic but possesses no analgesic effect. The hypnotic action is similar to that of chloral hydrate. It was once used for the treatment of nausea and vomiting. Presumably, it afforded relief because it acted as a topical anesthetic on the mucous membranes of the stomach and at the same time produced sedation after absorption. Its value for this purpose has been questioned and it is doubtful that it was effective as claimed because data to

support these contentions are not available. It has also been used in the treatment of coughs, hiccups, and other spasmodic conditions.

Chlorobutanol was formerly incorporated with talc as a dusting powder for the treatment of pruritus and other dermatologic conditions. It has been incorporated in suppositories for the treatment of painful hemorrhoids. However, it is no longer used for these purposes. A 1-percent solution of chlorobutanol in petrolatum has been used for the treatment of otitis media. A 25-percent solution in clove oil has been used as a dental analgesic for the treatment of toothache. It has been added to vasoconstrictors in nasal sprays to anesthetize the mucous membranes and thereby prevent the burning and stinging sensation of the vasoconstrictor. Chlorobutanol is also used as a bacteriostatic agent in vaccines and solutions of various drugs (Refs. 3 and 4).

The Panel considered several submissions in which chlorobutanol was one of the ingredients present in a combination (Refs. 5, 6, and 7). This mixture contained chlorobutanol combined with 1.18 percent menthol, 0.5 percent benzocaine, and 3.92 percent tannic acid. The Panel does not consider the data available in either the submission or the available textbooks sufficient to classify chlorobutanol as an effective external analgesic.

(3) *Proposed dosage—For adults and children 2 years of age and older:* Apply a 1 to 5 percent concentration of chlorobutanol to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See Part III, paragraph B.1. above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for OTC external analgesics. (See part III, paragraph C. below—Data Required for Evaluation.)

References

(1) Cushny, M., "Pharmacology and Therapeutics," 13th Ed., Lea and Febiger, Philadelphia, p. 314, 1947.

(2) Dalili, H. and J. Adriana, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itching, Burning and Pain in Normal 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics*, 12:913–919, 1971.

(3) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 290, 1973.

(4) Adriani, J., "Local Anesthetics," *in* "Chemistry and Physics of Anesthesia," 2d Ed., Charles C. Thomas Publishing Co., Springfield, IL, pp. 398–473, 1962.

(5) OTC Volume 060011.

(6) OTC Volume 060025.

(7) OTC Volume 060080.

d. *Cyclomethycaine sulfate.* The Panel concludes that cyclomethycaine sulfate is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetics, and antipruritics.

Cyclomethycaine sulfate is a topical anesthetic. Chemically, it is the cyclohexyloxybenzoic acid ester of 2-methylpiperidino propyl alcohol. It is a "caine" type of drug, having the general configuration of an aromatic nucleus, a dimethylene chain, and a tertiary amino group common to these drugs, but differing from the usual structure in that the pivot has three carbon atoms instead of two. The nitrogen atom forms a tertiary amine by virtue of its position in a methylpiperidino ring on carbon 3 of the propyl alcohol. Cyclomethycaine sulfate is an ester type of topical anesthetic. It is chemically allied to piperocaine, which is a benzoic acid ester. The compound was introduced in 1946 by McElvain and co-workers who also introduced piperocaine (Ref. 1). Cyclomethycaine is a base that forms salts with acids, such as hydrochloric or sulfuric acid. Both the hydrochloride and sulfate are available, but because no data were submitted on the hydrochloride salt, the only salt evaluated by the Panel is the sulfate. The sulfate is soluble in water and stable when exposed to air and light.

(1) *Safety.* Clinical use has confirmed that cyclomethycaine sulfate is safe in the dosage range used as an OTC external analgesic.

Cyclomethycaine sulfate is a "caine" type of drug and demonstrates a qualitatively similar toxicity systemically, as do other "caine" drugs. The LD_{50} intravenously in mice is 547 mg/kg. Subcutaneously in mice the LD_{50} is 447 mg/kg and in rats, 1,079 mg/kg.

Although cyclomethycaine is chemically allied to piperocaine, it is less toxic in mice than piperocaine. The LD_{50} intravenously for piperocaine is 32 mg/kg while the subcutaneous LD_{50} dose is 589 mg/kg. Rats injected for 4 weeks with doses ranging from 50 to 500 mg/kg showed no evidence of chronic toxicity.

The lethal dose for man is not known. A transitory stinging or burning is sometimes experienced before the onset of anesthesia. Sensitization is uncommon. Its sensitizing potential is no greater than that of other "caine" type drugs. Tenely and Friedman (Ref. 2) reported one case of a 2-month-old infant who developed convulsions, congestive heart failure, and heart block after application of cyclomethycaine combined with methapyrilene to extensive surfaces of the body for seborrheic dermatitis. The surface was abraded. The symptoms receded after the preparation was washed off and supportive measures instituted. The cardiac depression and convulsions suggest that the reaction was due to the cyclomethycaine. Blood levels were not determined.

A case of anaphylactoid reaction following the use of a rectal suppository in a patient has been reported (Ref. 3). Skin reactions due to irritation or sensitization may occur in hypersensitive individuals. Marketing experience shows 4 cases of minor adverse reactions in 1,500,000 units sold.

(2) *Effectiveness.* Cyclomethycaine sulfate is a potent topical anesthetic with a rapid onset of action that may persist for several hours. Cyclomethycaine is effective as a topical anesthetic on the cornea of rabbits in concentrations as low as 0.05 percent. The duration of anesthesia is approximately 12 minutes. Concentrations of 0.5 to 1 percent increased the duration to 60 minutes. Evidence of irritation appears when concentrations exceeding 0.05 percent are used. In man, concentrations of 0.05 percent produced doubtful results. It is effective in intracutaneous wheals on guinea pigs and man. In early studies after the introduction of cyclomethycaine, 429 patients with burns, lacerations, abrasions, and other minor skin lesions were treated with cyclomethycaine preparations with satisfactory results. These studies were not controlled (Ref. 3).

Cyclomethycaine sulfate does not appear to retard healing of minor superficial cutaneous lesions. It is indicated for the relief of burning, itching, or pain associated with damaged or diseased skin and mucous membranes of the rectum and the genitourinary tract. It is not effective on the mucosa of the mouth, nose, trachea, bronchi, and the eye. It is used for the temporary relief of discomfort due to burns, superficial cuts, itching, and insect bites. As is the case with other topical anesthetics of this type, the salt does not readily penetrate intact skin.

Adriani and Dalili found that it was not effective on intact skin burned by ultraviolet light (Ref. 4).

Brockemeyer and Guth noted in preliminary tests that ointments containing 1 percent cyclomethycaine sulfate produced only slight local anesthesia. They further noted that ointments containing 5 percent cyclomethycaine sulfate produced a "marked degree" of local anesthesia (Ref. 5).

Cyclomethycaine sulfate has been used in the concentrations specified in the proposed dosage section below, but the Panel concludes that there are insufficient clinical data and a lack of sufficient controlled studies of the ingredient as a topical analgesic and anesthetic to support the effectivenss of such concentrations.

(3) *Proposed dosage—For adults and children 2 years of age or older:* Apply a 0.5 to 1.0 percent concentration of cylcomethycaine sulfate to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.) In addition, the Panel recommends the following specific labeling: *Warning.* "Do not use in large quantities, particularly over raw surfaces or blistered areas."

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for OTC external analgesics. (See part III. paragraph C. below—Data Required for Evaluation.)

References

(1) McElvain, S. M., and T. P. Carney, "Piperidine Derivatives. XVII. Local Anesthetics Derived from Substituted Piperidinoalcohols," *Journal of the American Chemical Society,* 68:2592–2600, 1946.

(2) Tenley, J. A. and S. Friedman, "A Toxic Cardiac Reaction to Drugs Absorbed Percutaneously," *Pediatric Pharmacology and Therapeutics,* 69:299–301, 1966.

(3) OTC Volume 060141.

(4) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia,* 50:834–841, 1971.

(5) Brockemeyer, E. W. and E. P. Guth, "A Measurement of the Efficiency of Ointment Bases in Releasing a Local Anesthetic," *Journal of the American Pharmaceutical Association,* 44:706–709, 1955.

e. *Eucalyptus oil.* The Panel concludes that eucalyptus oil is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical counterirritants.

Eucalyptus oil is also known as oil eucalyptus and oil of eucalyptus. Eucalyptus oil is a volatile oil prepared by steam distillation from leaves of *Eucalyptus globulus* and other species of *Eucalyptus myrtaceae* containing 70 to 80 percent eucalyptol (Ref. 1). Eucalyptus oil is a colorless to pale yellow volatile liquid with a camphoraceous odor and cooling taste (Ref. 2). The eucalyptus tree is native to Australia, Tasmania, and Malaysian regions. The characteristic odor of eucalyptus oil is considered a "medicinal" odor by the laity.

One of the chief constituents of eucalyptus oil is eucalyptol, also known as cineol, cineole, cajeputol, and cajuptol. Eucalyptol is a colorless liquid with a characteristic aromatic camphoraceous odor. It is insoluble in water and miscible with alcohol, chloroform, and ether. Eucalyptus oil and eucalyptol have both been categorized in the National Formulary as flavors. They have both been categorized as having a mildly topical anesthetic, analgesic, and antiseptic effect. They have also been used as stimulating expectorants and as vermifuges (Ref. 3).

Eucalyptus oil has been used topically for the treatment of certain forms of skin disease. It is an active germicide, but not as effective as many other volatile oils (Ref. 2).

(1) *Safety.* Clinical use has confirmed that eucalyptus oil is safe in the dosage range used as an OTC external analgesic.

Eucalyptus oil is recognized in "National Formulary XIII" as a flavor. It has also been used internally as a stimulating expectorant (Refs. 4 and 5).

Meyer et al. studied the percutaneous absorption of essential oils. They found eucalyptol to be a substance showing fairly active topical absorption (Ref. 6). If eucalyptus is taken internally in large quantities as the oil or as the active ingredient eucalyptol, toxic symptoms may occur. These symptoms include epigastric burning, nausia, vomiting, tachycardia, dizziness, muscular weakness, a feeling of suffication, and in severe cases, delirium and convulsions. Death has occurred in about one-third of the human subjects who ingested between 10 and 30 mL of the oil. Idiosyncrasy toward small doses my be manifested by skin eruptions (Refs. 7 and 8). Sensitization to eucalyptus oil has been observed but is believed to occur infrequently (Refs. 9 and 10).

A study by Jenner et al. found that the LD_{50} for rats is 258 mg/kg, relatively safe when used topically (Ref. 11). Jori and Briatico studied the effect of giving eucalyptol subcutaneously to pregnant rats. It was found that eucalyptol greatly increased the liver microsomal activity during and after pregnancy. It was also found that this increased activity was higher in the fetal and newborn offspring (Ref. 12).

The question of carcinogenic activity of eucalyptus oil has been raised by several investigators (Refs. 13 and 14). It was found that in mice eucalyptus oil applied to the skin caused development of tumors in about 10 percent of the animals treated.

Marketing experience of a topical analgesic product containing small amounts of eucalyptus oil produced no evidence of a lack of safety (Refs. 15 and 16).

(2) *Effectiveness.* Martindale (Ref. 8), in reference to all essential oils, states that they have an irritant and rubefacient action and cause a sensation of warmth and smarting followed by mild topical anesthesia.

The Panel finds no sound scientific or sound theoretical basis for the classification of eucalyptus oil as a topical counterirritant in the dosage range deemed to be safe.

A counterirritant drug must evoke positive, perceptable irritation for a reasonable period of time following its application to healthy intact skin at a specified concentration.

The Panel finds nothing in the literature or in the submissions to the Panel to support a conclusion that eucalyptus oil or eucalytol has a unique vehicle-related irritancy, or that eucalyptus oil contributes any irritant activity to the formulation(s) in which it is employed.

Although eucalyptus oil has been used in concentrations ranging from 0.5 to 3.0 percent, there is insufficient data to support the effectiveness of such concentrations.

(3) *Proposed dosage—For adults and children 2 years of age and older:* Apply a 0.5 to 3.0 percent concentration of eucalyptus oil to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical counterirritant active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for OTC external analgesics. (See

part III. paragraph C. below—Data Required for Evaluation.)

References

(1) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 510, 1976.
(2) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 24th Ed., J. B. Lippincott Co., Philadelphia, pp. 458–460, 1950.
(3) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, pp. 561–562, 1955.
(4) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 517, 1973.
(5) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, p. 1230, 1975.
(6) Meyer, F. and E. Meyer, "Percutaneous Absorption of Essential Oils and Their Constituents," *Arzneimittel Forschung*, 9:516–519, 1959.
(7) Sollmann, T., "A Manual of Pharmacology and Its Applications to Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, p. 169, 1957.
(8) Todd, R. G., "Martindale, The Extra Pharmacopeia," 26th Ed., The Pharmaceutical Press, London, p. 169, 1975.
(9) Fisher, A. A., "Contact Dermatitis," 2d Ed., Lea and Febiger, Philadelphia, p. 379, 1973.
(10) Sanitz, M. H. and E. Shmunes, "Occupational Dermatoses in Dentists and Allied Personnel," *Cutis*, 5:160–164, 1969.
(11) Jenner, P. M., E. C. Hagan, J. M. Taylor, E. L. Cook, and O. G. Fitzhugh, "Food Flavorings and Compounds of Related Structure I. Acute Oral Toxicity," *Food and Cosmetics Toxicology*, 2:327–343, 1964.
(12) Jori, A. and G. Briatico, "Effects of Eucalyptol on Microsomal Enzyme Activity of Foetal and Newborn Rats," *Biochemical Pharmacology*, 22:543–544, 1973.
(13) Roe, F. I. C. and W. H. Field, "Chronic Toxicity of Essential Oils and Certain Other Products of Natural Origin," *Food and Cosmetics Toxicology*, 3:311–324, 1965.
(14) Homburger, F. and E. Boger, "The Carcenogenicity of Essential Oils, Flavors, and Spices: A Review," *Cancer Research*, 28:2372–2374, 1968.
(15) OTC Volume 060013.
(16) OTC Volume 060014.

f. *Eugenol.* The Panel concludes that eugenol is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetics, and antipruritics.

Eugenol is 4-allyl-2-methoxyphenol. It is, therefore, a phenolic type of compound and belongs to the class of the hydroxy type of topical anesthetics. Eugenol is the main constituent in clove oil. It is also present in pimento, cinnamon leaves, sassafras, and canella. It is prepared synthetically from vanillin. An isomer, isoeugenol, is also known. This is found in clove, nutmeg, and ylang-ylang (Ref. 1).

Eugenol is a colorless, pale yellow liquid. It has a strong aromatic odor of clove and a pungent spicy taste. It is slightly soluble in water and miscible in alcohol, ether, chloroform, and fixed oils. The specific gravity is 1.06 to 1.07 (Refs. 2 and 3). Eugenol darkens and thickens on exposure to air. Eugenol is acid in reason and reacts with sodium hydroxide to form a salt, sodium eugenolate, which is soluble in alkaline solution. Eugenol is optically inactive (Ref. 1).

(1) *Safety.* Clinical use has confirmed that eugenol is safe in the dosage range used as an OTC external analgesic.

Eugenol is not irritating and is safe for topical application to the intact and damaged skin (Refs. 1, 4, 5, and 6). There is no known reported toxicity when eugenol is ingested orally.

Eugenol has been used internally as an antispasmodic and carminative, and is sometimes used in the treatment of flatulent colic. It is employed in dentistry as a flavoring agent and mild rubefacient in dentifrices, and also as an obtundent for hypersensitive dentine, caries, or exposed pulp. When eugenol is mixed with zinc oxide, it is used as a temporary anodyne filling (Ref. 7).

The acceptable daily intake for man is up to 5 mg/kg of body weight. Applied externally, it is used as an analgesic (Ref. 7). It is as potent an antiseptic as phenol, possessing decidely less irritant properties (Ref. 8).

The acute toxicity (LD_{50}) was found to be 2.7 g/kg in rats, and 3.0 g/kg in mice (Ref. 9). Poisoned rats have exhibited paresis of the hind legs and jaw with eventual prostration and coma. Death is believed to be due to peripheral vascular collapse, with surviving rats showing hematuria (Ref. 9). Eugenol is not corrosive, like phenol, but ingestion results in gastroenteritis. Systemic toxicity is less than, but similar to, phenol. Aqueous emulsions taken by mouth induce vomiting in man and dogs and promote gastric secretion of mucus (Ref. 9).

A 5-percent eugenol emulsion stimulates secretion of gastric mucus without an increase of acid. Three or four applications of eugenol at 3-hour intervals to the gastric mucosa exhausts the mucous response after which a nonviscous exudate is released. Partial recovery occurs in 36 hours, but complete recovery usually requires 3 to 5 months (Ref. 10).

(2) *Effectiveness.* Eugenol has been used in dentistry for disinfecting root canals, as a topical analgesic for the relief of hypersensitive dentine pain and irritation due to hyperemic inflamed viral polyps, and as a component of a zinc eugenol cement used as a temporary filling for carious teeth (Refs. 1, 4, and 5). Formerly, eugenol was used internally as an antiseptic and as an antiputrescent, but it is no longer employed for this purpose. Eugenol appears to be slightly less active as an antiseptic than the natural oil. Eugenol stimulates peristalsis by virtue of its local irritant effect and has been used in the treatment of flatulent colic (Ref. 1). It also possesses some topical anesthetic action by virtue of its phenolic nature, being a favored remedy for toothache. Small pledgets of cotton saturated with the oil are inserted into the carious cavity. However, its topical anesthetic action is considered to be weak and evanescent. Eugenol manifests antimicrobial activity in some cases, being approximately eight times stronger than phenol in this respect. But because of its irritant properties on the mucous membranes, it is not frequently used for this purpose except by dentists. The Panel did not receive data in any submission, and was unable to find data in controlled or uncontrolled studies, to substantiate the claims that eugenol is a topical analgesic, anesthetic, and antipruritic (Ref. 11). Although 1 to 2 percent concentrations of eugenol have been used clinically, there is insufficient evidence as to the effectiveness of such preparations.

(3) *Proposed dosage—For adults and children 2 years of age and older:* Apply a 1 to 2 percent concentration of eugenol to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for OTC external analgesics. (See part III. paragraph C. Below—Data Required for Evaluation.)

References

(1) Osol, A., "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, p. 565, 1955.
(2) "The United States Pharmacopeia," 19th Ed., United States Pharmacopeial Convention, Inc., Rockville, MD, p. 193, 1975.
(3) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 551, 1976.
(4) DiPalma, J. R., "Drill's Pharmacology in Medicine," 4th Ed., McGraw-Hill Book Co., New York, p. 1036, 1971.

(5) Grollman, A. and E. F. Grollman, "Pharmacology and Therapeutics," 7th Ed., Lea and Febiger, Philadelphia, p. 416, 1970.
(6) Stecher, P. G., "The Merck Index," 7th Ed., Merck and Co., Rahway, NJ, p. 440, 1960.
(7) Todd, R. G., "Martindale, The Extra Pharmacopeia," 26th Ed., The Pharmaceutical Press, London, pp. 1239–1241, 1972.
(8) Dobbs, E. C., "Pharmacology and Oral Therapeutics," C. V. Mosby Co., St. Louis, p. 448, 1961.
(9) Gosselin, R. E., H. C. Hodge, R. P. Smith, and M. N. Gleason, "Clinical Toxicology of Commercial Products," 4th Ed., The Williams and Wilkins Co., Baltimore, p. 168, 1975.
(10) Sollmann, T., "A Manual of Pharmacology and Its Application to Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, p. 170, 1957.
(11) OTC Volume 060007.

g. *Glycol salicylate.* The Panel concludes that glycol salicylate is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetics, and antipruritics.

Glycol salicylate is also known as glycol monosalicylate, monoglycol salicylate, ethylene glycol monosalicylate, and 2-hydroxyethyl salicylate. It is the mono ester of ethylene glycol. It is prepared synthetically by esterification of ethylene glycol with salicylic acid. Its chemical nature and pharmacologic activities appear to be similar to methyl salicylate. It is a colorless, odorless liquid that boils at 169° to 172° C. One part of glycol salicylate is soluble in 110 parts water and in 8 parts olive oil. It is very soluble in alcohol, benzene, chloroform, and ether (Ref. 1).

(1) *Safety.* Clinical use has confirmed that glycol salicylate is safe in the dosage range used as an OTC external analgesic. In full strength concentrations, it has an irritant effect on the skin. Toxicity from oral ingestion is alleged to be due to the release of salicylate in the bowel and the absorption of the salicylate into the bloodstream. The symptoms are similar to those induced by other esters of salicylic acid.

Glycol salicylate is an ester of ethylene glycol. Absorption of the drug through the skin or after oral ingestion may result in hydrolysis of the ester to ethylene glycol and salicylic acid. Ethylene glycol is oxidized to oxalic acid in the body. Oxalic acid is toxic if excessive quantities form. The Panel has no proof that this occurs with this ingredient when applied topically but feels this should be a point of interest in considering safety.

(2) *Effectiveness.* Glycol salicylate possesses no significant topical anesthetic activity and does not block the neuronal membranes as do the topical anesthetics, such as benzocaine, butamben, etc. It lacks sufficient counterirritant activity to be classified as a counterirritant. Although some degree of percutaneous absorption of salicylate esters occurs through the intact skin, no significant topical analgesic or anesthetic activity can be demonstrated. The Panel has insufficient evidence to classify glycol salicylate as a counterirritant.

It is claimed that glycol salicylate exerts its effect topically to relieve pain in muscles and structures beneath the skin by acting as an anti-inflammatory agent, as do other salicylates. Glycol salicylate does not act as a counterirritant in the dosage form described below. Salicylate blood levels have been demonstrated after topical application in animals, but these have not been correlated with those occurring after oral ingestion of salicylate analgesics. Excretion of salicylates or metabolites has been demonstrated in the urine, but this is not proof of effectiveness. Claims are made that localized areas of myalgia and other painful musculo-skeletal disorders are relieved by the application of esters of salicylic acid to the affected part. The Panel concludes from available data that this action, if indeed analgesia results, is due to a systemic effect, and any analgesic effect is due to the blood-borne drug.

No evidence that relief of pain is due to a counterirritating effect of the drug has been submitted from controlled studies. It is employed at concentrations of 1.9, 1.93, and 10 percent in combination products. In these combinations, counterirritants are included in the formulation. Data from controlled studies demonstrating the analgesic effect claimed has not been available.

The exact mechanism by which salicylates produce their analgesic effects is not known, but it is generally conceded that they act in part centrally, and in part by exerting an anti-inflammatory effect peripherally, as does aspirin, by inhibiting prostaglandin synthesis. (See part III. paragraph B.3.a. above—Aspirin.) It is possible that the salicylate activity of glycol salicylate may also be due to an inhibitory effect on prostaglandin synthesis. There is no evidence that cutaneous analgesia or anesthesia results.

The Panel does not give serious consideration to the claim that glycol salicylate penetrates the skin and passes directly into the affected deeper structures to exert its analgesic effect. Although 8 to 10 percent concentrations of glycol monosalicylate have been used clinically, there is insufficient evidence on the effectiveness of such concentrations.

(3) *Proposed dosage—For adults and children 2 years of age and older:* Apply an 8 to 10 percent concentration of glycol salicylate to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1 above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for OTC external analgesics. (See part III. paragraph C. below—Data Required for Evaluation.)

References

(1) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 583, 1976.

h. *Hexylresorcinol.* The Panel concludes that hexylresorcinol is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetics, and antipruritics.

Hexylresorcinol, an aromatic alcohol, is a dihydroxybenzene with a normal hexyl group on position 4 and hydroxyl groups on positions 1 and 3 of the aromatic nucleus. It is, therefore, classifiable as a phenol. It responds to certain specific chemical tests characteristic of phenols. Hexylresorcinol is prepared by condensing resorcinol with caproic acid in the presence of zinc chloride. The resulting intermediate product is reduced to hexylresorcinol (Refs. 1, 2, and 3).

Hexylresorcinol is a white or yellowish-white powder composed of needle-shaped crystals. It has a faint "fatty" odor and a sharp astringent taste. When placed on the tongue, the ingredient produces a sensation of numbness. Hexylresorcinol melts at between 62° and 67° C. It turns from a white to a brownish-pink tint on exposure to light and air due to oxidation to quinones. One g of hexylresorcinol dissolves in

approximately 2,000 mL of water. It is freely soluble in alcohol, methanol, glycerine, ether, chloroform, benzene, and vegetable oils. For many years hexylresorcinol was considered official and was included in the "United States Pharmacopeia."

(1) *Safety.* Clincial use has confirmed that hexylresorcinol is safe in the dosage range used as an OTC external analgesic.

Because hexylresorcinol was extensively used as an anthelmintic and adminstered orally in both adults and children, the Panel considers it to be safe for topical application to the skin (Ref. 4). The usual adult dose as an anthelmintic is 1 g as a single dose in a 24-hour period. For children, the usual dose is 0.1 g for each year of age up to 10 years. The drug is usually given orally after an overnight fast. The presence of food lessens the effectiveness of the drug. A saline purge is usually given the following morning to clear the bowel of dead worms. Treatment may be repeated after 3 days (Ref. 1). Hexylresorcinol has also been shown to have some antimicrobial effects. The drug has been used as a gargle and as a urinary antiseptic. Experiments by Leonard (Ref. 5) resulted in the use of hexylresorcinol as a urinary antiseptic. He found that hexylresorcinol at pH 6 to 6.4 in a 1:60,000 concentration killed microbes in the urine in 1 hour, and that at pH 7.6 to 8.2, a concentration of 1:18,000 was required for the same effect. Robbins (Ref. 6) observed that after oral administration of hexylresorcinol to man, 18 percent was eliminated in the urine in a conjugated form, and 64 percent was eliminated in the feces in an uncombined state.

Animal studies indicate a low degree of acute and chronic toxicity. In rats, the oral minimum lethal dose of a suspension is 50 mg/kg. A suspension in 5 percent olive oil solution administered subcutaneously resulted in a minimum lethal dose of 750 to 1,000 mg/kg. A similar low degree of toxicity was found in guinea pigs, rabbits, cats, and dogs. In dogs, doses of 1 to 3 g produced no signs of toxicity. When the dogs were sacrificed, mild irritation of the stomach was noted 4 to 5 hours after ingestion of the drug. Lesions in the mucosa were superficial. If the animals were sacrificed 48 hours later, the lesions were not present. Oral administration in rats revealed no signs of toxicity when a dose of 12 mg/kg was given 6 times over an 8-hour period and was well tolerated (Ref. 7).

Pure hexylresorcinol is irritating to the respiratory tract and to the skin. A concentrated solution of hexylresorcinol in alcohol has vesicant properties. It lacks the irritancy and caustic properties of resorcinol and phenol. Use over a period of 40 years and extensive marketing experience indicate that hexylresorcinol possesses a low degree of sensitization.

(2) *Effectiveness.* The Panel finds that hexylresorcinol has been used as an analgesic, anesthetic, and antipruritic on the skin to relieve pain due to sunburn. In one study (Ref. 7) 100 adults participated. Their ages ranged from 14 to 74 years. Fifty subjects were treated with another agent. All 50 subjects treated with 0.1 percent hexylresorcinol obtained relief from pain and discomfort due to sunburn. No other clinical studies are available for the use of hexylresorcinol on the skin. However, hexylresorcinol is a phenol, and the substitution of an aliphatic radical on the side chain of this phenol attenuates the caustic activity but allows the retention of its phenolic qualities, which include analgesic, anesthetic, and antipruritic activity. Therefore, it is the Panel's opinion that hexylresorcinol does have analgesic properties.

In the cornea of rabbits, hexylresorcinol solution, 0.1 percent, produces topical anesthesia lasting various periods of time up to 10 minutes or more depending on the concentration of the hexylresorcinol. Hexylresorcinol has been incorporated in lozenges for the relief of sore throat and other painful ailments of the oral cavity.

Adriani and DiLeo (Ref. 8) found that the application of a commercial preparation consisting of a 1:1000 solution produced analgesia on the gums and at the tip of the tongue, after stimulation by an electric current, but did not completely abolish sensation. With the exception of this study, the Panel has not received other reports of controlled studies on the analgesic effect of hexylresorcinol on the intact or damaged skin.

The ingredient has been recommended as an antimicrobial agent for cuts, wounds, and burns, but judgment of its effectiveness for these conditions does not come under this Panel's purview.

The range between the minimum effective dosage and the maximum allowable dosage as an external analgesic on the skin has not been established with certainty. The Panel questions the dosage recommended in the labeling of products on the market, which is that the ingredient be used full strength (0.1 percent) or diluted with an equal part of water. Therefore the Panel recommends that the effectiveness of this dosage range be adequately tested. (See part III. paragraph C. below—Data Required for Evaluation.)

(3) *Proposed dosage—For adults and children 2 years of age and older:* Apply a 0.05 to 0.1 percent concentration of hexylresorcinol to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for OTC external analgesics. (See part III. paragraph C. below—Data Required for Evaluation.)

References

(1) Osol, A. and R. Pratt, " The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 582–583, 1973.

(2) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 618, 1976.

(3) Osol, A. and G. E. Farrar, "The Dispensatory of the United States," 25th Ed., J. B. Lippincott Co., Philadelphia, pp. 1691–1692, 1955.

(4) Brown, E. A., W. Krabek, and R. Skiffington, "A New Antiseptic Solution for Topical Application (Comparative In Vitro Studies)," *New England Journal of Medicine,* 234:468–472, 1946.

(5) Leonard, V., "Secretion of Bactericidal Urine and Disinfection of Urinary Tract Following Oral Administration of Certain Alkyl Derivatives and Resorcinol," *Journal of the American Medical Association,* 83:2005–2012, 1924.

(6) Robbins, B. H., "Quantitative Studies on the Absorption and Excretion of Certain Resorcinols and Cresols in Dogs and Man," *Journal of Pharmacology,* 52:54–60, 1934.

(7) OTC Volume 060138.

(8) Adriani, J. and J. DiLeo, "The Effectiveness of Hexylresorcinol as a Topical Analgesic on the Mucous Membranes of the Oral Cavity," Draft of unpublished paper, in OTC Volume 060150.

i. *Salicylamide.* The Panel concludes that salicylamide is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetics, and antipruritics.

Salicylamide, the amide of salicylic acid, is 2-hydroxybenzamide. It is a white, crystalline, almost odorless powder. It is poorly soluble in water. One g dissolves in 500 mL water, 15 mL alcohol, 100 mL chloroform, and approximately 35 mL ether (Refs. 1 and 2).

(1) *Safety.* Clinical use has confirmed that salicylamide is safe in the dosage range used as an OTC external analgesic.

Although salicylamide is the amide of salicylic acid and is generally discussed along with the salicylates as an analgesic, it is not converted to free salicylates in the body when the ingredient is ingested orally (Ref. 1). It is rapidly conjugated with glucuronic and sulfuric acids by enzymes in the mucosal wall of the intestines and the liver. The conjugates are excreted into the urine. Patients sensitive to aspirin apparently are not sensitive to salicylamide, because it is not converted to salicylic acid or any of its salts or esters. Its use topically is safe and it causes no irritation to the skin (Ref. 3).

Spickard (Ref. 3) reported no evidence of irritancy after application of a preparation containing 5 percent salicylamide and 1 percent benzocaine dissolved in isopropyl alcohol and polyoxyethylene lauryl ether to 237 subjects. Three drops were applied to the forearm every other day. Readings for any evidence of rash or irritation were made 24 hours after each application. After a series of 10 applications and a rest period of 10 days, a single repeat application was made and the effects of this application were noted 24 hours later. Seven subjects reacted with itching and redness after the first or subsequent applications. After the 10-day rest period, only two individuals reacted. The two individuals would be considered to have shown an allergic reaction according to the Draize method.

Salicylamide is used orally as an analgesic; however, there is some question concerning its safety after oral ingestion. The oral lethal dose of salicylamide in man has not been established. A minimum of 1,000 mg administered orally every 4 hours must be used to obtain analgesia, but not more than 6,000 mg should be used in 24 hours. This dosage must not be used for more than 10 days (see the report of tthe Advisory Review Panel on OTC Internal Analgesic and Antirheumatic Products, published in the **Federal Register** of July 8, 1977 (42 FR 35346)). Higher oral doses of salicylamide may produce drowsiness, dizziness, and gastrointestinal upset (Ref. 1). Another toxic manifestation in analgesic dosages is hepatic insufficiency in children. Damage to blood-forming elements following chronic use is sufficiently serious to warrant additional study. Whether sufficient quantities are absorbed through the skin to produce these effects is not known, but none of these adverse reactions has been brought to the attention of the Panel. Salicylamide, in contrast to aspirin and other salicylates, has no effect on the clotting mechanism or platelet aggregation and does not affect bleeding time or clotting time. Allergic reactions to salicylamide are rare. Cross-sensitivity to aspirin does not occur.

(2) *Effectiveness.* Salicylamide or its metabolites can be detected in the urine when the drug is applied topically to the skin (Ref. 3). A submission to the Panel contained the following statement: "The determination of blood levels in rabbits and of the urinary excretion in humans and in rabbits of benzocaine and salicylamide had established that the active ingredients are absorbed through the intact skin. However, these experiments did not permit any direct conclusion concerning the possible penetration of these drugs into the muscle tissues." The Panel agrees with these statements in the submission. The following statement is also found in the submission: "By inference, such a penetration is indicated by the relief of pain following topical application." The Panel does not agree with this statement, however (Ref. 3).

Studies carried out in six rats revealed the presence of salicylamide in muscle tissue. The Panel does not disagree that percutaneously absorbed drugs can be detected in tissue, because such drugs pass into the systemic circulation and are redistributed to various organs and tissues. However, the mere presence of the drugs in tissues does not necessarily mean that their effect is based there, unless the tissue concentration approaches that found in the plasma when these drugs are given orally and cause their effects. No data derived from controlled studies in man have been submitted to substantiate claims of pain relef in muscles and other structures beneath the skin. Evidence of pain relief in a double-blind, crossover type of study would be helpful in making a judgment.

Letters from users of the marketed preparation describing the relief of muscular aches and pains were submitted as evidence of muscular aches and pains were submitted as evidence of the effects claimed in the labeling (Ref. 3). The Panel regards these reports as anecdotal and considers them to be testimonials not based on facts. Factual data to substantiate the claims made in the labeling have not been submitted.

When ingested orally, salicylamide is almost completely metabolized to pharmacologically inactive substances during its passage from the gastrointestinal tract to the liver, before it is even absorbed into the systemic circulation to become available at the therapeutic site of action. This initial absorption before it becomes therapeutically effective in sufficient concentrations in the systemic circulation is sometimes referred to as the absorptive phase. In this absorptive phase, the salicylamide is metabolized by conjugation with glucuronic acid and sulfuric acid. The conjugates are excreted into the urine. The biotransformation at low oral doses is so extensive that little, if any, active unmetabolized drug is available for absorption into the systemic circulation for distribution to the sites of therapeutic action (see 42 FR 35346, July 8, 1977) (Ref. 4).

Because the drug is poorly water soluble, the Panel feels the amount available for absorption via the skin is limited. The bioavailability through the skin, therefore, is questionable. Evaluations of analgesic potency of salicylamide in animals indicate that a wide range of effectiveness exists and that there is considerable disparity between the results of different observers when the drug is compared to aspirin. In man, however, salicylamide has been shown to have little, if any, superiority over aspirin. Oral doses below 600 mg are not effective and the analgesic effects are indistinguishable from the placebo. For two reasons the Panel doubts that quantities absorbed through the skin are effective, even when blood-borne. First, the substance is metabolized quickly, and second, its efficacy is questionable because the effect of 600 mg orally is indistinguishable from placebo. It is doubtful that 600 mg is absorbed by local application to the skin. Furthermore, salicylamide has no anti-inflammatory activity (see 42 FR 35346, July 8, 1977).

The Panel has had no evidence submitted to it that salicylamide possesses topical anesthetic activity and blocks neuronal membranes as do the topical anesthetics of the "caine" type, such as benzocaine, tetracaine, lidocaine, etc. There is no evidence that salicylamide possesses topical analgesic, anesthetic, or antipruritic activity for the relief of cutaneous disorders (Ref. 3).

There is no disagreement that some degree of percutaneous absorption of salicylic acid derivatives occurs through the intact skin (Ref. 5). Blood levels of salicylates have been demonstrated in animals. Claims are made that pain and discomfort resulting from myalgia and other musculoskeletal disorders are relieved by the application of

preparations containing derivatives whose effect is systemic and that any analgesic effect is due to the blood-borne drug. The Panel does not consider the quantity that would be absorbed by percutaneous routes to be sufficient to induce analgesia systemically as is the case with oral preparations. The exact mechanism by which derivatives of salicyclic acid produce their analgesic action is not known, but it is generally conceded that they act not only centrally but also in part by exerting an anti-inflammatory effect. Not all derivatives of salicylic acid exert anti-inflammatory effects. Salicylamide does not have an anti-inflammatory effect. Therefore the Panel does not give serious consideration to the claim that the drug penetrates the skin and passes directly into the affected deeper structures to exert an analgesic effect (see 42 FR 35346, July 8, 1977).

Salicylamide has been used in a concentration of 35 percent with benzocaine.

(3) *Proposed dosage—For adult and children 2 years of age and older:* Apply a 3 to 10 percent concentration of salicylamide to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for external analgesics. (See part III. paragraph C. below—Data Required for Evaluation.)

References

(1) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, p. 1033, 1973.

(2) Windholz, M., "The Merck Index," 9th Ed., Merck and Co., Rahway, NJ, p. 1079, 1976.

(3) OTC Volume 060119.

(4) Goodman, L. S. and A. Gilman, "The Pharmacological Basis of Therapeutics," 5th Ed., Macmillan Publishing Co., Inc., New York, p. 348, 1975.

(5) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co. Philadelphia, p. 1035, 1973.

j. *Thymol.* The Panel concludes that thymol is safe but there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetics, and antipruritics.

Thymol, also known as thyme camphor, is 5-methyl-2-isopropyl-1-phenol. It may be prepared synthetically or obtained from volatile oils distilled from *Thymus volgaris* and other related plant sources. Thymol occurs as colorless crystals, which are often large, or as a white crystalline powder. It melts at 51° C and boils at 233° C. One g dissolves in 1 liter water. It is highly soluble in alcohol, chloroform, and in mineral oil and other fixed and volatile oils (Ref. 1). It has a characteristic aromatic thyme-like odor and a pungent taste. Thymol has appreciable volatility in water vapor when it is prepared in aqueous solutions.

(1) *Safety.* Clinical use has confirmed that thymol is safe in the dosage range used as an OTC external analgesic.

Thymol has a pleasant aromatic odor. In the past, it has found its way into a wide variety of medicinal uses but has in many cases been superseded by other newer and more effective drugs. It has been incorporated into mouthwashes for its antiseptic action and has been used topically and orally for the treatment of actinomycosis. It has also been used internally as an intestinal antiseptic and anthelmintic, especially against hookworm (Refs. 2 and 3).

The LD_{50} in mice was found to be 74 mg/kg when thymol was injected intravenously (Ref. 4). Jenner (Ref. 5) studied the acute oral toxicity of thymol by intubation in the rat and guinea pig. The LD_{50} for the rat was found to be 980 mg/kg, and for the guinea pig, 880 mg/kg.

Chronic toxicity was observed in five male and four female rats given an oral dose of 10,000 parts per million for 19 weeks. No untoward effects were found (Ref. 6).

Ingestion of 1 g thymol usually does not cause any adverse symptoms other than a feeling of warmth generated in the stomach. Doses larger than 1 g have resulted in gastrointestinal irritation marked by dizziness, excitement, and severe epigastric pain, followed by vomiting, nausea, marked weakness, sweating, collapse, and slowed pulse and respiration. Abortion has also resulted (Ref. 3).

Worm infestations have been treated in the past with thymol, especially in the Far East. A report by Barnes noted that over a million doses of thymol averaging 1 g per dose resulted in reported deaths of 20 debilitated patients (Ref. 7).

Samitz and Shmunes noted that dentists and other allied personnel found thymol one of the less frequent sensitizers in occupational dermatoses (Ref. 8). Thymol irritates the mucous membranes, but has little effect when applied topically to the skin and is virtually unabsorbed (Ref. 3). The oral toxicity of thymol is about one-fourth that of phenol; if absorbed, half is metabolized totally, and the remainder is conjugated with sulfuric and glucuronic acids and excreted into the urine (Ref. 3).

(2) *Effectiveness.* Thymol was first introduced as a disinfectant. It has a phenol coefficient of 27.6, but its activity is greatly reduced in the presence of proteins. It also has some antiviral activity (Ref. 9). Potter, in 1891 (Ref. 10), stated that thymol was a topical anesthetic for use on the skin and mucous membranes. Buckley (Ref. 11) also noted that thymol had topical analgesic properties and considered it superior to phenol as an antiseptic.

Thymol has been referred to another Panel for the determination of its safety and efficacy as an antimicrobial and antifungal agent.

The Panel concedes it is possible that thymol is a topical analgesic, anesthetic, and antipruritic because of its phenolic nature, but the Panel does not have sufficient evidence and documentation to support this claim. Most of the literature refers to the antimicrobial and antifungal effects of thymol. Although 1 to 2 percent concentrations of thymol have been used clinically for topical analgesia and anesthesia, there is insufficient evidence of the effectiveness of such concentrations.

(3) *Proposed dosage—For adults and children 2 years of age and older:* Apply a 1 to 2 percent concentration of thymol to affected area not more than 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for OTC external analgesics. (See part III. paragraph C. below—Data Required for Evaluation.)

References

(1) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 1189–1190, 1973.

(2) Osol, A., "Remington's Pharmaceutical Sciences," 15th Ed., Mack Publishing Co., Easton, PA, p. 1101, 1975.

(3) Sollmann, T., "A Manual of Pharmacology and Its Application to Therapeutics and Toxicology," 8th Ed., W. B. Saunders Co., Philadelphia, pp. 227–228, 1957.

(4) Edwards, E. H. and B. Hall, "Thymol as a Bacteriostatic Agent," *The Pharmaceutical Journal*, 166:54, 1951.

(5) Jenner, P. M., E. C. Hagan, J. M. Taylor, E. L. Cook, and O. G. Fitzhugh, "Food Flavorings and Compounds of Related Structure I. Acute Oral Toxicity," *Food and Cosmetics Toxicology*, 2:327–343, 1964.

(6) Hagan, E. C., W. H. Hansen, O. G. Fitzhugh, P. M. Jenner, W. I. Jones, J. M. Taylor, E. L. Long, A. A. Nelson, and J. B. Brouwer, "Food Flavorings and Compounds of Related Structure. II. Subacute and Chronic Toxicity," *Food and Cosmetics Toxicology*, 5:141–157, 1967.

(7) Barnes, M. E., "Death Following the Administration of Thymol," *Journal of the American Medical Association*, 79:964–965, 1922.

(8) Samitz, M. H. And E. Shmunes, "Occupational Dermatoses in Dentists and Allied Personnel," *Cutis*, 5:180–184, 1964.

(9) Dunham, W. B. and W. J. MacNeal, "Culture on the Chick Chorioallantosis as a Test of Inactivation of Coccinea Virus," *Journal of Bacteriology*, 44:413–424, 1942.

(10) Potter, S., "Handbook of Materia Medica Pharmacology and Therapeutics," 3d Ed., Blakiston Press, Philadelphia, p. 389, 1891.

(11) Buckley, J. P., "Modern Dental Materia Medica Pharmacology and Therapeutics," 5th Ed., W. B. Saunders Co., Philadelphia, pp. 48, 50, and 515, 1926.

k. *Triethanolamine salicylate.* The Panel concludes that triethanolamine salicylate is safe but that there are insufficient data available to permit final classification of its effectiveness for use as an OTC external analgesic. During the testing period provided to demonstrate effectiveness, the ingredient may bear the labeling provided for topical analgesics, anesthetics, and antipruritics.

Triethanolamine salicylate is an ester produced by the interaction of equal amounts of triethanolamine and salicylic acid. Triethanolamine salicylate is a light reddish, viscous liquid with a faint odor and a specific gravity of 1.280 to 1.980. Triethanolamine salicylate is miscible in all proportions with water, glycerine, propylene glycol, isopropyl alcohol, and 95 percent ethyl alcohol. It is insoluble in mineral oil and vegetable oils.

(1) *Safety.* Clinical use has confirmed that triethanolamine salicylate is safe in the dosage range used as an OTC external analgesic.

The oral LD_{50} of triethanolamine salicylate in rats is 2.8 g/kg. Animal and human toxicological data indicate that it is safe for topical application. Its average Draize primary skin irritation index is 1.5. Triethanolamine salicylate is not a topical irritant and has minimal sensitizing potential (Refs. 1, 2, and 3). An intracutaneous sensitization test in 10 guinea pigs over 5 weeks revealed no sensitization reactions on repetitive examinations. Repeated insult patch tests of the lotion formulation, using the Draize human skin irritancy test in 52 women and 5 men gave the following results: After 9 applications to the upper arm in 21 days and a challenge at 35 days, there was revealed a slight erythema at the application sites in 4 individuals. This is presumptive evidence that triethanolamine salicylate is not a sensitizer (Ref. 2).

(2) *Effectiveness.* Triethanolamine salicylate, which penetrates the intact and damaged skin, does not block the neuronal membranes as do the topical anesthetics, such as benzocaine, etc., and therefore possesses no topical anesthetic activity. Some degree of percutaneous absorption of salicylic esters occurs through the intact skin (Refs. 4, 5, and 6), but no significant analgesic or anesthetic activity has been demonstrated. Blood levels have been demonstrated following topical application with various techniques in animals. These blood levels have not been correlated to blood levesl fo salicylate-type analgesic ingredients administered by the oral route. Triethanolamine salicylate is not a counterirritant analgesic salicylate ester.

In the absence of such comparative data, the Panel does not give serious consideration to claims made for the effectiveness of triethanolamine salicylate as an analgesic for muscles aches and pains because it is doubtful that sufficient quantities are absorbed from the skin to be blood-borne. Gaudin (Ref. 7) noted that approximately 15 percent of a topically applied amount of triethanolamine salicylate on rabbit skin appeared in the urine as salicylic acid and that 9.46 percent sodium salicylate was found in the urine by comparison (Ref. 1). The Panel does not disagree that salicylates are absorbed from the skin, but it does not agree that this is proof of effectiveness of these drugs as analgesics on the structures beneath the skin to which they are applied. Excretion of salicylates or metabolites into the urine has been demonstrated (Ref. 1).

Claims have been made the localized areas of myalgai and other painful musculoskeletal disorders are relieved by the application of esters of salicylic acid to the affected part. The Panel concludes from available data that this action most likely is systemic and any analgesic effect is due to the blood-borne drug. The Panel does not believe that evidence has been provided to indicate that sufficient quantities are absorbed to induce analgesia. The exact mechanism by whcih salicylates produce their analgesic effect is not know, but it is generally conceded that they act in part centrally, and in part peripherally, by exerting an anti-inflammatory effect by inhibiting the synthesis of protaglandins. (See part III. paragraph B.3.a. above—Aspirin.)

Some evidence exists that salicylates inhibit the synthesis of prostaglandins and relieve pain in this manner. References cited in the submission for effectiveness of the ingredient refer to salicylates but provide no data concerning triethanolamine salicylate (Refs. 1 and 3). The only proof of efficacy is that salicylates are absorbed percutaneously (Ref. 8).

The Panel does not give serious consideration to the claim that the drug penetrates the skin and passes directly into the affected deeper structures in sufficient concentration to be effective because there is not data to substantiate this claim (Refs. 1 and 3).

Triethanolamine salicylate has been used topically in concentrations of 5 to 10 percent, but there are no data available to substantiate its effectiveness in that dosage range.

(3) *Proposed dosage—For adults and children 2 years of age and older:* Apply a 5 to 10 percent concentration of triethanolamine salicylate to affected area 3 to 4 times daily. For children under 2 years of age, there is no recommended dosage except under the advice and supervision of a physician.

(4) *Labeling.* The Panel recommends the Category I labeling for products containing topical analgesic, anesthetic, and antipruritic active ingredients. (See part III. paragraph B.1. above—Category I Labeling.)

(5) *Evaluation.* Data to demonstrate effectiveness will be required in accordance with the guidelines set forth below for external analgesics. (See part III. paragraph C. below—Data Required for Evaluation.)

References

(1) OTC Volume 060024.

(2) OTC Volume 060091.

(3) OTC Volume 060144.

(4) Osol, A. and R. Pratt, "The Dispensatory of the United States," 27th Ed., J. B. Lippincott Co., Philadelphia, pp. 1034–1035, 1973.

(5) Todd, R. G., "Martindale, The Extra Pharmacopeia," 25th., Ed., The Pharmaceutical Press, London, p. 26, 1967.

(6) Davison, C. and H. G. Mandel, "Nonnarcotic Analgesics and Antipyretics 1: Salicylates," *in* "Drill's Pharmacology in Medicine," 4th Ed., Edited by DiPalma, J. R., McGraw-Hill Book Co., New york, p. 383, 1971.

(7) Gaudin, O., "Amine Salicylate Ointment," U.S. Patent: 2, 596, 674, May 13, 1952.

(8) Plein, J. B. and E. M. Plein, "A Comparison of In Vivo and In Vitro Tests for the Absorption, Penetration, and Diffusion of

Some Medicinals from Silicone and Petrolatum Ointment Bases," *Journal of the American Pharmaceutical Association*, 12:705–717, 1957.

Category III Labeling

The Panel concludes that there are insufficient data available at this time to permit final classification of the following claims:

Claims for relief of deep-seated pain. The Panel finds that there is insufficient evidence that external analgesic ingredients penetrate beneath the skin to relieve deep-seated pain. Claims such as "penetrates deep into the skin and relieves pain arising from deep down inside," "penetrating heat relief," and "deep strength" are unsubstantiated and require further testing. The Panel has classified such claims as Category III.

C. Data Required for Evaluation.

The Panel considers that the protocols recommended in this document for the studies required to bring Category III external analgesic ingredients into Category I reflect the present state of the sciences of pharmacology and toxicology. The protocols do not preclude the use of newer or more refined laboratory or clinical investigative methods to establish safety or effectiveness of an ingredient. Manufacturers are expected to furnish only data relevant to unanswered questions regarding the safety and efficacy of the ingredients in their product. They are not expected to furnish all the data listed in the guidelines below.

Safety studies are required if the data submitted to data have not substantiated claims that an ingredient is safe when applied externally on the intact or damaged skin. Efficacy studies are required if the data submitted to date have not substantiated the claim that an ingredient is effective.

1. *General considerations.* a. Pain is a subjective sensation in response to noxious stimuli. Lack of reactivity when noxious stimuli are applied without production of pain indicates that a state of analgesia has been induced. The appraisal of the analgesic activity of an ingredient or a combination of ingredients must be based upon their ability to relieve pain caused by a disease process or trauma. The pain experience in man consists of perception of painful stimuli, together with the psychologic modification of the response to these stimuli. Animal screening tests and methods using experimentally induced pain in normal human volunteer subjects generally do not yield consistent results nor are the results in humans similar to those obtained in studies of pain of pathologic origin (Ref. 1). The only exceptions the Panel considers applicable are pain due to burns of the skin induced by ultraviolet radiation and pain due to experimentally produced abrasions or excoriations. Skin pain is localized. Experimentally induced pain from ultraviolet light burns is generally the same type as pathologically induced sunburn pain, and pain due to abrasions in volunteers is similar to that caused accidentally by trauma to patients. Objective methods for studying pain in humans, either experimentally produced pain or pathologic pain, are not available. The efficacy of analgesic drugs, both in laboratory and clinical situations, must be appraised by accepting the subject's own reports on indices of pain experiences and the relief obtained by topical administration of external analgesics.

b. Certian general comments pertaining to the preparation of protocols in the evaluation applicable to all external analgesic ingredients considered by the Panel (analgesics, anesthetics, antipruritics, and counterirritants) are discussed below. Comments applicable only to analgesics, anesthetics, and antipruritics and those pertaining only to counterirritants are also considered below in separate discussions.

The Panel concludes it is reasonable to allow 3 years for the development and review of evidence that will permit final classification of the effectiveness of the Category III ingredients aspirin, glycol salicylate, salicylamide, triethanolamine salicylate, and thymol, and for the indication for deep-seated pain. The Panel concludes that it is reasonable to allow 2 years for the development of data for all other Category III conditions. The ingredients pose no serious problem for the consumer. Marketing need not cease during this time if adequate testing is undertaken. If data regarding adequate effectiveness and safety are not obtained within 2 or 3 years as specified, the ingredients shoud no longer be marketed in OTC products.

2. *Procedure for conducting studies on normal volunteer subjects and patient.* Investigational studies of a proper design should be conducted on human volunteers if reproduction of a particular skin condition is feasible (Ref. 2). Examples of experimental designs that may be appropriate include crossover, double-blind, factorial, sequential trial, single-blind trial, and therapeutic equivalency. Preference should be given to a double-blind study with controls, so that it will demonstrate the efficacy of the product. The cross-over technique should be used, if possible. When that technique is used, a period of 12 hours or more should be allowed to eliminate all of an absorbed drug from the system. If the identity of an ingredient cannot be masked when a double-blind study is performed, and if a suitable placebo is not available, control and treatment periods should be of sufficient duration to allow subjects to serve as their own control. The number of subjects used in such a study should be sufficient to permit statistical analysis of the data obtained (Ref. 2). The number tested should be sufficient to eliminate examiner bias, bias due to placebo effect, and the effects of psychological responses to pain in tested subjects. The subjects should be of both sexes and within the age groups for which use of the product is intended. The subjects should be healthy and free from any ailment and should not be receiving any oral, parenteral, or topical medication. Female subjects should not be pregnant. The study should be of sufficient duration to demonstrate efficacy. The treatments should be selected on a random basis. The number and frequency of the applications of the preparation should be the same as would be the case for clinical use. Any manifestation of local or systemic irritancy, sensitivity, or toxicity in these tests should be recorded.

When studies are performed in clinical situations, a large number of appropriate subjects with different types of pain should be studied. Differentiation of patients should be made in accordance with the type of pain, i.e., pain due to inflammation, burns, or that arising in joints, muscle, etc. The randomization procedure should be made so that variables not otherwise controlled balance out.

There should be detailed explanation of the criteria for assessment of the condition to be treated by the ingredient, of the method employed in testing, and of the validity of the method or methods used. A medical history, demographic data, and physical data including physical examination, laboratory studies, and other pertinent data should be obtained and recorded for each subject.

Studies should be performed on patients who have lesions, pain, burns, etc. Subjects who have similar kinds of conditions and are being treated with a preparation should be divided into a treated group and a "placebo" group to obtain a controlled study. Again, "before treatment" data should be obtained and recorded. The degree of relief of symptoms, the onset of action,

whether partial or complete, the duration of action, and the presence or absence of any rebound after the analgesic effect wears off should be noted. A grading or scoring technique should be used to determine degree of relief. The application of the medicament should be in accordance with the method outlined below and the indication for use on the labeling. The tests should be performed using the final product formulation.

The range between the minimum effective concentrations and the maximal allowable (safe) concentration should be supplied when lacking. This may be expressed as a percent concentration of the preparation. Consideration should be given to how the drug is absorbed or penetrates the skin, its duration of action, and its relationship to the length of time it remains on the skin. In cases where claims are made that a drug penetrates the skin and passes directly into deeper structures such as muscles and joints and causes relief of pain, such direct penetration and pain relief must be shown to occur. The mere fact that the drug is absorbed and is detectable in the blood, or is excreted into the urine in its pure form or as metabolites, will not be sufficient evidence of efficacy.

An attempt should be made to determine the possible mechanism of action or actions of the drug.

3. *Interpretation of data.* Records should be detailed and should include legends, with specific explanation of codes, doses, mode and time of application, the period of latency from the moment of application to the development of the desired therapeutic effect, the frequency of testing, and the duration of test period. Investigative methods should be described in detail so that the experiments can be repeated to verify and confirm results obtained by the investigator (Ref. 2).

Provision should be made to eliminate examiner bias in either volunteer or clinical trials. Proper interpretation and explanation of the results should be provided. Whenever possible, statistical analysis should be employed to evaluate the results. Consideration should be given to the placebo effect of a drug.

Evidence of drug effectiveness is required from a minumum of two positive studies based on the results of two different investigators or laboratories.

All data submitted to the Food and Drug Administration must present both favorable and any unfavorable results.

4. *Safety evaluation.* Adequate, acceptable controlled in vivo studies of acute and chronic toxicity in several species of animals should be supplied. The oral LD_{50} in animals should be established. The range of the toxic dose in humans should be made available if possible, because individuals, especially children, may accidentally ingest or inhale overdoses of these medications (Ref. 2). If the ingredient has been classified Category III for safety reasons, studies on chronic toxicity should be performed by two independent investigators over a 3-month period.

Tests should be performed for acute eye irritancy, primary skin irritancy, corrosivity, acute dermal toxicity, and subacuter dermal toxicity in animals (rabbits). Tests for topical irritancy and topical and systemic sensitivity in man should be performed if such data are not available. Acceptable methods for testing for irritancy and sensitivity are described by Kligman and by Shelanski and Shelanski (Refs. 3 and 4).

Data on systemic absorption, distribution, metabolic fate, half-life, rate of excretion, and possible cumulative effects should be supplied wherever indicated in the ingredient statements discussed elsewhere in this document. (See part III. paragraph B.3. above—Category III active ingredient.)

a. *Recommended toxicological studies.* The Panel used data on "complaints per unit sold" submitted by the various companies as one of the criteria for evaluating human safety of ingredients and combination products. However, anecdotal descriptions of toxicity were not given serious consideration.

A variety of toxicological methods may be used to obtain data substantitating that a preparation is safe manufacturers are expected to conduct studies using the first five methods listed below. Methods 6 through 8 may be used to augment and confirm data obtained using methods 1 through 5. The Panel recognizes that better testing methods may be developed in the future. The requirements listed below will not preclude use of such methods in the event that they become available.

b. *Preclinical animal studies.*

(1) Acute oral LD_{50} toxicity in rats.

(2) Acute eye irritation in rabbits.

(3) Primary skin irritation and corrosivity in rabbits.

(4) Acute dermal toxicity in rabbits.

(5) Phototoxicity and photosensitization studies.

(6) Acute toxicity of inhaled aerosols and sprays in rats.

(7) Subacute dermal (21-day) toxicity in rabbits.

(8) Skin sensitization in rabbits or other suitable test animals.

c. *Safety studies in man.* A number of patch test methods have proven valuable in predicting skin irritancy and sensitization. These involve the use of occlusive dressings impregnated with the drug applied at various time intervals to selected sites in the subject's skin, allowing rest periods for possible sensitization to develop. Responses occurring within several days are indicative of irritancy. These areas are then challenged with the test drug after rest periods to determine whether sensitization has occurred. The Panel recommends the use of one of the following methods:

(1) The Draize human skin irritancy and sensitization tests and its various modifications utilizing the subject's back or arm may be used (Ref. 5).

(2) The method of Shelanski and Shelanski (Ref. 4) is one in which the active ingredient or formulation is applied regularly to the test site for 3 to 4 weeks. Then, following a rest period of 2 weeks, there is a single challenge application of the drug or formulation (Ref. 4). The early applications are to detect primary skin irritants and initiate sensitization in susceptible persons. The challenge dose is to detect skin sensitizers.

(3) The maximization procedure of Kligman or its modifications uses an irritant on the test site, therby hastening and accentuating the skin-sensitizing potential of a substance (Ref. 3).

The effectiveness of certain ingredients can be correlated with the degree of percutaneous absorption, which may also be correlated with systemic and local toxicity. Studies on penetration of drugs through the skin of animals unfortunately cannot be extrapolated to man. Some drugs are absorbed in excessive quantities if applied to large surface areas of the body. The degree of absorption or penetration may be determined by studying blood levels and measuring the total quantity excreted. Inferences of safety may be based on the observed drug levels and their correlation with toxicity studies.

The Panel considers certain in vitro studies applicable for establishing criteria for safety and effectiveness. The method of Fritsch and Stoughton is an example of an in vetro method in which excised human skin is used for studies on penetration (Ref. 6). Studies utilizing the friction blister, suction blister, sunburn blister, blister caused by freezing skin with liquid nitrogen, dermatome specimens, and excised skin are acceptable. Drug penetration through a blister top may be determined by analyzing the blister fluid. In addition, the top of the blister may be excised and analyzed quantitatively for

the drug to determine the degree of absorption into the skin layers.

Topical anesthetics, topical analgesics and topical antipruritics, once through the epithelial barrier, pass into the tissue fluids beneath, into the venules and lymphatics and are distributed to various tissues, particularly those that are capillary rich. Some esters of topical anesthetics, such as tetracaine, are hydrolyzed by plasma esterases into the alcohol and acid from which they were formed, and are thereby inactivated. The amide type of topical anesthetic is not altered by esterases but ultimately passes from the blood and tissues to the liver, where it undergoes biodegradation (detoxification). The byproducts are eliminated into the urine. Topical anesthetics that are not hydrolyzed by plasma esterases or easily detoxified by the liver, such as dibucaine or cocaine, are eliminated unchanged by the kidney. Alcohol-type topical anesthetics are not affected by the plasma esterases. They are detoxified by the liver through various types of chemical reactions, such as oxidation, reduction, conjugation, or transfer reactions. Unmetabolized portions are excreted into the urine.

Solvents and other substances used to formulate a finished product that penetrates the barriers are detoxified in the same manner as the active ingredients. It is possible for highly lipophilic substances that are used daily for long periods of time to accumulate in the adipose and other lipid-rich tissues, particularly if they are not readily biodegradable, where they may remain for days, weeks, or months (Refs. 7 and 8). None of the ingredients the panel has evaluated is retained for long periods of time in adipose or lipid-rich tissues. Methods to detect minute quantities of some substances are not available, and in general, no standard procedure to measure skin penetration in humans exists. Animal studies should be performed as a preliminary to human in vivo testing (Ref. 2).

Note.—The above considerations pertain to all external analgesics. The following two sections deal with methods of evaluating analgesics, anesthetics, and antipruritics, on the one hand, and counterirritants, on the other.

5. *Evaluation of analgesics, anesthetics, and antipruritics.* Anesthetics, analgesics, and antipruritics produce their effects by depressing cutaneous sensory receptors or by the removal of noxious stimuli that induce pain. Corroborating data for many ingredients and preparations evaluated by the Panel can be obtained by inducing pain experimentally in normal volunteers. Methods for inducing experimental pain are described below, as are methods for measuring the intensity of pain. Some of these methods are suitable for determining effectiveness of analgesic ingredients on both the intact skin and damaged skin. Data obtained using these ingredients to relieve experimentally induced pain are acceptable as corroborating evidence only, but data from clinical studies must be submitted in support of an evaluation. Although the general comments outlined above for preparation of protocols are applicable to this group of ingredients, certain modifications or additional comments are necessary in obtaining data for evaluation of anesthetics, analgesics, and antipruritics.

a. *Mode of application.* The Panel emphasizes that the mode of application of the ingredient under study is an important consideration and should be specified in the evaluation report. Some preparations are merely applied, without rubbing or massaging, in the form of a film on the intact skin or over a lesion where the skin is not intact. Rubbing and massaging may accelerate the absorption as much as 24 to 50 percent (Ref. 9).

The frequency of application should be recorded. Data obtained following a single application cannot be used to substantiate claims made when a preparation is intended for multiple applications.

b. *Studies on the damaged or abraded skin.* The Panel stresses that there is considerable difference between studies performed on intact skin and those performed on skin that has been damaged as a result of injury, trauma, disease, or other causes. When an ingredient is applied to the abraded skin, the avenues of access for an active ingredient to subepidermal structures are open and absorption occurs readily. Contact, therefore, is readily made with the terminal receptors that subserve pain and itch and other sensations. If the agent is of sufficient potency, anesthesia may result.

The minimum effective concentration on the damaged abraded skin is less than it is on the intact skin. The "horny layer" or dermis provides an effective barrier, through which drugs, chemicals, or noxious agents are not able to pentrate unless they are of a lipophilic nature (Refs. 9 and 10). The stratum corneum, the outer horny layer of the epidermis, is made of dead, keratinized cells that have lost their nuclei in the process of keratinization. They maintain their physiologic connection with neighboring cells through bridges called desmosomes. This layer of keratin acts as a barrier and protects humans from the environment (Ref. 9).

The stratum corneum is strongly hydrophilic. The amount of water in this layer depends mostly on the moisture content of the environment and partly on the water supply available from the body itself. This water-holding capacity of keratin confers upon the skin its property of suppleness (Ref. 9). Substances soluble in both water and lipids readily and easily pass through this layer. Damage to, or removal of, the stratum corneum allows practically any molecule, regardless of size, to pass through the skin (Ref. 9). Meaningful data can be obtained by abrading the skin of normal volunteers and studying the effect of topical analgesics, anesthetics, and antipruritics on these areas. The techniques that can be used are described below.

c. *Evaluation of analgesic and antipruritic agents exerting anti-inflammatory effects.* The Panel also recognizes that the methods described below may not be suitable for evaluating the effectiveness of analgesic and anitpruritic drugs that do not block nerve fibers and prevent transmission of nerve impulses, such as the anti-inflammatory agents. The steroids, antihistamines, and other drugs are anti-inflammatory agents that act by reducing edema and alleviating pressure on cutaneous receptors that incite the sensation of pain. The Panel recommends in these instances that studies of these products be performed on patients with edema of the skin and inflammatory conditions using the protocol described above. (See part III. paragraph C.1. above—General considerations.)

d. *Methods of studying salts of bases.* Some active ingredients considered by the Panel are bases but are present in the formulation in the form of a salt, or the media in which they are incorporated are acidic and convert the bases to salts. The salts do not penetrate the intact skin because they are ionized and are not lipophilic (salts of lidocaine, tetracaine, dibucaine, etc.) (Ref. 10). In most instances, these salts have been placed in Category I for use on the damaged, excoriated, or abraded skin because they readily come into contact with the nerve endings in the tissues and are effective for relief of pain and itching on the skin.

It is the opinion of the Panel that these ingredients that are active as bases on the intact skin, but are not active as salts, could be buffered or neutralized and converted to bases. The finished product could be reformulated to contain the concentration of the ingredient that is effective. The salt may

be effective at a higher concentration than is present in the formulation, in which case the concentration may have to be increased to the effective level. In either case, efficacy and safety studies that meet the criteria in the above guidelines should be conducted. The concentration of active ingredients that are present in less than the minimum concentration considered to be effective by the Panel should be increased to the minimum effective concentration in the formulation (Ref. 10).

e. *Techniques of algometry*—(1) *Biologic methods.* Biologic methods have been used in laboratory studies to assess the effectiveness of analgesics. The Panel does not require such studies, but if they are available, they may assist in evaluation of the ingredient. For example, solutions of known concentrations of analgesics have been applied to the skin of the limbs of frogs (Ref. 11). The areas are tested with a physical or chemical stimulus of known intensity, and the motor responses are observed. In one method, a paper disk impregnated with a known concentration and volume of acetic acid is applied to the skin, and the effect upon the withdrawal of the extremity is observed. Other amphibia and reptiles have been immersed in solutions of anesthetic or analgesic agents, and the responses to reflex stimulation have been observed and quantitated. The skin of the frog, however, is vastly different from that of humans and other mammals, both in histologic structure and absorptive capacity. Therefore, these data cannot be extrapolated to humans and are only supportive.

The cornea of the rabbit or guinea pig likewise is often used as a test site for topical anesthetics. The disappearance of the blink reflex in the eye after application of a stumulus of known intensity yields data that are considered to be objective. Tests on the cornea of animals, again, are by themselves not meaningful because the surface of the cornea cannot be likened to human skin. Such data are merely supportive and must be accompanied by data on humans.

(2) *Methods used in humans.* Pain may be superficial or deep. It may be elicited by thermal, mechanical, electrical, or chemical stimuli. The impulses that incite cutaneous pain and itch are carried by the same fibers and can be reproduced by varying the intensity of a stimulus. Therefore, the methods described below are useful for studying both pain and itch.

(i) *Stimulation using radiant heat.* Some investigators have used the Hardy-Woolf-Goodell pain threshold apparatus as a source of painful stimuli (Refs. 12 and 13). The apparatus described in the literature consisted of a calibrated radiometer that provided a thermal stimulus to the skin. The source of energy was a 1,000-watt incandescent lamp, a condensing lens that permits the rays to be focused on the areas to be tested, and a rheostat to vary the intensity of the beam. Test areas approximately 3.5 cm in diameter were blackened with some form of finely pulverized purified carbon, such as carbon black or a suspension of India ink. This insured complete absorption and conversion of the radiant energy to heat and prevented penetration of the rays below the surface of the skin. The effects of pigmentation of the skin were also eliminated. The subject verbally reported what sensation was experienced at the end of a particular interval of time. Usually a 3-second exposure with a standard beam intensity was necessary to evoke a sensation of pricking, pain, itching, or burning and was considered to be the least perceptible stimulus, and therefore, the pain threshold.

In using this method, results are best obtained by approaching the pain threshold by using two or three subminimal stimuli. Thus, overstimulation of a test area is avoided. Such overstimulation may cause subsequent hypalgesia (decrease in the sensation of pain), which could alter the absorption of the agents being tested due to injury of the skin, even though the skin remains intact. The blackened areas are coated with the preparations to be studied , including one which contains only the medium used for incorporating the active ingredients. This, therefore, serves as a control. The subjects should be unaware of the composition of preparations applied to a particular area. Sensations of warmth or coolness, if they are caused by one of the ingredients, may prevent the test from being completely blind because they may stimulate sensory receptors other than those of pain. The subject is, therefore, able to identify the preparation on reapplication or retesting and to distinguish it from other preparations and the control. Blind studies may be performed only if neither the subject nor the individual interpreting the responses to the stimuli knows the nature of the preparation that has been applied over the test area. The material may be applied by a third person who knows its identity or it may be coded so that no one knows its identity. The code is broken after the tests are complete. Thus, such an experiment can be considered blind, particularly if none of the ingredients evokes sensations other than analgesic or antipruritic. Enough data should be obtained for statistical analysis.

The objection to this technique is that the thermal stimulus may elicit a response from receptors subserving warmth, rather than those subserving pain and itch. Furthermore, the application of carbon black and the heat from the radiant energy may change the water content of the skin, and thereby alter its absorptive capacity during the experiments.

(ii) *Method using pricking as a stimulus.* Monash (Ref. 14) devised several topical analgesic testing methods that permit the continuous application of a test solution. The testing was done by pricking with a sharp instrument. A ball of absorbent cotton approximately 1 cm in diameter soaked with the desired solution was placed on the skin and covered with waxed paper or cellophane and then fixed in place with adhesive plaster. thirty minutes later the cotton was removed and the area pricked with a sharp instrument to determine whether anesthesia was present. If not present, the cotton was then again soaked with the solution and reapplied. The testing was performed at 15-minute intervals. When anesthesia was complete, the patch was removed and the duration of anesthesia determined by subsequent testing at 15- to 30-minute intervals.

The chief objection to this technique is that the agents are not ordinarily applied to the skin in this manner. Furthermore, it is difficult to quantitate the intensity of the stimulus by merely pricking the surface, unless the study is designed to observe only the anesthetic effect, and not the analgesic effect, of a preparation. The method tests for anesthesia, partial or complete blockade, or hypalgesia, but does not test for analgesia in cases where relief of burning or itching is obtained without the patient experiencing numbness. Pricking does not evoke a sensation of itch, because itch is evoked by subminimal stimulus while the nerve endings still remain partially active and are able to perceive pain. However, this method is useful in determining whether percutaneous absorption of topical anesthetic bases and salts occurs.

(iii) *Electrical stimulation.* Electric currents have been used to evoke the sensation of pain and itching on the skin. Hardy et al. (Ref. 12) note that the first recorded use was that by Macht et al. in 1916, who applied faradic current to the scrubbed skin of the dorsum of the hand and determined the increase in the pain threshold after the application of cocaine and certain opium alkaloids.

Dalili and Adriani (Refs. 10 and 15) have recently devised a method utilizing a pulsatile alternating current delivered from a Grass 44 Model stimulator that selectively activates the receptors in the cutaneous nerves that subserve pain and itch. A subminimal stimulus evokes a sensation of itching and burning (Ref. 16). Increasing the intensity of the stimulus induces pain. Further increases cause the current to penetrate the subcutaneous structures and stimulate the motor fibers, producing muscle contraction, twitching, and cramping. A pulsatile current consisting of sine waves of 30 cycles per second of 5 milliseconds duration with 2-millisecond periods of silence between impulses is used. Repeated stimulation reproduces a sensation of itching and pricking without apparent injury to the cutaneous structures. A pinpoint metal tip is necessary as the exploring electrode. The type of electrode used is important because current density becomes a factor. The minimal quantity of current that, when localized over a small area of pinpoint size, is effective in causing a stimulus fails to evoke a response when applied over a wider area. From 25 to 40 volts are generally necessary to deliver the required amperage. This is due to the variation of the resistance of the skin in different subjects. The resistance of the skin varies from subject to subject and even in the same subject at different times. The threshold of excitation may be reduced to 0.3 milliampere by pinpointing the contact area with the fine tip of the electrode. The necessary amperage varies from subject to subject, ranging from 1 to 10 milliamperes, but remains constant for each subject and for the same subject in each period of testing.

Adriani and Dalili (Ref. 10), as well as the investigators using the thermal stimulation technique described above, selected the volar surface of the forearm as the test site. An indifferent electrode is fixed to the dorsum of the forearm over gauze soaked in saline. Control values are established at multiple points over the test site, which measures from 5 to 7.5 cm^2. The preparation under investigation is applied for 30 minutes. Areas 1 x 1 cm are wiped dry at 15-minute intervals and stimulated for 1- to 2-second intervals until itching is perceived. Generally 1 hour elapses before the entire area is wiped and tested. A single application for 60 minutes established the clinical usefulness of a preparation. At is the case with other workers, test sites coated with a placebo are used as controls. One possible objection to this method is that a stimulus greater than is necessary to cause itch may be applied, causing tingling, which may be misinterpreted by some subjects.

Adriani and Dalili (Ref. 10) produced ultraviolet light burns using a GE Model 1F2 lamp held 60 cm from the volar surface of the forearm for 8 to 18 minutes and tested the effectiveness of various agents in relieving the discomfort. Patients not complaining of itching and burning after developing erythema and not experiencing hypersensitivity to touch were excluded from study. Obviously, data obtained in such a study are subjective because reliance must be placed upon the patient's interpretation of the degree of the degree of relief obtained. A xenon lamp may be used to provide radiation of known and fixed wavelengths, as would be the case in evaluating sunscreens, but is not necessary. Thus, studies could be simultaneously performed on both the injured intact skin and the intact skin. Efficacy is determined subjectively by questioning the subject on the degree of the relief of the ensuing discomfort. Responses to electrical stimulation are graded 0 if no relief of discomfort resulted, 1+ if a partial block is obtained, or 2+ if no itching or burning occurs from the electrical stimulation. Painful tingling or vibratory sensations result if the current is increased beyond the control value or if the intensity of the current is increased when a blockade is obtained. These workers also noted that in some cases subjects complained that an aggravation of discomfort resulted after application of the preparation. This increase in discomfort has been termed "antianalgesia." Tests of such a response were recorded and coded as E. In addition, the subject's evaluation of the relief of discomfort on the injured skin was graded as 0 if no relief of symptoms resulted, 1+ if the relief was partial, and 2+ if there was complete relief of itching, pricking, and burning (Ref. 15).

(iv) *Using intradermal wheals as test sites.* Adriani and Dalili (Refs. 10 and 15) also infiltrated successive strata of the epidermis with 0.01 to 0.02 mL of a soluble topical anesthetic with the 30-gauge needle of a tuberculin syringe. Stimulation over the treated area with the electric current no longer caused itching and burning. Increasing the amperage and voltage elicited vibratory and tingling sensations, indicating that the current acted on receptors of different types. The nerves in the deeper layers of the skin and muscle apparently were not blocked and were stimulated.

Data in which studies have been performed using an intradermal wheal are of no value in support of a submission that makes claims for therapeutic effectiveness of a particular ingredient when applied topically to the intact skin. An ingredient applied in this manner is introduced beneath the stratum corneum into the stratum germinativum, where it is readily bioavailable and comes into contact with the nerve endings in the skin and produces anesthesia. Some investigators have used such data to support claims for effectiveness of topically applied preparations. The area over the wheal is not responsive to pricking or other forms of stimulation because complete anesthesia ensues.

(v) *Additional methods for inducing experimental pain.* It has been indicated above that induced pain differs from pathologic pain due to trauma or disease (Ref. 14). Tests of the effectiveness of analgesics in the laboratory using experimentally induced pain may not coincide with the results obtained when pain is of pathologic origin. Fortunately, the situation is different as far as the skin is concerned, because pain of pathologic origin can be produced by thermal injury or by abrading the skin.

Burning with ultraviolet light has been described above in the section on electrical stimulation. Adriani and Dalili (Ref. 10) used a template which has six openings to permit specific areas to be exposed to ultraviolet radiation to cause a burn on the forearm. This results in six areas for use as test sites. At least five ingredients and a placebo may be used simultaneously. If both arms are used, this permits the testing of 10 preparations, or a cross-over technique, if so desired.

Although many techniques are available for producing abraisons and disrupting the skin for investigational purposes, the most popular, the least traumatic, and most commonly used method is that in which sticky tape is used for excoriation of the skin. The tape is applied over the desired area and removed 10 to 15 times in succession. In the process, the epidermis is disrupted and the stratum corneum is removed, thereby breaking the integrity of the epitherlial barrier. Burning sensations can be elicited by application of dilute alcohol or citric or acetic acid solutions to the abraded area, after which the analgesic is applied.

Another method that has been used for causing very fine abraisons of the skin is to apply cowhage (itch powder) to an area of the skin. Cowhage is derived from a tropical woody vine covered with barbed hairs that, when applied to the skin, cause intense itching. Tests using cowhage are valid if the experiment is designed to test the

effectiveness of a preparation on the damaged skin, but not on the intact skin. The fact that the agents are absorbed easily following such treatment and exert a topical anesthetic or hypalgesic effect must be recognized. They are not acting through intact skin.

(vi) *Abrading the skin.* Vigorous scrubbing with a brush may also be used as a method of abrading the skin. Abrasions may be obtained by rubbing the skin with a fine grade of sandpaper or other abrasive material. These techniques are not only less acceptable to volunteers than stripping, but are also less controllable.

Application of an ingredient that is only analgesic on the intact skin may produce total anesthesia on the damaged or abraded skin (Ref. 12). This can be easily tested by pinpricking, radiant heat, electric current, or application of chemicals that cause stinging but no injury. In some cases the agent is not sufficiently potent, and partial anesthesia or, more accurately, hypalgesia is obtained. Testing on abraded skin is considerably less subjective than methods for resting the effects of drugs on the intact skin.

(3) *Selection of test sites.* The thickness of the skin is an important consideration in conducting investigations of topical anesthetics and analgesics. Thickness of all layers varies from one are of the body to another. The epidermis, particularly the stratum corneum, is thickest in the soles and the palms (Ref. 9). Penetration and absorption are poorest at these sites because the outer, horny keratin layer is dense in these areas and the stratum lucidum, which is thin in other areas of the body, is well defined beneath the stratum corneum. In most cases, investigators have used the volar surface of the forearm as the most convenient site for testing. This area is most amenable for the quantiation of the degree of analegsia and anesthesia. The thickness of skin in the volar surface appears to be less than it is in most areas of the body (Ref. 9). And because the number of hair follicles and sebaceous glands in this area is sparse compared with other areas of the body, any absorption or penetration that occurs via the hair follicles and other appendages in the skin is reduced. Most investigators doubt that the therapeutic effects obtained from these ingredients are due to absorption along the hair follicles and from the sebaceous glands. Ample evidence exists that absorption occurs directly through the stratum corneum (Ref. 9).

The selection of the test site area is important because the number of terminal nerve endings per cm^2 of skin varies from one area of the body to another. Meaningful data may not be obtained if an area of low pain sensitivity is selected.

Mucocutaneous junctions as test sites:. Studies performed at test sites utilizing mucocutaneous junctions are not acceptable for obtaining data on the skin alone because preparations that are readily absorbed and effective on the mucous membranes are not necessarily absorbed and effective on the skin. Data obtained by applying analgesics and anesthetics at the lips, nares, anorectal areas, and the female genitalia are not suitable except in instances whre the product is intended to be applied to these areas (Refs. 10 and 15).

(4) *Use of other or new techniques.* The Panel recognize that there is a dearth of methods for determining the analgesic effects on the skin and that other methods may be developed in the future. The determination of the degree of penetration of a radioactive ingredient into the skin has been suggested as one possible technique. However, the fact that a drug penetrates the skin does not necessarily mean that it is effective as a topical analgesic. It is doubtful that this technique will yield data of value. Systemically administered drugs that produce itching could be used but are not practical at this time. Morphine exerts such an effect. Morphine, however, is not the agent of choice, nor does it produce itching in all subjects to whom it is given. Morphine apparently acts peripherally to reduce the threshold for itch, even though centrally it elevates the threshold for pain. The analgesic effect may counterbalance the pruritic effect, and no sensation of itch may result. Methods utilizing pressure or ischemia are suitable for evaluating deep pain but not cutaneous pain. Although other methods and techniques are available for use in evaluating pain, they are too detailed to discuss in this document.

6. *Evaluation of counterirritants and claims for deep-seated pain.* a. *Introduction.* The methods described above are intended to evaluate anesthetics, antipruritics, and drugs that produce analgesia by depressing cutaneous sensory receptors, and are not applicable in evaluating the effectiveness of analgesics that stimulate cutaneous sensory receptors and exert their effects by counterirritation. The Panel recogizes that methods are not available for experimentally inducing pain of the type relieved by counterirritants. Investigators cannot rely upon normal subjects to obtain data to evaluate effectiveness. The Panel, therefore, recommends that studies be performed on patients with pathologic pain with well-defined discomfort involving the musculo-sketetal system, such as arthritis, tendonitis, bursitis, myositis (traumatic or otherwise), neuritis, strains, sprains, related syndromes, or deep-seated skin. The general comments on the selection and treatment of subjects for study, the evaluation of data, the establishment of dose-effect relationships, labeling, etc. are also applicable to drugs acting by counterirritations. Studies on patients are to be conducted as described below.

If possible, studies should be double-blind. Patients who have similar types of disorders should be randomly selected for treatment, divided into two groups, and the groups compared. One group is treated with the drug being tested and another group with the vehicle alone, suitably controlled. The disease process for which the testing is done should have the same etiology. For example, when tests are performed on patients with arthritis, all patients should have the same type of arthritis, i.e., rheumatoid, osteoarthritis, etc. The cross-over technique may be used when the condition under study is chronic and only temporary symptomatic relief is obtained by application of the medicament. The cross-over technique is not suitable in subjects who experience partial improvement of symptoms after application of a medicament or in self-limiting conditions. A minimum of 25 subjects should be tested with the drug and 25 with the suitable vehicle for each type of syndrome by two independent investigators in single sequence methodology. In cross-over studies, 25 subjects altogther are sufficient. The effects could be evaluated on at least two types of painful disorders, e.g., arthritis, bursitis, myositis, tendonitis, and traumatic injuries. The mode of application of the drug must be specified and should be uniform in a particular clinical trial. The data on testing should include application frequency, as specified in the labeling, for not less than a 48-hour period. A washout period of at least 12 hours should be used in cross-over studies (Ref. 2).

b. *Methods of evaluation.* The following subjective and objective methods of evaluation are available to determine the effectiveness of analgesics that act by counterirritation:

(1) *Evaluation of the effects on pain.* Certain musculoskeletal disorders are accompanied by inflamation that causes swelling, tenderness, and redness, as well as pain. A description of the type of pain relief should be recorded and the degree of relief based upon an

applicable scoring system, as for example, 0 = none, 1 = slight, 2 = moderate, and 3 = complete. The scores should be evaluated statistically and values compared with those obtained from treatment with a placebo vehicle control. The Panel recognizes that the inflammatory process may not recede, but the preparation may cause varying degrees of pain relief and such data is acceptable (Refs. 13 and 17).

The presence of erythema and its intensity, and the appearance of edema (indurated, pitting, or soft) may be parameters that could be objectively evaluated and correlated with the degree of relief of pain and changes mentioned above.

(2) *Effects on range of motion of joints.* The range of motion in degrees should be determined using a protractor or other device acceptable for mensuration of angles. Pretreatment values should be established for both active and passive movement and changes in the degree of extension, flexion, adduction, or abduction of a limb. This data should be accompanied by a description of the type and intensity of pain and degree of pain relief during each maneuver before and after treatment. The degree of pain should be rated on an acceptable scoring system as described above.

Measurements of the effect of the medication on motion should be made at sufficiently frequent intervals to determine the onset of analgesic effect, duration, degree of pain relief, and time of return of syptoms. Measurements should be objectively made. The technique of measurement should be consistent throughout the study and made by the same observer throughout a trail period. The Panel recognize that counterirritant analgesics are not curative and may cause no improvement in mobility of the joints or limbs but may still relieve pain and provide comfort as long as there is no attempt to move a limb or an extremely. Subjective data on pain relief are acceptable. The Panel also recognizes that although motion may not be restricted, pain will be elicited when a muscle or joint is activated voluntarily or moved passively, and that a topically applied medication may relieve such pain on movement of an extremity or a limb. In these instances, subjective data will be accepted by the Panel.

(3) *Effects of pressure or palpation on musculoskeletal pain.* Pain can be induced by using an inflatable cuff that exerts pressure on a metal or plastic plate over the affected area. The pressure in the cuff is measured by a manometer. The amount of pressure necessary to inflate the cuff to elicit pain is an indicator of the relief obtained. The degree of pain should be based upon subjective response conceptions (Ref. 18). Pretreatment readings are established, and the variations in pressure noted at necessary intervals established by the observer. Pressure induced by adding a series of weights or applying pressure with a loaded spring could also be used.

(4) *Relief of muscle spasm.* Hypertonus or muscle spasm accompanies musculoskeletal disorders to protect an affected part by splinting. Changes in muscle tone may be detected by use of the electromyograph. Pretreatment electromyographic values followed by measurements at appropriate time intervals may be instituted to determine the relief of spasm. If such studies are undertaken, these should be correlated with the degree of range of motion and the subjective evaluation of degree of pain relief mentioned above (Refs. 19 and 20).

(5) *Measurement of skin temperatures.* Topical analgesics which stimulate cutaneous receptors, send impulses into central receptors that excite centers that control the caliber of the blood vessels and reflexly cause vasodilation. An increase in blood flow results over the area of application of the medicament and in the vessels in the skin area subserved by the spinal segment receiving these cutaneous impulses. An increase in skin temperature results, which can be detected by using a thermocouple, thermistor, or other device that detects changes in skin temperature. An increase in skin temperature is not proof of efficacy but does provide confirmatory evidence with other data obtained and the subjective responses of the patient that a drug is exerting a pharmacologic effect.

(6) *Blood plasma levels.* Certain analgesics with counterirritant effects may be absorbed percutaneously and disseminated to the tissues, where they may exert an anti-inflammatory effect that is presumed to produce analgesia. Other effects may be produced. The Panel could accept data to support effectiveness of an ingredient as a topical analgesic if the action is systemic and not topical in the skin.

Method (1) or (2) or (3) discussed above is mandatory and must be used in the evaluation of the effectiveness of an ingredient. Methods (4), (5), or (6) are optional methods that may be used in support of the results obtained from any one of the above tests.

7. *Summary outline of required testing.* The following outline summarizes the tests required to reclassify a Category III active ingredient to Category I status:

a. *Studies required to demonstrate safety.* The following studies are required to reclassify external analgesic active ingredients classified as Category III for safety considerations:

(1) *Preclinical studies.* The required preclinical studies have been discussed in detail elsewhere in this document. (See part III. paragraph C.4.a. above—Recommended toxicological studies.)

(i) Animal toxicity studies.

(ii) Skin irritancy, dermal toxicity, and phototoxicity and photosensitization studies in animals.

(2) *Clinical studies.* Irritancy and sensitization studies in humans, utilizing the patch tests, are required.

b. *Studies required to demonstrate effectiveness.* (1) The following clinical studies are required to reclassify all topical analgesic, anesthetic, and antipruritic active ingredients classified as Category III for effectiveness:

(i) When possible, one double-blind study on a minimum of 25 normal human subjects (volunteers) demonstrating topical analgesic effects of the final formulated product using one or more of the algesimetric methods discussed above. The test sites should be those areas of the skin known to be richly endowed with terminal painperceiving nerve endings.

(ii) When possible, one double-blind study on a minimum of 25 subjects with pathologic cutaneous lesions that cause pain, burning, or itch. The dose-response relationship should be established indicating the range between the minimum effective dose and the maximum safe dose. Where applicable, a comparison between the effects on the intact skin and the effects on damaged skin should be included in the study. The study should be done using the final formulated product and a placebo.

(iii) Where using the studies described above is not applicable, as with active ingredients that act by exerting an anti-inflammatory effect, when possible, double-blind studies should be done in a minimum of 25 subjects with edema or inflammatory disturbances of the skin that are as similar as possible and are at approximately the identical test site in all subjects. The studies should be done using the final formulated product and a suitable vehicle. The dose-response relationship should be established indicating the range between the minimum effective dose and the maximum safe dose. Where applicable, a comparison between the effects on the intact skin and the effects on damaged skin should be included in the study.

(2) The following clinical studies are required to reclassify all topical

counterirritant active ingredients classified as Category III for effectiveness: When possible, double-blind studies on a minimum of 25 subjects using the ingredient and a suitable vehicle for a control for 2 different types of painful disorders and evaluation with methods (1), (2), or (3) described above. Tests should be performed by two independent investigators for each of the painful disorders studied.

References

(1) Beecher, H. K., "Measurement of Subjective Responses: Quantitative Effects of Drugs," Oxford University Press, New York, 1959.

(2) Modell, W., H. Schild, and A. Wilson, "Applied Pharmacology," W. B. Saunders Co., Philadelphia, pp. 21–47, 1976.

(3) Kligman, A. M., "The Identification of Contact Allergens by Human Assay III. The Maximization Test: A Procedure for Screening and Rating Contact Sensitizers," *Journal of Investigative Dermatology*, 47:393–409, 1966.

(4) Shelanski, H. A. and M. V. Shelanski, "A New Technique of Human Patch Tests," *in* "Proceedings of Scientific Section of the Toilet Goods Association," 19:46–49, 1953.

(5) Draize, J. H., "Appraisal of Safety of Chemicals in Foods, Drugs and Cosmetics," The Association of Food and Drug Officials of the United States, Texas State Department of Health, Austin, Texas, pp. 46–59, 1959.

(6) Fritsch, W. C. and R. B. Stoughton, "The Effect of Temperature and Humidity on the Penetration of C^{14} Acetylsalicylic Acid in Excised Human Skin," *Journal of Investigative Dermatology*, 41:307–310, 1963.

(7) Modell, W. H., Schild, and A. Wilson, "Applied Pharmacology," W. B. Saunders Co., Philadelphia, pp. 41–44, 145–154, 1976.

(8) Adriani, J. and M. Naraghi, "Pharmacologic Basis of Regional Pain Relief," *Annual Review of Pharmacology and Toxicology*, 17:223–242, 1977.

(9) Criep, L. H., "Dermatologic Allergy," W. B. Saunders Co., Philadelphia, pp. 3–30, 1967.

(10) Adriani, J. and H. Dalili, "Penetration of Local Anesthetics through Epithelial Barriers," *Anesthesia and Analgesia*, 50:834–841, 1971.

(11) Regnier, J., R. Quevauriller, and L. Fornault, "Measurement of the Activity of Anesthetics by the Frog Skin Method," *Anesthesia and Analgesia*, 5:555–557, 1939.

(12) Hardy, J. D., H. G. Wolff, and H. Goodell, "Studies on Pain. A New Method for Measuring Pain Threshold: Observations on Spatial Summation of Pain," *Journal of Clinical Investigation*, 19:649–658, 1940.

(13) Wolff, H. G. and S. Wolf, "Pain," Charles C. Thomas Publishing Co., Springfield, IL, pp. 3–10, 1958.

(14) Monash, S., "Topical Anesthesia of the Unbroken Skin," *Archives of Dermatology*, 76:752–756, 1957.

(15) Dalili, H. and J. Adriani, "The Efficacy of Local Anesthetics in Blocking the Sensations of Itching, Burning, and Pain in Normal and 'Sunburned' Skin," *Clinical Pharmacology and Therapeutics*, 12:913–919, 1971.

(16) Graham, D. T., H. Goodell, and H. G. Wolff, "Itch Sensation in the Skin: Experimental Observations of the Neural Mechanisms Involved," *in* "Proceedings of the Association for Research in Nervous and Mental Disease," The Williams and Wilkins Co., Baltimore, 1950.

(17) Kolodny, A. L. and P. McCloughin, "Comprehensive Approach to Therapy of Pain," Charles C. Thomas Publishing Co., Springfield, IL, pp. 27–33, 1966.

(18) Beecher, H. R., "The Powerful Placebo," *Journal of the American Medical Association*, 159:602, 1955.

(19) White, J. R. and J. M. Sage, "Effects of a Counterirritant on Muscular Distress in Patients with Arthritis," *Physical Therapy*, 51:36–42, 1971.

(20) White, J. R. and J. M. Sage, "Topical Analgesic on Induced Muscular Pain," *Physical Therapy*, 50:166–172, 1970.

The Food and Drug Administration has determined that this document does not contain an agency action covered by 21 CFR 25.1(b) and consideration by the agency of the need for preparing an environmental impact statement is not required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371)), and the Administrative Procedure Act (secs. 4, 5, and 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 554, 702, 703, 704)), and under authority delegated to the Commissioner (21 CFR 5.1), it is proposed that Subchapter D of Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 348, to read as follows:

PART 348—EXTERNAL ANALGESIC PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.
348.1 Scope.
348.3 Definitions.

Subpart B—Active Ingredients

348.10 External analgesic active ingredients.
348.20 Combinations of external analgesic active ingredients.

Subpart C—[Reserved]

Subpart D—Labeling

348.50 Labeling of external analgesic products.

Authority: Secs. 201, 502, 505, 701, 52 Stat. 1040–1042 as amended, 1050–1053 as amended, 1055–1056 as amended by 70 Stat. 919 and 72 Stat. 948 (21 U.S.C. 321, 352, 355, 371); (5 U.S.C. 553, 554, 702, 703, 704).

Subpart A—General Provisions

§ 348.1 Scope.

An over-the-counter external analgesic product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions on this Part 348 and each of the general conditions established in § 330.1 of this chapter.

§ 348.3 Definitions.

(a) *Age.* Infant (under 2 years of age), child (2 to under 12 years of age), and adult (12 years of age and over).

(b) *Cutaneous sensory receptor.* A sense organ that is connected to the terminal fibers of a network of nerves in the skin for the perception of pain, itching, cold, warmth, touch, and pressure.

(c) *External analgesic.* A topically applied drug that has a topical analgesic, anesthetic, or antipruritic effect by depressing cutaneous sensory receptors, or that has a topical counterirritant effect by stimulating cutaneous sensory receptors.

(d) *Topical analgesic.* An externally (topically) applied drug that, by depressing cutaneous sensory receptors, relieves pain without necessarily abolishing other sensations, or that causes partial blockades of subcutaneous terminal nerve endings so that a minimal stimulus evokes no painful response, but a greater stimulus does.

(e) *Topical anesthetic.* An externally (topically) applied drug that completely blocks pain receptors, resulting in a sensation of numbness and an abolition of responses to painful stimuli by depressing cutaneous sensory receptors.

(f) *Topical antipruritic.* An externally (topically) applied drug that relieves itching by depressing cutaneous sensory receptors.

(g) *Topical counterirritant.* An externally (topically) applied drug that causes irritation or mild inflammation of the skin for the purpose of relieving pain in muscles, joints, or viscera distal to the site of application by stimulating cutaneous sensory receptors.

Subpart B—Active Ingredients

§ 348.10 External analgesic active ingredients.

The external analgesic active ingredients of the product consist of the ingredients identified below, within the concentrations established.

(a) *External analgesic active ingredients that stimulate cutaneous sensory receptors (counterirritants).*

(1) Allyl isothiocyanate 0.5 to 5.0 percent.

(2) Ammonia water, stronger 1.0 to 2.5 percent.

(3) Camphor exceeding 3.0 percent up to 11 percent.

(4) Capsaicin 0.025 to 0.25 percent (or the equivalent amount of capsaicin in capsicum or capsicum oleoresin).
(5) Histamine dihydrochloride 0.025 to 0.10 percent.
(6) Menthol exceeding 1.25 percent up to 16 percent.
(7) Methyl nicotinate 0.25 to 1.0 percent.
(8) Methyl salicylate 10 to 60 percent.
(9) Turpentine oil 6 to 50 percent.

(b) *External analgesic active ingredients that depress cutaneous sensory receptors (analgesics, anesthetics, and antipruritics.*
(1) Benzocaine 5 to 20 percent.
(2) Benzyl alcohol 10 to 33 percent.
(3) Butamben picrate 1 percent.
(4) Camphor 0.1 to 3.0 percent.
(5) Dibucaine 0.25 to 1.0 percent.
(6) Dibucaine hydrochloride 0.25 to 1.0 percent.
(7) Dimethisoquin hydrochloride 0.3 to 0.5 percent.
(8) Diphenhydramine hydrochloride 1 to 2 percent.
(9) Dyclonine hydrochloride 0.5 to 1.0 percent.
(10) Hydrocortisone preparations (hydrocortisone, hydrocortisone acetate) 0.25 to 0.5 percent.
(11) Juniper tar 1 to 5 percent.
(12) Lidocaine 0.5 to 4 percent.
(13) Lidocaine hydrochloride 0.5 to 4 percent.
(14) Menthol 0.1 to 1.0 percent.
(15) Methapyrilene hydrochloride 1 to 2 percent.
(16) Phenol 0.5 to 2.0 percent.
(17) Phenolate sodium 0.5 to 2.0 percent.
(18) Pramoxine hydrochloride 0.5 to 1.0 percent.
(19) Resorcinol 0.5 to 3.0 percent.
(20) Tetracaine 1 to 2 percent.
(21) Tetracaine hydrochloride 1 to 2 percent.
(22) Tripelennamine hydrochloride 0.5 to 2.0 percent.

§ 348.20 Combinations of external analgesic active ingredients.

(a) *Combinations of external analgesic active ingredients that stimulate cutaneous sensory receptors (counterirritants).* (1) The active ingredients of the combination product consist of no more than one active ingredient from each of any two, three, or four of the following groups of counterirritant active ingredients when used within the concentrations identified in § 348.10(a):
(i) Allyl isothiocyanate, ammonia water, methyl salicylate, or turpentine oil.
(ii) Camphor or menthol.
(iii) Histamine dihydrochloride or methyl nicotinate.
(iv) Capsaicin, capsicum, or capsicum oleoresin.
(2) The active ingredients of the combination product consist of no more than one active ingredient from each of any one, two, or three of the counterirritant groups identified in paragraph (a)(1) (i), (iii), or (iv) of this section, and camphor and menthol when used within the topical concentration limits identified in § 348.10(a).

(b) *Combinations of external analgesic active ingredients that depress cutaneous sensory receptors (analgesics, anesthetics, and antipruritics).* (1) The active ingredients of the combination product consist of no more than one single active ingredient from each of the following two groups of analgesic, anesthetic, and antipruritic active ingredients within the concentrations identified in § 348.10(b):
(i) Benzocaine, butamben picrate, dibucaine, dibucaine hydrochloride, dimethisoquin hydrochloride, dyclonine hydrochloride, lidocaine, lidocaine hydrochloride, pramoxine hydrochloride, tetracaine, or tetracaine hydrochloride.
(ii) Benzyl alcohol, camphor, juniper tar, menthol, phenol, resorcinol, phenolate sodium, or thymol.
(2) The active ingredients of the combination product consist of any single active ingredient identified in paragraph (b)(1)(ii) of this section, and any single active ingredient in the following group of analgesic, anesthetic, and antipruritic active ingredients: diphenhydramine hydrochloride, methapyrilene hydrochloride, or tripelennamine hydrochloride.
(3) The active ingredients of the combination product consist of any single active ingredient identified in paragraph (b)(1)(ii) of this section, and camphor and menthol.

(c) *Combinations of external analgesic active ingredients with other externally applied active ingredients.* (1) The active ingredients of the combination product consist of any single active ingredient identified in either paragraph (b)(1)(i), (b)(1)(ii), or (b)(2) of this section, or any combination identified in paragraph (b) of this section, and any generally recognized safe and effective skin protectant active ingredient or skin protectant combination of ingredients, provided the product is labeled for the concurrent symptoms involved, e.g., "For the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasion, insect bites, and minor skin irritations, and for the temporary protection and lubrication of minor skin irritations."
(2) The active ingredients of the combination product consist of any single active ingredient identified in either (b)(1)(i), (b)(1)(ii), or (b)(2) of this section, or any combination identified in paragraph (b) of this section, and any generally recognized safe and effective topical antimicrobial active ingredient or topical antimicrobial combination, provided the product is labeled for the concurrent symptoms involved, e.g., "For the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bits, and minor skin irritations, and for protection against wound contamination."

Subpart C—[Reserved]

Subpart D—Labeling

§ 348.50 Labeling of external analgesic products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug(s) identified under § 348.10 and identifies the product as follows:
(1) For products containing any external analgesic active ingredients identified in § 348.10 other than hydrocortisone preparations (hydrocortisone, hydrocortisone acetate) identified in § 348.11(b)(10): the labeling identifies the product as an "external analgesic."
(2) For products containing external analgesic products active ingredients identified in § 348.10(b)(10): the labeling identifies the product as an "antipruritic."

(b) *Indications.* The labeling of the product contains a statement of the indications under the heading "Indication(s)" that is limited to the following phrases:
(1) For products containing any external analgesic active ingredients identified in § 348.10(a): "For the temporary relief of minor aches and pains of muscles and joints, such as simple backache, lumbago, arthritis, neuralgia, strains, bruises, and sprains."
(2) For products containing any external analgesic active ingredients identified in § 348.10(b) other than hydrocortisone preparations (hydrocortisone, hydrocortisone acetate) identified in § 348.10(b)(10): "For the temporary relief of pain and itching due to minor burns, sunburn, minor cuts, abrasions, insect bites, and minor skin irritations."
(3) For products containing external analgesic active ingredients identified in § 348.10(b)(10): "For the temporary relief of minor skin irritations, itching, and rashes due to eczema, dermatitis, insect bites, poison ivy, poison oak, poison

sumac, soaps, detergents, cosmetics, and jewelry, and for itchy genital and anal areas."

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) For products containing any external analgesic active ingredient identified in § 348.10(a) and (b):

(i) "For external use only."

(ii) "Avoid contact with the eyes."

(iii) "If condition worsens, or if symptoms persist for more than 7 days, discontinue use of this product and consult a physician."

(iv) "Do not use on children under 2 years of age except under the advice and supervision of a physician."

(2) For products containing any external analgesic active ingredient identified in § 348.10(a):

(i) "Do not apply to wounds or damaged skin."

(ii) "Do not bandage."

(3) For products containing butamben picrate identified in § 348.10(b)(3):

(i) "Do not use over extensive areas of the body."

(ii) "This product stains the skin and tissues, clothing, and other objects yellow."

(4) For products containing any external analgesic active ingredient identified in § 348.10(b)(5), (6), (12), (13), (20), and (21): "Do not use in large quantities, particularly over raw surfaces or blistered areas."

(5) For products containing phenol identified in § 348.10(b) (16): "Do not apply this product to extensive areas of the body or under compresses or bandages."

(6) For products containing resorcinol identified in § 348.10 (b) (18): "Do not apply this product to large areas of the body."

(d) *Directions for use.* The labeling of the product contains the following statement under the heading "Directions": *For adults and children 2 years of age and older:* Apply to affected area not more than 3 to 4 times daily. For children under 2 years of age there is no recommended dosage except under the advice and supervision of a physician.

Interested persons are invited to submit their comments in writing (preferably in quadruplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this proposal on or before March 6, 1980. Such comments should be addressed to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be accompanied by a supporting memorandum or brief. Comments replying to comments may also be submitted on or before April 3, 1980. Comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: November 19, 1979.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 79–36583 Filed 12–3–79; 8:45 am]

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federal register

Tuesday
December 4, 1979

Part III

Department of the Interior

Bureau of Land Management

Land Withdrawal Procedures

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Parts 2090, 2300, 2310, 2320, 2340 and 2350

Land Withdrawals; Amendment to Withdrawal Procedures

AGENCY: Bureau of Land Management, Interior

ACTION: Proposed rulemaking.

SUMMARY: This proposed rulemaking sets out the procedures by which the Secretary of the Interior will process withdrawal applications and make, modify or extend Federal land withdrawals. This proposed rulemaking would implement the authority of the Secretary of the Interior derived from various statutes, but principally from section 204 of the Federal Land Policy and Management Act of 1976, to entertain withdrawal related applications and to make, modify or extend Federal land withdrawals. It is also intended to implement the authority of the Secretary of the Interior to process certain military defense withdrawal applications under the Act of February 28, 1958.

DATE: Comments by March 3, 1980.

ADDRESS: Comments are to be sent to: Director (650), Bureau of Land Management, 1800 C Street NW., Washington, D.C. 20240.

Comments will be available for public review in Room 5555 of the above address during regular working hours (7:45 a.m.–4:15 p.m.) Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Keith Corrigall, (202) 343–8693 or Robert C. Bruce, (202) 343–8735.

SUPPLEMENTARY INFORMATION: The general authority granted the Secretary of the Interior by section 204 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1714) to make, modify, extend or revoke Federal lands withdrawals replaced similar authority that had been granted in a number of withdrawal statutes, nearly all of which were repealed by section 704(a) of the Federal Land Policy and Management Act, (43 U.S.C. 1701). The establishment of new withdrawal authority in the Secretary of the Interior pursuant to section 204 of the Federal Land Policy and Management Act, and the repeal of much of the withdrawal authority that was formerly exercised by the Secretary, has prompted this proposed rulemaking. Except as otherwise noted below, the procedures established by this proposed rulemaking will, when the rulemaking becomes final, govern the exercise by the Secretary of the Interior of the authority vested in the Secretary to process withdrawal applications and, in his discretion, to make, modify or extend Federal land withdrawals. Procedures for emergency withdrawals also are included. Procedures applicable to withdrawals authorized under the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1272(b); 1281), and procedures relating to the Secretary of the Interior's authority to establish Indian reservations or to add lands to the reservations pursuant to special legislation or in accordance with section 7 of the Act of June 18, 1934 (25 U.S.C. 467), as supplemented by section 1 of the Act of May 1, 1936 (25 U.S.C. 473a), are not included in this proposed rulemaking. General procedures relating to withdrawal revocation and to the relinquishment of reserved areas are not included in this proposed rulemaking. There are, however, several provisions that take withdrawal revocations into account. This proposed rulemaking would substantially revise or delete Parts 2300, 2310, 2320, and 2350 of this title. Section 2311.4 of subpart 2311 of this title, relating to leases authorized under the Act of March 3, 1925 (43 U.S.C. 971), and all of Part 2340 of this title, relating to the Federal Power Act of 1920 (16 U.S.C. 818), would be retained without any substantive change. Eventually, the provisions of §2311.4 of this title will be transposed to a new subpart 2915 of this title. Sections 2091.2–4 and 2091.2–5 of this title would be deleted in their entirety. The proposed rulemaking requires the submission by an applicant of a substantial body of information in order to provide the Secretary of the Interior with the facts necessary to make a decision on an application. The land use requirements of section 202 of Federal Land Policy and Management Act (43 U.S.C. 1712), including management decisions for implementaion, would be made applicable to withdrawals in appropriate cases. The proposed rulemaking provides for rejection of an application by the Secretary of the Interior if the estimated costs to be incurred by the Department of the Interior, without reimbursement, of processing an application or developing information required to perfect an application are determined to be unreasonable and excessive in relation to available funds appropriated for processing applications relating to discretionary withdrawal actions.

The principal authors of this proposed rulemaking are Keith Corrigall, Division of Land Resources and Realty, and Robert C. Bruce, Office of Legislation and Regulatory Mangement, Bureau of Land Management.

It is hereby determined that the publication of this document is not a major Federal action significantly affecting the quality of the human environment and that no detailed statement pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)) is required.

The Department of the Interior has determined that this document is not a significant regulatory action requiring the preparation of a regulatory analysis under Executive Order 12044 and 43 CFR Part 14. Under the authority of section 204 of the Federal Land Policy and Mangement Act of 1976 (43 U.S.C. 1714), the Federal Power Act of 1920 (16 U.S.C. 818), the Act of February 28, 1958 (43 U.S.C. 155 et seq.), and Executive order 10355 (17 FR 4831), it is proposed to revise Group 2300, Subchapter B, Chapter II, Title 43 of the Code of Federal Regulations as set forth below:

1. Part 2300 is revised as follows:

PART 2300—LAND WITHDRAWALS

Subpart 2300—Withdrawals, General.

Sec.

2300.0–1 Purpose.
2300.0–3 Authority.
2300.0–5 Definitions.

Subpart 2310—Withdrawals, General—Procedure.

Sec.

2310.1 Applications.
2310.2 Segregative effect of application or Secretarial proposal.
2310.2–1 Termination of segregative effect.
2310.3 Action on requested withdrawal, modification or extension.
2310.3–1 Review of action on an application.
2310.3–2 Compensation for improvements.
2310.3–3 Duration of withdrawals.
2310.3–4 Costs of processing applications.
2310.3–5 Public land orders and notices.
2310.3–6 Transfer of administrative jurisdiction.
2310.4 Extensions.
2310.5 Special action on emergency withdrawals.

Subpart 2320—Federal Energy Regulatory Commission Withdrawals.

Sec.

2320.0–3 Authority.
2320.1 Public lands considered withdrawn or classified for power purposes.
2320.2 General determinations under the Federal Power Act.
2320.3 Petitions for restoration.

Authority.—43 U.S.C. 1201; 43 U.S.C. 1740; Executive Order No. 10355 (17 FR 4831, 4833).

GROUP 2300—WITHDRAWALS

PART 2300—WITHDRAWALS

Subpart 2300—Withdrawals, General

§ 2300.0-1 Purpose.

These regulations set forth procedures for the exercise of the authority vested in the Secretary of the Interior to process Federal land withdrawal applications and, in his discretion, to make, modify or extend Federal land withdrawals. Procedures for emergency withdrawals are also included. The regulations do not apply to withdrawals that are made by the Secretary pursuant to an Act of Congress directing the issuance of an order by the Secretary. Likewise, procedures applicable to withdrawals authorized under the Surface Mining and Reclamation Act of 1977 (30 U.S.C. 1272(b); 1281), and procedures relating to the Secretary of the Interior's authority to establish Indian reservations or to add lands to the reservations pursuant to special legislation or in accordance with section 7 of the Act of June 18, 1934 (25 U.S.C. 467), as supplemented by section 1 of the Act of May 1, 1936 (25 U.S.C. 473a), are not included in these regulations. General procedures relating to processing requirements for withdrawal revocation applications and to the relinquishment of reserved areas are not included in this part.

§ 2300.0-3 Authority.

(a)(1) Section 204 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1714) confers on the Secretary of the Interior general authority to make, modify, extend or revoke withdrawals, but only in accordance with the provisions and limitations of that section. Among other limitations, the Federal Land Policy and Management Act provides that the Secretary does not have authority to:

(i) Make, modify or revoke any withdrawal created by an Act of Congress;

(ii) Make a withdrawal which can be made only by an Act of Congress;

(iii) Modify or revoke any withdrawal creating national monuments under the Act of June 8, 1906 (16 U.S.C. 431–433);

(iv) Modify or revoke any withdrawal which added lands to the National Wildlife Refuge System prior to the date of approval of the act or which thereafter adds lands to that System under the terms of the Federal Land Policy and Management Act.

(2) Executive Order 10355 of May 26, 1952 (17 FR 4831), confers on the Secretary of the Interior all of the delegable authority of the President to make, modify and revoke withdrawals.

(3) The Act of February 28, 1958 (43 U.S.C. 155–157), places on the Secretary of the Interior the responsibility to process withdrawal applications for military defense withdrawals aggregating 5,000 or more acres for any project.

(b) The following statutory references do not afford withdrawal authority but are provided as general background information.

(1) Executive Order 6910 of November 26, 1934, and Executive Order 6964 of February 5, 1935, as modified, withdrew sizable portions of the public lands for classification. These lands and the grazing districts established under the Taylor Grazing Act of 1934, as amended, are subject to the classification and opening procedures of 43 U.S.C. 315f; however, they are not closed to the operation of the mining or mineral leasing laws unless separately withdrawn or classified for retention from disposal under other authority.

(2) Section 202 of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1712), provides for land use planning and management decisions based thereon which may operate to totally eliminate a particular land use, including one or more "principal or major uses," as defined in 43 U.S.C. 1702(1). Withdrawals made pursuant to section 204 of the Federal Land Policy and Management Act may be used in appropriate cases, to carry out management decisions, except that "public lands," as defined in 43 U.S.C. 1702(e), shall be removed from or restored to the operation of the Mining Law of 1872, as amended, or transferred to another department, agency or office only by withdrawal action pursuant to section 204 of the Federal Land Policy and Management Act or other applicable law.

(3) Section 701(c) of the Federal Land Policy and Management Act of 1976 (43 U.S.C. 1701 note), provides that all withdrawals, reservations, classifications and designations in effect on its effective date shall remain in full force and effect until modified under the provisions of the act or other applicable law.

§ 2300.0-5 Definitions.

As used in this part, the term:

(a) "Secretary" means the Secretary of the Interior or a secretarial officer subordinate to the Secretary who has been appointed by the President by and with the advice and consent of the Senate and to whom has been delegated the authority of the Secretary to perform the duties described in this part to be performed by the "Secretary."

(b) "Authorized officer" means any employee of the Bureau of Land Management to whom has been delegated the authority to perform the duties described in this part to be performed by the "authorized officer."

(c) "Act" means the Federal Land Policy and Management Act of 1976 as amended, (43 U.S.C. 1701 et seq.), unless otherwise specified.

(d) "Lands" includes both land and water areas.

(e) "Cultural resources" means those fragile and nonrenewable physical remains of human activity, occupation and endeavors found in districts, sites, structures, burial mounds, petroglyphs, artifacts, objects, ruins, works of art, architecture or natural settings or features which were important to legendary, prehistoric, historic, sacred or other land and resource use events.

(f) "Archeological areas/resources" means sites or areas containing important evidence and/or the physical remains of former but now extinct cultural groups, their skeletons, settlements, implements, artifacts, monuments or inscriptions.

(g) "Areas of critical environmental concern," means areas identified as a result of the inventory required by section 201(a) of the act where special management attention is required (when such areas are developed or used or where no development is required) to protect and prevent irreparable damage to important historic, cultural or scenic values, fish and wildlife resources, or other natural systems or processes or to protect life and safety from natural hazards.

(h) "Withdrawal" means, for the purposes of the act, the withholding of an area of Federal lands from settlement, sale, location or entry under some or all of the general land laws, including the mining laws, for the purpose of limiting activities under those laws in order to maintain other public value in the area or reserving the area for a particular public purpose or program; or transferring jurisdiction over an area of Federal lands, other than "property" governed by the Federal Property and Administrative Services Act (40 U.S.C. 472), as amended, from one department, office or agency to another department, office or agency. Within the meaning of the Act of February 28, 1958 (43 U.S.C. 155–158), "withdrawal or reservation" means "withdrawal, reservation or restriction."

(i) "Department" means a unit of the Executive branch of the Federal Government which is headed by a member of the President's Cabinet.

(j) "Agency" means a unit of the Executive branch of the Federal Government which is not under the jurisdiction of a head of a department.

(k) "Office" means an office or bureau under the administrative and supervisory jurisdiction of the Secretary.

(l) "Applicant" means any Federal department or agency or any office.

(m) "Minerals" means petroleum, natural gas, geothermal, ferrous and nonferrous metals, sand and gravel, precious and semiprecious stone, coal, oil shale, potassium, sodium, phosphates and all other deposits commonly accepted as a mineral resource.

(n) "Costs" include, but are not limited to, the reasonable cost of special studies, environmental assessments, environmental statements and public meetings and/or hearings.

(o) "Legal description" means a formal land description, based on the United States Public Land Survey System, where applicable, or an accurate, professional land survey.

Subpart 2310—Withdrawals, General—Procedure.

§ 2310.1 Applications.

(a) Applications for the making, modification or extension of a withdrawal shall be submitted, in duplicate, for filing in the proper BLM State Office as set forth in § 1821.2–1 of this title, except for emergency withdrawal requests and applications that are classified for national security reasons. Emergency withdrawal requests and applications that are classified for national security reasons shall be submitted, in duplicate, for filing in the Office of the Secretary, Department of the Interior, Washington, D.C. 20240.

(b) Upon submission, emergency withdrawal requests shall contain as much of the information required in paragraph (c) of this section as is practical at that time.

(c) No specific form is required, but the application shall contain, as a minimum, the following information:

(1) The name and address of the applicant;

(2) In the case of a department or agency other than the Department of the Interior or an office thereof, a full statement of the delegation or delegations of authority of the official acting on behalf of the agency or department submitting an application, substantiating that the official is empowered to act on behalf of the head of the agency or department in connection with all matters pertaining to the application and to its submission for filing.

(3) A legal description of the lands involved in the application. If the application is for a withdrawal that will be superimposed upon, or that will supplement, an existing withdrawal, it shall include a legal description of the lands in the original withdrawal and also a legal description of any lands included in the requested withdrawal that are located outside of, or would be withdrawn in addition to the lands in the existing withdrawal. When the Act of February 28, 1958 (43 U.S.C. 155–158), is applicable, location of the area involved shall include a detailed description of the exterior boundaries of the area requested to be withdrawn and of those acquired, State and public lands within the exterior boundaries that are to be excepted from the proposed withdrawal.

(4) The gross area of land, expressed in acreage within the exterior boundaries of the withdrawal sought to be made or extended, and the net acreage of the Federal lands covered by the application. When the Act of February 28, 1958, is applicable, the provisions of section 3(3) of that Act (43 U.S.C. 157(3)), shall be complied with.

(5) The purpose, if any, for which the lands would be reserved and whether the public lands embraced in the application are proposed to be withheld totally or partially from settlement, sale, location or entry under the public land laws.

(6) A clear and detailed statement of the statutory authority for the program or public purpose for which the withdrawal, modification, or extension action is sought, a justification or analysis of the manner in which the lands and resources will be used in implementing the proposed action and statutory program and an explanation of why either a right-of-way under section 507 or a cooperative agreement under section 302(b) of the Act would not adequately provide for the proposed use. If the purpose or purposes of the proposed action are classified for national security reasons, a statement to that effect should be included.

(7) Identification of present users of the land involved, and how the users will be affected by the proposed use.

(8) Where applicable, identification of land areas subject to existing or anticipated contamination, and the types, duration and intensity levels of any such contamination.

(9) The proposed time period for the withdrawal or for extension of an existing withdrawal with a statement in justification thereof. (See § 2310.3–3 of this title.)

(10) Whether the use of water in any State is necessary to fulfill the purposes of the withdrawal, and whether, subject to valid existing rights, the applicant has acquired, or proposes to acquire, rights to the use of said water in conformity with State laws and procedures relating to the control, appropriation, use and distribution of water or whether the applicant proposes that the withdrawal is also intended to withdraw and reserve pursuant to Federal law sufficient unappropriated water to fulfill the purposes of the withdrawal. Water shall be reserved pursuant to Federal law for use in carrying out the purposes of the withdrawal only if specifically so stated in the relevant withdrawal order, as provided in § 2310.3–5 of this title.

(11) An environmental assessment and/or impact statement in compliance with requirements of the National Environmental Policy Act of 1969 (42 U.S.C. 4332 (2)(C)), and the regulations applicable thereto. The following items shall either be included in the assessment or impact statement, as appropriate, or in lieu thereof, shall be submitted separately as part of the application and the application shall be appropriately cross-referenced as to each category of information:

(i) A cultural paleontological/archeological resources analysis prepared by a qualified specialist as determined by the authorized officer.

(ii) An inventory, evaluation and analysis of roadless areas or roadless islands having wilderness characteristics as described in the Wilderness Act of 1964 (16 U.S.C. 1131, et seq.).

(iii) A mineral resource analysis prepared by a qualified mining engineer, engineering geologist or geologist which shall include, but not be limited to, information on: general geology, known mineral deposits, past and present mineral production, mining claims, mineral leases, evaluation of future mineral potential, and present and potential market demands. The qualifications of the engineer, engineering geologist or geologist shall be provided in the analysis.

(iv) A fish and wildlife resources inventory and analysis of the effects of the existing and proposed use on both Federal and State lands.

(v) A rare and endangered plant resources inventory and analysis of the effects of the existing/proposed use on both Federal and State lands.

(vi) An analysis of the economic impact of the proposed withdrawal, modification or extension on individuals, local communities and the Nation.

(vii) Information as to the public participation in the environmental assessment/statement process.

(12) A statement, with specific supporting data, as to:

(i) Whether the lands involved are floodplains or are considered wetlands; and

(ii) Whether the existing and proposed uses would affect such floodplains or wetlands and, if so, in what manner. The statement should indicate whether the proposed action is to be in compliance with the provisions of Executive Orders 11988 and 11990 of May 24, 1977 (42 FR 26951; 26961).

(13) An analysis of the manner in which existing and potential land and resource uses are incompatible with or conflict with the proposed use, together with a statement of the provisions to be made for continuation, alteration or termination of existing land and resource uses, including an economic analysis of such alteration, continuation or termination.

(14) A statement as to whether any suitable alternative sites are available (including comparative costs estimates) for the proposed use or uses, if any, or for uses the proposed withdrawal, modification or extension would displace.

(15) A statement of the consultation which has been or shall be conducted with other Federal departments or agencies; with regional, State and local government bodies; and with individuals and nongovernment groups regarding the proposed withdrawal.

(16) The place where the applicant's records relating to the application can be examined by interested persons.

(d) Prior to final action being taken in connection with any application, the applicant, at the request of the authorized officer, shall prepare with the participation and approval of the Bureau of Land Management and other affected departments, agencies or offices, a plan and implementation program for the use and management of any Bureau of Land Management managed public lands and the related land resources that are involved in the proposed withdrawal. In developing the plan/program, consideration shall be given to the uses needed to implement the statutory program or public purpose for which the withdrawal would be made. Also, consideration shall be given to all resources such as forage, timber, water, recreation, wildlife, minerals, as well as access to and development of mineral deposits in adjacent areas. The plan and the program shall be drawn up in the form of a memorandum of understanding, which shall be referenced in the withdrawal order, if the order and the plan/program are approved by the Secretary.

§ 2310.2 Segregative effect of application or Secretarial proposal to withdraw.

(a) Withdrawal applications filed on or after October 21, 1976—Publication in the **Federal Register** of a notice of a withdrawal application or of a proposal made upon the motion of the Secretary, as provided for in § 2310.3(b) of this title, shall, unless otherwise specified in the notice, temporarily segregate the public lands described in the application or proposal from settlement, sale, location or entry under the public land laws, including the mining laws, for a period of 2 years from the date of publication. Action on all other applications, the allowance of which is discretionary, covering any public lands described in the withdrawal application or proposal, shall be suspended until final action on the withdrawal application has been taken.

(b) Withdrawal applications filed before October 21, 1976. The segregative effect of a withdrawal application filed before October 21, 1976, shall continue through October 20, 1991, unless sooner terminated. Any amendment, made on or after October 21, 1976, of a withdrawal application filed before October 21, 1976, for the purpose of adding public lands to the lands described in such application, shall terminate the segregative effect of the application.

(c) The temporary segregation of lands in connection with a withdrawal application shall not have the effect of authorizing any use to be made of the lands by the applicant for the withdrawal or of transferring administrative jurisdiction, in whole or in part, over the lands.

(d) Notation of a withdrawal application or proposal shall not be made to the land status records that are open to public inspection until such time as a notice of the submission of the application or the making of the proposal has been published in the **Federal Register.**

§ 2310.2-1 Termination of segregative effect.

(a) A withdrawal application, or a withdrawal proposal made upon the motion of the Secretary, may be amended at any time by the applicant or an appropriate official so as to cancel the application or proposal with respect to any land area that is no longer needed in connection with the requested withdrawal. When the application or proposal is so cancelled, the segregative effect of the published notice shall terminate automatically with respect to the lands that are no longer subject to the application or the proposal. (See § 2310.3-5(c) of this title.)

(b) The segregative effect of a withdrawal application or of a withdrawal proposal made upon the motion of the Secretary shall be terminated automatically by:

(1) The signing and publication in the **Federal Register** of a withdrawal order allowing the application or proposal in whole or in part;

(2) The denial of the application or proposal in whole or in part;

(3) Enactment of legislation to withdraw the lands;

(4) The voluntary cancellation of the application or proposal at the request of the applicant; or

(5) The expiration of:

(i) Two years from the date of publication of the notice of a requested withdrawal (for those applications or Secretarial proposals submitted on or after October 21, 1976) during which a Secretarial decision allowing or denying the application or proposal has not been made; or

(ii) Fifteen years from October 21, 1976, i.e., October 20, 1991 (for withdrawal applications pending before October 21, 1976), during which time a Secretarial decision allowing or denying the application has not been made.

§ 2310.3 Action on requested withdrawal, modification or extension.

(a) This section relates to all applications and proposals seeking to withdraw lands or to modify or extend an existing withdrawal.

(b) Within 30 days of the receipt of the submission of an application or the making of a proposal by the Secretary, the authorized officer shall publish in the **Federal Register** a notice stating that the application has been submitted for filing or that the proposal has been made. Among other relevant provisions, the notice shall give the public an opportunity to object to or comment on the requested withdrawal, modification or extension and an opportunity to ask for or comment on the need for a public hearing. In case of a new withdrawal application or proposal, the notice shall state the extent to which any public lands that would be included in the withdrawal are segregated from the operation of the public land laws, including the mining laws. The exact date and hour (local time) upon which the segregative effect of the published notice shall end shall be specified in the notice. In cooperation with the applicant, the authorized officer shall also provide for publicity sufficient to inform the interested public of the proposed withdrawal, modification or extension. Publication of a withdrawal application is not required in connection

with an emergency withdrawal under section 204 of the act.

(c) A public hearing may be held at a time and place convenient to the interested public, the applicant and the authorized officer. In determining whether a public hearing will be held, the authorized officer shall consider whether:

(1) A large number of persons have expressed objections to the proposed withdrawal;

(2) Expressed objections appear to have merit, regardless of the number of persons making protest;

(3) A public hearing will effectively develop information which would otherwise be difficult or costly to accumulate;

(4) The withdrawal, because of its size or strategic location, would have an important effect on the local economy;

(5) A large number of pending and conflicting applications indicate an appreciable private interest in the lands; and

(6) Prevailing public opinion in the area places great emphasis on public hearings or shows great concern over withdrawals.

(d) At the discretion of the authorized officer, a memorandum of understanding between the affected departments, offices or agencies may be negotiated to provide for a plan and implementation program as provided in § 2310.1(c) of this title and, in appropriate cases, for the allocation of administrative jurisdiction. The memorandum of understanding shall be limited in its scope to the performance of functions by the concerned departments, agencies or offices that are within their lawful responsibilities and authorizations. In appropriate cases, resource management of withdrawn areas may be governed by the issuance of management decisions by the authorized officer to implement land use plans developed or revised under the provisions of and in accordance with section 202 of the act.

(e) In the case of lands under the administration of any department or agency other than the Department of the Interior, the Secretary shall make, modify or revoke a withdrawal only with the consent of the head of the department or agency concerned, except in the case of an emergency withdrawal.

§ 2310.3-1 Review of action on an application.

The applicant shall receive a report of all of the authorized officer's findings concerning the requested withdrawal action and the recommendations of the authorized officer based thereon. If the applicant does not concur with a finding of the authorized officer, the applicant may, within 30 days of the receipt thereof, state its reasons for not concurring and request the Director, Bureau of Land Management, to review the finding. If the applicant disagrees with the decision of the Director, the applicant may, within 30 days of receipt of the Director's decision, file a statement of reasons for its disagreement. The statement shall be considered by the Secretary together with the findings and recommendations of the authorized officer and the decision of the Director, Bureau of Land Management. If the action sought by the applicant involves the exercise by the Secretary of authority delegated by Executive Order No. 10355 (17 FR 4831), and an applicant does not concur in the final decision of the Secretary, and the Secretary is promptly notified to that effect, the matter shall be referred to the Office of Management and Budget for resolution.

§ 2310.3-2 Compensation for improvements.

The approval of a requested withdrawal of public lands under the regulations of this part shall be conditioned upon the payment by the applicant or upon agreement by the applicant to pay the owner or owners of improvements placed upon the lands that are subject to the withdrawal under the terms of a permit, license, grant, lease or other authorization, a reasonable compensation for the adjusted value of such improvements. The adjusted value of the improvements is to be determined by the authorized officer but shall not exceed the fair market value of the terminated portion of the licensee's, grantee's, permittee's or lessee's interest in such improvements. Any improvements constructed with Federal funds or under Federal contracts are not compensable. This provision shall only apply to the extent that the improvements will interfere with the use of the lands so authorized by the withdrawal.

§ 2310.3-3 Duration of withdrawals.

(a) An order withdrawing 5,000 or more acres of lands on the basis of the Secretary's withdrawal authority under section 204 of the act shall limit the duration of the withdrawal to a period not to exceed 20 years from the date the order is signed, and each such order shall be subject to the congressional review provisions of section 204(c) of the act. A withdrawal application shall be denied if, in the opinion of the Secretary, the applicant is seeking to circumvent the 5,000-acre provision of section 204(c) of the act.

(b) An order such as that described in paragraph (a) of this section, except that it withdraws less than 5,000 acres, may be made:

(1) For such a period of time as the Secretary determines desirable for a resource use;

(2) For a period of not more than 20 years for any other use, including, but not limited to, use for administrative sites, location of facilities, and other proprietary purposes;

(3) For a period of not more than 5 years to preserve the lands for a specific use then under consideration by either House of the Congress; or

(4) For a period of not more than 3 years, when the Secretary determines, or designated Committees of the Congress notify the Secretary, that an emergency situation exists and that extraordinary measures have to be taken to preserve values that would otherwise be lost.

§ 2310.3-4 Costs of processing applications.

The Secretary may deny an application if the costs estimated to be incurred by this department without reimbursement by the applicant would, in the judgment of the Secretary, be unreasonable and excessive in relation to available funds appropriated for processing applications relating to the discretionary making, modification or extention of a withdrawal.

§ 2310.3-5 Public land orders and notices.

(a) When an application, a proposal or emergency request seeking to withdraw land has been ordered or allowed in whole or in part by the Secretary, or when an application seeking to modify, extend or revoke a withdrawal has been allowed by the Secretary, an order to that effect shall be published in the **Federal Register**. Each such order shall be designated as, and shall be signed by the Secretary and issued in the form of a "public land order." Water shall be reserved pursuant to Federal law for use in carrying out the purposes of the withdrawal only if specifically so stated in the relevant public land order. In appropriate cases, the Secretary shall immediately notify both Houses of Congress of the withdrawal action taken as required under section 204(c)(1) of the act. The congressional notices shall be accompanied by the information required by section 204(c)(2) of the act, except that in case of an emergency withdrawal, transmittal of the information may be delayed as provided in § 2310.5(c) of this title.

(b) The denial or rejection for any reason, of a withdrawal application or proposal, or the denial or rejection of

any withdrawal modification, extension or revocation application, may only be made by the Secretary. When an application or proposal is denied or rejected in whole or in part by the Secretary, a notice to that effect shall be published promptly in the **Federal Register.** The notice shall specify the reasons for denial or rejection and the date and, in the case of a withdrawal application or proposal, the time the segregative effect was terminated.

(c) If a published application, or a published proposal is cancelled voluntarily, in whole or in part, a notice to that effect shall be promptly published in the **Federal Register.** The notice shall state the date and the time the segregative effect was terminated as to the affected public lands.

(d) If the segregative effect of a pending withdrawal application or proposal expires through lapse of time, a notice to that effect shall be published in the **Federal Register.** The notice shall state the date and the time that the segregative effect was terminated.

§ 2310.3-6 Transfer of administrative jurisdiction.

(a) A withdrawal order that reserves lands for the use of a Federal statutory program or other public purpose shall specify, either in the order or by reference to a memorandum of understanding, the extent to which administrative jurisdiction over the lands and its related resources is being transferred to the department, agency or office for the benefit of which the reservation is being made.

(b) A transfer of "administrative jurisdiction" between offices of the Department of the Interior in relation to a reserved area means a transfer of management functions from one office to another office of this department.

(c) A transfer of "administrative jurisdiction" does not include the relinquishment of jurisdiction over a reserved area in connection with a withdrawal revocation.

(d) Requests for the transfer of administrative jurisdiction over reserved lands shall require the submission of an application containing the information required by § 2310.1 of this title.

§ 2310.4 Extensions.

Discretionary administrative withdrawals of specific duration may be extended by a withdrawal order of the Secretary. Such withdrawals of specific duration, whether made prior to or after the effective date of the act, shall be reviewed by the Secretary commencing at least 2 years before the expiration date of the withdrawal. When requested, the department, agency or office benefiting from the withdrawal shall provide the Secretary the information required by § 2310.1(c) of this title in the form of a withdrawal extension application. Such withdrawals may be extended only upon compliance with the provisions of the act and these regulations, and only if the Secretary determines that the purpose for which the withdrawal was first made requires the extension, and then only for a period no longer than the length of the original withdrawal period. The Secretary shall report on the review and extension decision for each withdrawal to the Committee on Energy and Natural Resources of the Senate and the Committee on Interior and Insular Affairs of the House of Representatives as required in section 204(f) of the act.

§ 2310.5 Special action on emergency withdrawals.

(a) When the Secretary determines, or when either the Committee on Energy and Natural Resources of the Senate or the Committee on Interior and Insular Affairs of the House of Representatives notifies the Secretary that an emergency exists and that extraordinary measures need to be taken to protect natural, physical, ecological or environmental resources and values that would otherwise be lost, the Secretary shall immediately make a withdrawal which shall be limited to only meeting the emergency. An emergency withdrawal shall be effective when signed, but shall not exceed 3 years and may not be extended except under the provisions of sections 204(c)(1) or (d) of the act (43 U.S.C. 1714), whichever is applicable, and section 204(b)(1) of the act (43 U.S.C. 1714).

(b) The Secretary shall immediately send a notice of the emergency withdrawal to the Committee on Energy and Natural Resources of the Senate and the Committee on Interior and Insular Affairs of the House of Representatives.

(c) The Secretary shall forward a report to each of the aforementioned committees within 90 days after filing with them the notice of emergency withdrawal. The report shall contain the information required by section 204(c)(2) of the act.

Subpart 2320—Federal Energy Regulatory Commission Withdrawals

§ 2320.0-3 Authority.

(a) Section 24 of the Federal Power Act of June 10, 1920 (16 U.S.C. 818) provides that any lands included in an application for power development under that Act shall, from the date of filing of an application therefor, be reserved from entry, location or other disposal under the laws of the United States until otherwise directed by the Federal Energy Regulatory Commission or by Congress. This statute also provides that whenever the Commission shall determine that the value of any lands withdrawn or classified for power purposes shall not be injured or destroyed for such purposes by location, entry or selection under the public land laws, the Secretary of the Interior shall declare such public lands open to location, entry or selection for such purposes under such restrictions as the Commission may determine are necessary, and subject to and with a reservation of the right of the United States or its permittees or licensees to enter upon, occupy and use any and all of these public lands for power purposes. Before the public lands are declared open to location, entry or selection, the Secretary of the Interior shall give notice of his intention to make this declaration to the Governor of the State within which these public lands are located, and the State shall have a preference for a period of 90 days from the date of this notice to file under any applicable law or regulation an application for the State, or any political subdivision thereof, of any lands required as a right-of-way for a public highway or as a source of materials for the construction and maintenance of such highways. The 90-day preference does not apply to lands which remain withdrawn for national forest or other purposes.

(b) The Act of August 11, 1955 (30 U.S.C. 621), opened lands which were then, or thereafter, withdrawn or classified for power purposes, with certain specified exceptions, to mineral location and development under certain circumstances.

§ 2320.1 Public lands considered withdrawn or classified for power purposes.

The following classes of lands are considered as withdrawn or classified for the purposes of section 24 of the Federal Power Act (16 U.S.C. 818): Public lands withdrawn for powersite reserves under the Act of June 25, 1910 (36 Stat. 847), as amended by the Act of August 24, 1912 (43 U.S.C. 141–143); lands included in an application for power development under the Federal Power Act; lands classified for powersite purposes under the Act of March 3, 1879 (43 U.S.C. 31); lands designated as valuable for power purposes under the Act of June 25, 1910 (36 Stat. 858), the Act of June 9, 1916 (39 Stat. 218, 219), and the Act of February 26, 1919 (40 Stat. 1179, 1181); lands

within final hydroelectric power permits under the Act of February 15, 1901 (43 U.S.C. 959); and lands within transmission line permits or approved rights-of-way under the Act of February 15, 1901, or the Act of March 4, 1911 (43 U.S.C. 961).

§ 2320.2 General determinations under the Federal Power Act.

(a) On April 22, 1922, the Federal Power Commission (as predecessor to the Federal Energy Regulatory Commission) made a general determination "that where lands of the United States have heretofore been or hereafter may be reserved or classified as powersites, such reservation or classification being made solely because such lands are either occupied by power transmission lines or their occupancy and use for such purposes have been applied for or authorized under appropriate laws of the United States, and such lands have otherwise no value for power purpose, and are not occupied in trespass, the Commission determines that the value of such lands so reserved or classified or so applied for or authorized, shall not be injured or destroyed for the purposes of power development by location, entry or selection under the public land laws, subject to the reservation of section 24 of the Federal Power Act."

(b) The regulations governing mining locations on lands withdrawn or classified for power purposes, including lands restored under section 24 of the Federal Power Act, are contained in Group 3800 of this title.

§ 2320.3 Petitions for restoration.

(a) Petitions for restoration of lands withdrawn or classified for power purposes under the provisions of section 24 of the Federal Power Act shall be filed, in duplicate, in the proper State Office of the Bureau of Land Management as set forth in § 1821.2–1 of this title. No particular form of petition is required, but it shall be typewritten or in legible handwriting. Each petition shall be accompanied by a service charge of $10 which is not returnable.

(b) Favorable action upon a petition for restoration shall not give the petitioner any preference right if or when the lands are restored.

PARTS 2310, 2320, 2340, AND 2350 [DELETED]

2. The following parts are deleted or revised as indicated:

(a) Part 2310—deleted in its entirety.

(b) Part 2320—deleted in its entirety.

(c) Part 2340—deleted in its entirety.

(d) Part 2350—deleted in its entirety.

PART 2090—SPECIAL LAWS AND RULES

3. Sections 2091.2–4 and 2091.2–5 are deleted from subpart 2091.

November 28, 1979.

Guy R. Martin,

Assistant Secretary of the Interior.

[FR Doc. 79–37166 Filed 12–4–79; 8:45 am]

BILLING CODE 4310–84–M

federal register

Tuesday
December 4, 1979

Part IV

Office of Personnel Management

Proposed Demonstration Project; An Integrated Approach To Pay, Performance Appraisal, and Position Classification for More Effective Operation of Government Organizations

OFFICE OF PERSONNEL MANAGEMENT

Proposed Demonstration Project; An Integrated Approach To Pay, Performance Appraisal, and Position Classification for More Effective Operation of Goverment Organizations

AGENCY: Office of Personnel Management.

ACTION: Notice of proposed demonstration project.

SUMMARY: Title VI of the Civil Service Reform Act of 1978 authorizes the Office of Personnel Management to conduct demonstration projects which experiment with new and different personnel management concepts under controlled conditions. Before conducting or entering into any agreement or contract to conduct a demonstration project, the Office of Personnel Management is required to publish the project plan in the **Federal Register.** This notice meets that legal requirement.

DATES: Comment date: Written comments will be considered if received no later than February 4, 1980. Hearing dates: Public hearings will be held on the proposed project plan on: (1) January 21, 1980, in San Diego, California, from 9 a.m. to 1 p.m. (2) January 22, 1980, in Ridgecrest, California, from 9 a.m. to 1 p.m. (3) January 31, 1980, in Washington, D.C., from 9 a.m. to 12 noon.

ADDRESSES: Comment address: Send written comments to Mr. Edward A. Schroer, Director, Office of Planning and Evaluation, U.S. Office of Personnel Management, Room 3305, 1900 E Street NW., Washington, D.C. 20415.

Public hearing addresses: (1) January 21, 1980. Naval Ocean Systems Center Auditorium, 271 Catalina Boulevard, Building A–33, San Diego, California 95152; (2) January 22, 1980. Burroughs Lecture Center, Burroughs High School, Ridgecrest, California 93555; and (3) January 31, 1980. U.S. Office of Personnel Management, Room 5H09, 1900 E Street NW., Washington, D.C. 20415.

FOR FURTHER INFORMATION CONTACT: (1) On proposed demonstration project and San Diego, California, public hearings: Sue Rainville, (714) 225–2132; (2) On proposed demonstration project and Ridgecrest, California, (China Lake) public hearings: Dick Johnson (714) 939–2434; and (3) On proposed demonstration project and Washington, D.C., public hearings: Donald Hill (202) 632–6077.

SUPPLEMENTARY INFORMATION: On Proposed Demonstration Project: The Department of the Navy has submitted a proposal for consideration as a demonstration project under Title VI of the Civil Service Reform Act of 1978 (92 Stat. 1185) entitled "An Integrated Approach to Pay, Performance Appraisal, and Position Classification for More Effective Operation of Government Organizations." The purpose of the project is to demonstrate that the effectiveness of Federal laboratories can be enhanced by developing an integrated approach to pay, performance appraisal and position classification and by allowing greater managerial control over personnel functions. At the same time, the proposed systems would expand the opportunities available to employees through a more responsive and flexible personnel system. In order to accomplish these purposes, changes are proposed that include (1) a more flexible, manageable, and understandable classification system; (2) a performance appraisal system that links performance objectives, compensation, and organizational effectiveness; (3) an expanded application of the merit pay concept; (4) recognition of demonstrated individual performance in the reduction-in-force (RIF) process; (5) substitution of streamlined procedures for performance-based-action procedures for the movement of employees between classification levels; and (6) use of suspended penalties in certain adverse action situations. The demonstration base will comprise professionals (all scientists and engineers, and non-scientists and non-engineers GS–13 through 15) at the two participating organizations: the Naval Ocean Systems Center (NOSC), San Diego, and the Naval Weapons Center (NWC), China Lake, California. Additional categories that may be included subsequently are technicians and administrative professionals below GS–13 and clerical personnel. The basic increment will include 1,417 professionals at NOSC and 1,427 at NWC.

On Public Hearings: Public hearings will be held by the U.S. Office of Personnel Management at San Diego, California, Ridgecrest, California (China Lake), and Washington, D.C., during which interested persons or organizations may present their written or oral views concerning the proposed demonstration project. The hearings will be informal in nature. However, in order to regulate the course of the hearings and to provide ample opportunity for all persons and organizations desiring to present comments to do so, parties desiring to testify at one of the public hearings are requested to contact one of the persons listed under "For Further Information Contact" for a specific scheduled time. Priority will be given to scheduled parties; others will be heard in the remaining available time. Moreover, each speaker's presentation will be limited to 10 minutes. Finally, the hearing record shall be left open until February 14, 1980, to receive additional written data, views, and arguments from the parties participating in the hearings.

Office of Personnel Management.

Beverly M. Jones,

Issuance Systems Manager.

The proposed demonstration project plan reads as follows:

An Integrated Approach to Pay, Performance Appraisal, and Position Classification for More Effective Operation of Government Organizations

A Plan for a Demonstration Project Authorized by Title VI of the Civil Service Reform Act of 1978

October 1979.

Prepared by Naval Ocean Systems Center San Diego, California 92152 Naval Weapons Center, China Lake, California 93555.

Executive Summary

The enclosed proposal is submitted to the Office of Personnel Management for consideration as a demonstration project designed to improve the performance of federal employees, as authorized by Title VI of the Civil Service Reform Act (CSRA). For the reader's convenience, a broad summary of the information contained in this proposal is provided below. For more information, the reader is referred to corresponding sections of the report.

Purpose

The purpose of the project is to demonstrate that the effectiveness of federal laboratories can be enhanced by allowing greater managerial control over personnel functions and, at the same time, expanding the opportunities available to employees through a more responsive and flexible personnel system. In order to accomplish this purpose, changes are proposed that include (1) a more flexible, manageable, and understandable classification system; (2) a performance appraisal system that links performance objectives, compensation, and organizational effectiveness; (3) an expanded application of the merit pay concept; (4) recognition of demonstrated individual performance in the reduction-in-force (RIF) process; and (5) the use of suspened penalties in certain adverse action situations. Together these

changes can help managers to operate with more authority, responsibility, and skill to increase work force and organizational effectiveness and efficiency.

Participating Organizations

The Naval Ocean Systems Center (NOSC), San Diego, and the Naval Weapons Center (NWC), China Lake, Calif., will be joint participants in the project. The School of Public Administration, University of Southern California, Los Angeles, will serve as an independent project evaluator. The Office of Personnel Management (OPM), including the San Francisco Regional Office, will provide assistance to the project, as will components of the Department of the Navy.

Types and Numbers of Participating Employees

The demonstration base will comprise professionals (scientists, engineers, and all non-scientist or engineer GS–13 through –15 employees) at the two participating Centers. Additional categories that may be included subsequently are technicians and administrative professionals below GS–13 and clerical personnel. The basic increment will include 1,417 professionals at NOSC and 1,427 at NWC.

Methodology

This proposal spells out the methodology to accomplish over a 5-year demonstration period the following specific changes: (1) Five levels of classification; (2) broad pay bands within classification levels, with individual placement into one of five basic incentive pay groups; (3) development of general classification/performance standards; (4) performance appraisal based on Performance by Objectives; (5) reduction-in-force procedures that emphasize performance while substantially retaining existing ranking factors; and (6) implementation of a modified adverse action process that features the use of suspended penalties in certain adverse action situations. Figure 1 illustrates the pay and performance changes of this proposal.

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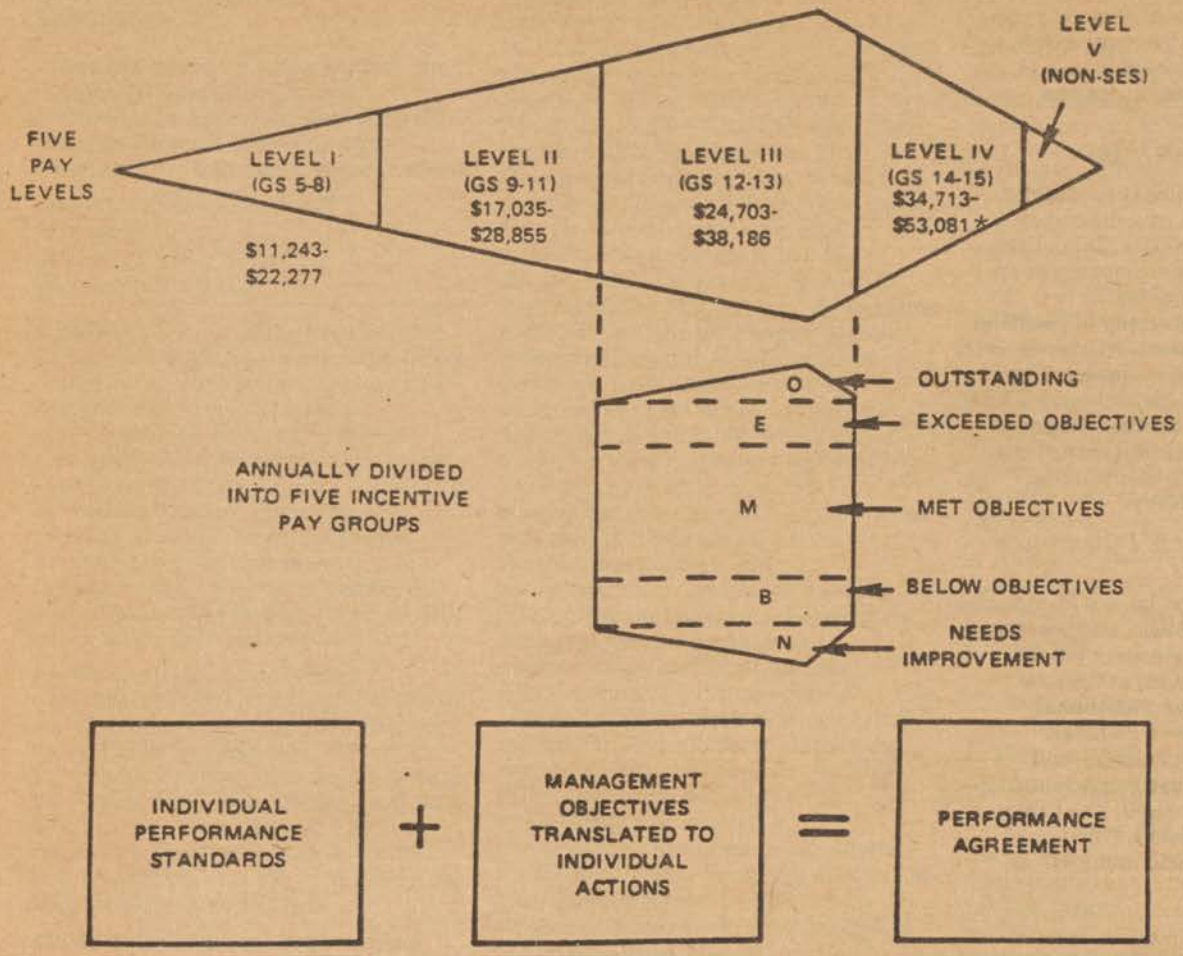


FIGURE 1. Pay and Performance Scheme.

*Subject to statutory limitation

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Training

Three groups will be trained during the first year of project implementation: (1) Supervisors of demonstration employees, (2) demonstration employees, and (3) personnel professionals and other administrative staff. Included in training for each of these groups will be information on the new system and how it works, and on employee and supervisor rights and responsibilities under this system. In addition, instruction and practice in objective-setting skills will prepare supervisors and employees for the Performance by Objectives process. Training for new supervisors and employees will be given throughout the 5 years of the project.

Evaluation Plan

In order to assess project outcomes and to evaluate the feasibility of applications to other federal organizations, a comprehensive and methodologically rigorous evaluation model is being developed. Figure 2 summarizes the major categories of variables involved and specifies a set of relationships that will be monitored and evaluated. The evaluation effort will include (1) pre-implementation criteria-setting and baseline data collection, (2) multidimensional performance measurements and trend evaluations at specified stages of the demonstration, and (3) a summative-phase comprehensive assessment of the project's overall impact on a set of outcome measures.

In addition to the above-mentioned measures and data, there will be an ongoing monitoring of existing records and reports on the laboratories. Unobtrusive measures will be kept on such basic considerations as the profile of the scientific and engineering work force of the laboratories, including EEO profiles to enable measurement of EEO impact as defined in the uniform guidelines.

When methodologically justifiable, control group data will be obtained from other Navy laboratories not involved in the project.

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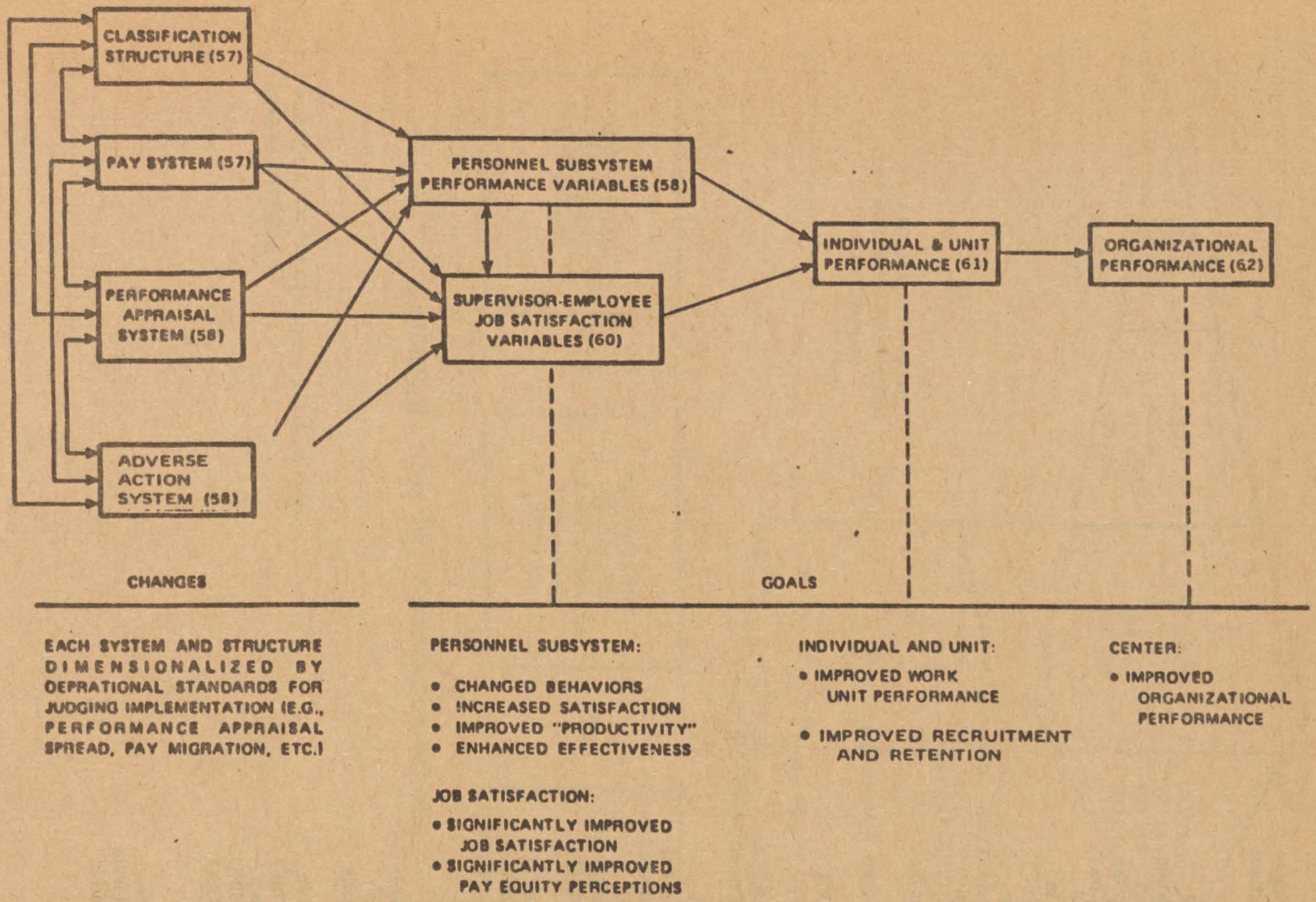


FIGURE 2. General Evaluation Schematic for Demonstration Project. The relationships between implementation of the planned changes and variables to be evauated are shown. Numbers in parentheses refer to corresponding pages in this proposal for further discussion.

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Longitudinal measures, beginning with pre-implementation data, will be collected from the affected Centers in an effort to track impacts.

The evaluation staff will be drawn from internal and external sources. Qualified laboratory staff members will work with members of the faculty of the School of Public Administration, University of Southern California, on the design and execution of the evaluation package.

Costs

Efforts will be made to obtain congressional funding for this demonstration project. If congressional funding is not available, the costs associated with the project will be borne by the Department of the Navy and the two participating Centers, with funding provided out of normal activity training and administrative overhead funds. The total cost for the 5-year project is estimated to be $2,700,000 (in fiscal year 1979 dollars).

Authorities and Waivers of Law and Regulation Required

Specific authorities are needed by the participating Centers to establish and implement new merit pay control techniques not currently in the law. In addition, authority is needed to waive or modify certain sections of Title 5 in order to give project participants the necessary classification authority, merit pay flexibility, and other authorities to accomplish the demonstration project.

Benefits of Proposed Project

The project is expected to demonstrate that a genuinely management-centered personnel administration process will lead to more efficient and effective use of the resources of the participating Centers. In addition, by providing a means of real-world testing for models of improved and simplified classification and performance evaluation systems, the project will have results that can be applied throughout the Federal service. Some examples of anticipated effects caused by the proposed changes and corresponding measures for evaluating these effects are depicted in Table 1.

Table 1.—*Some Examples of Anticipated Effects Caused by the Proposed Changes, With Measures for Evaluating These Effects*

Change	Anticipated effects	Evaluation measures
Classification and pay	Increased recruitment success	Cost per recruit, recruit quality and quantity.
	Flexibility of workload assignment	Time, cost of reassignments and transfers.
	Increased personnel subsystem "productivity".	OPM productivity measurement approach
Performance appraisal	Correlation of pay and performance	Perceived equity.
	Increased employee commitment	Satisfaction and commitment instruments ("A" Survey).
	Decreased turnover of "desirable" employees.	Turnover rate of critical employees.
	Increased turnover of low performers	Turnover rate.
	Increased organizational effectiveness	Peer, sponsor, and user evaluations; cost to conduct business.
Retention	Retention of high performers	Retention rates.
Adverse action	Improved behavior of problem employees	Number of suspended penalties effected as opposed to those not effected.

An Integrated Approach to Pay, Performance Appraisal, and Position Classification for More Effective Operation of Government Organizations

Introduction

The demonstration project described here is designed to make operational and systematically test a set of major modifications in federal personnel practices. These changes are intended to move the affected organizations toward a management-centered personnel administration prosess. The proposed demonstration project postulates that increased authority, flexibility, and accountability for civil service managers will lead to more productive use of federal resources and higher levels of organizational effectiveness. It is also expected that many employees will benefit from the project's performance-linked pay incentives; the opportunity for better (and more frequent) communication with supervisors on performance objectives; increased opportunity to benefit from the "dual ladder" concept that will be expanded as a result of new, more flexible classification standards; and more opportunity to move between organizational units through the use of standardized position descriptions.

The project will implement a system under which personnel administration is not approached as something to be done *for* public managers, but, rather, as something to be done *by* managers as an integral element of their range of responsibilities. The project is intended to carefully evaluate the proposition that effective public administration depends in large measure on the individual manager's capacity to deal with situations through the active design, administration, and evaluation of personnel policies and procedures.

In the competitive environment of the private sector, an organization must be capable of sensing and responding to change rapidly. the organizations that are unable to adapt to change are often forced out of existence by their more innovative, adaptive competitors. In comparison to public managers, private sector managers typically have much more flexibility in disposition and application of resources (especially personnel resources) and have much more accountability for their performance in managing these resources.

Under the existing federal personnel system, managers are denied direct control, are not encouraged to innovate, and are tightly constrained in many areas. This project, if approved, will reverse many of these conditions. Public managers in two Navy research and development organizations will be given the opportunity to function in an environment structured to promote direct managerial control over and accountability for several cirtical personnel functions.

It is anticipated that the project will demonstrate that public managers can be trusted to take these new and changed responsibilities seriously, and that they will act in the best interests of the public service, their organizations, and their personnel. It is also expected that the creation of a management-centered personnel system will, to an extent far exceeding that of the present system, stimulate managers to respond creatively to the problems of goal-oriented manpower management, to develop the required skills, and to economize in their uses of the resources allocated to them. Finally, the project will actualize the principle that public managers, once given the tools and resources, should be held accountable for their decisions and practices with regard to personnel administration, and that such accountability is an essential ingredient of effective and efficient administrative action.

It should be noted that nothing in the demonstration project proposal is intended to minimize the importance of the "human element" in personnel administration. While the project is management-centered, it has evolved with an ongoing concern for the welfare

of employees, both supervisory and nonsupervisory, who will have to jointly adhere to project provisions during the project term. None of the elements of the proposal were designed to minimize the rights of individuals or in any way diminish the concern management has for the general welfare of the work force. This demonstration will be conducted in accordance with all EEO laws, regulations, and guidelines.

Under the provisions of Title VI of the Civil Service Reform Act, OPM approval of this demonstration project constitutes approval for its potential application to all employees at the participating Centers, subject to the statutory ceiling limitation of 5,000. The initial implementation increment will include all scientists and engineers (S&Es) and all GS–13s and above, with additional career paths the subject of future discussion, consultation, and agreement with OPM.

Problem Areas in Current Personnel System

In its findings, the Task Force on the Federal Personnel Management Project identified a number of areas where changes in the federal personnel system were needed to increase the efficiency and effectiveness of the federal work force. Many of these problem areas were directly addressed by the Civil Service Reform Act (CSRA) of 1978. The CSRA also provided for demonstration projects where additional areas could be explored to determine if the removal or change of constraints or regulations could increase effectiveness and efficiency.

This proposed demonstration project addresses problems in key areas within the existing personnel system. The project proposes solutions for these problems, outlined below, by giving managers the authority and accountability to increase both the efficiency and the effectiveness of the work force by stimulating individual and organizational performance. It is expected that this approach to personnel resource management will prove adaptable to a wide spectrum of federal organizations.

Classification

The current classification system is confusing and complex; to a large extent, it diminishes the manager's role in setting pay and gives personnel classifiers an inordinate degree of responsibility in this process. Neither managers nor employees understand the current method of classifying positions; they see the system as one that impinges on their flexibility. The system delays recruitment actions, which must wait for positions to be classified. It also limits managers' ability to transfer personnel from one functional area to another; delays occur while managers wait for positions to be classified or find that the position to which an employee is to be moved is not classifiable at the appropriate grade level. Classification of positions consumes the time and energy of the personnel staff and precludes their involvement in assisting management with other critical personnel resource problems. In addition, the complex classification system causes some professionals to leave federal service for private industry, where managers can reward performance, contributions, and responsibility with pay.

The current average grade level and high grade level ceilings also limit management flexibility under the current classification system. Once a number of employees reach a given grade level, current limitations preclude promoting other deserving employees. While the demands of projects and work assignments change, management has very limited flexibility to move employees up or down. This project proposes to demonstrate that this flexibility can be obtained by placing budgetary rather than grade constraints on activities, and by giving them greater flexibility to adjust pay. Availability of broad categories of capability and responsibility in lieu of the present too finely segmented classification standards will allow suitable recognition for project mangers and technical specialists and will minimize supervisory layering.

Performance Appraisal

The performance appraisal systems existing prior to the Civil Service Reform Act were unsatisfactory to both supervisors and employees. This project will increase the importance of performance appraisals because it provides that these systems will have a close link with pay decisions.

Any system becomes meaningless without pay incentives to reward good performance or penalize low performance. While the supervisor may have high expectations for subordinate performance, a system that does not translate these expectations into meaningful management actions cannot be effective. The proposed change ensures that this translation will take place.

An associated problem is the lack of a universally applied, objective system to measure the employee's effectiveness in relation to organizational goals. The Performance by Objectives system proposed here will provide a means for generation of objective and useful feedback for the employee from the performance appraisal, as well as a basis for decision-making for the supervisor.

Merit Pay

A major problem area in the current system is the lack of sufficient incentives and rewards for good performance and disincentives and meaningful sanctions for poor performance. The CSRA changes in the merit pay concept address this problem. The participating Centers feel, however, that they do not apply to enough of the work force. The rigid classification system also works counter to the principle of flexibility for incentives and disincentives. In addition, the present practice of granting "automatic" step increases for all employees working at acceptable levels of competence limits a tool that managers could better utilize.

An effective recruitment tool that is denied to today's federal organizations is the ability to offer to recent college graduates or other potential employees the incentive that their pay will increase to keep pace with their performance and responsibilities.

While the CSRA provides a basis to address the merit pay problem for mid-level supervisors and managers, this demonstration project proposes applying CSRA concepts to a much broader base.

Reduction in Force

In existing RIF procedures, the regulations do not appropriately recognize performance as a factor in a RIF situation. The granting of 4 years' seniority on the basis of an outstanding performance rating rarely has a significant effect on RIF actions. Managers typically see some of their better performers move to lower grades or leave the organization because their performance is not adequately recognized in the RIF process. The EEO program often suffers, too, from a RIF situation where those with the lowest retention standings are recently hired female or minority-group employees.

The demonstration project addresses this problem by including performance as the prime factor in rankings for retention standings, and thus giving managers a better change to retain outstanding performers all all levels and from all EEO categories.

Suspended Penalty

Currently, situations exist where otherwise capable and previously productive employees suffer from alcohol- and drug-related disorders or become inadvertently involved in

situations of real or apparent conflict of interest. Current penalties for these offenses are frequently excessively severe if improvement or corrective behavior results, while lesser penalties are sometimes insufficient to motivate higher quality performance or changed behavior. A process that permits the assignment of relatively severe penalties that can be suspended during a specified improvement/correction period (much like a suspended sentence in the courts) is proposed as a useful management tool.

Approach of Proposed Demonstration Project

Purpose

The purpose of the project is to demonstrate that the effectiveness of federal government organizations can be enhanced by allowing greater managerial control over personnel functions. The proposed approach will move managerial responsibilities in the direction of those available to the private sector. Profit is the prime measure of efficiency and effectiveness for private sector managers. Since measures of profit are nonexistent in the public sector, the demonstration project contains a thorough and critical evaluation plan designed to measure other relevant factors that indicate effectiveness.

The demonstration project is expected to provide the two participant Centers with a means to respond much more effectively to the demands of their assigned missions. In addition, broad applicability is anticipated; by providing a means of real-world testing for models of improved and simplified classification and performance evaluation systems, the project will have results than can be applied throughout the federal service.

Changes Required

In order to accomplish the purpose of the demonstration project, it will be necessary to effect the following changes:

1. Simplify the classification system to make it more flexible, manageable, and understandable.

2. Make the performance appraisal system more realistic by including compensation as the outcome and by developing performance objectives that are tied to organizational effectiveness.

3. Provide a positive link between performance and compensation by expanding the application of the merit pay concept.

4. Emphasize performance as a primary criterion in the retention process by giving due emphasisa to demonstrated individual performance.

5. Encourage behavioral changes by use of suspended penalties in certain adverse action situations.

These changes will be effected through a model that will provide increased personnel management authority to the line supervisor, and at the same time expand the opportunities available to employees through a more responsive and flexible personnel system. The simplified classification system will group all affected personnel into broad occupational and responsibility categories. Each such classification category will have a significantly wider range of pay than is provided by the grade level boundaries of the present classified schedule. Line managers will have discretion to establish individual pay rates within the classification categories through initial offers and through performance evaluation.

Participating Organizations

It is proposed to demonstrate the model over a 5-year period at the Naval Ocean Systems Center (NOSC), San Diego, and at the Naval Weapons Center (NWC), China Lake, Calif. Although there are many differences between these two Centers (misson areas, climate, geographic location, cultural milieu), similarities of position within the Department of the Navy, types of employees, and types of work functions greatly outweigh these dissimilarities and make the two Centers uniquely fitted as a two-site experimental group. (Appendix A contains additional information on NWC and NOSC.) It is proposed to begin the demonstration with scientists, engineers, and other GS–13 through –15 employees and follow with other specific segments of the work force as feasible within the 5-year time frame.

Table 2.—*All Scientists and Engineers and All Non-S. & E. GS-13's Through -15's Involved in Demonstration Project*

	Type of occupation	Number of eligible personnel by participating activity	
	Title	NOSC	NWC
Series:			
28	Environmental protection specialist		1
132	Intelligence specialist	6	2
150	Geographer		1
180	Engineering psychologist	18	1
330	Digital computer systems administrator	2	
334	Computer specialist	94	
340	Program manager	5	2
345	Program analyst	3	
401	Biological scientist	10	1
403	Microbiologist	1	
408	Ecologist	1	
413	Physiologist	2	
701	Veterinary scientist	1	
801	General engineer	55	169
806	Materials engineer	7	8
808	Architect		7
810	Civil engineer/structural engineer	1	7
830	Mechanical engineer	91	192
850	Electrical engineer	4	8
855	Electronics engineer	66	433
861	Aerospace engineer		90
893	Chemical engineer	1	20
896	Industrial engineer	2	1
1301	Physical scientist	15	14
1306	Health physicist	1	
1310	Physicist	236	205
1313	Geophysicist	1	
1320	Chemist	11	54
1321	Metallurgist		4
1350	Geologist		3
1360	Oceanographer	19	
1515	Operations research analyst	58	63
1520	Mathematician	76	87
1529	Mathematical statistican	1	3
1550	Computer scientist	7	7
Various	GS–13 through –15 non–S&Es	27	44
Total		1,417	1,427

Table 3.—*Summary of Categories and Numbers of Participating Employees*

Category of employees	Participating activity		Total
	NOSC	NWC	
Scientist and engineer	1,390	1,381	2,752
Technician	396	735	1,131
Administrative professional	245	435	680
Clerical	[1]352	[1]546	871
Total	2,383	3,097	[1]5,434

[1] Only selected groups of clerical personnel would participate to keep the total number of participating employees within the 5,000-employee demonstration project limitation.

The School of Public Administration of the University of Southern California (USC), Los Angeles, will be responsible for an independent evaluation of the project. The USC evaluation team will make this evaluation both through their own methods and measures and through validation and interpretation of the participants' evaluation processes.

The OPM, including the San Francisco Regional Office, will provide consulting assistance during the term of the project and will coordinate the personnel evaluation function to insure compliance to laws, regulations, and policies not waived by the project.

Components of the Department of the Navy will provide assistance to the demonstration project. Assistance will include cooperation of control groups (other Navy laboratories) and waiver of infernal DOD and Navy regulations and rules that infringe on the purpose of the project.

Types and Numbers of Participating Employees

The demonstration base will comprise professionals (scientists, engnineers, and other GS–13 through –15 employees) at the two participating Centers. Subsequently, as project number limitations and successful experience permit, additional categories may be included in the following order, subject to consultation and agreement with OPM (approximate target dates provided):

1. Technicians below GS–13 (August 1981)
2. Administrative personnel below GS–13 (August 1982)
3. Clerical personnel (August 1983)

Table 2 lists the professional series and numbers of scientists, engineers, and GS–13 through –15 employees who will be included in the demonstration base. Table 3 summarizes the numbers of participating employees by category.

The proposal is limited to a description of the activities required to demonstrate success for the personnel in the base increment; the requirements for the other employee categories would be similar and are therefore not specified in order to avoid repetition.

Methodology

General Approach

The proposed demonstration project is geared to the Civil Service Reform Act of 1978, existing public and private personnel systems, and anticipated additional Civil Service legislation in the area of classification and pay. The project proposes a closely linked classification, performance, and compensation system, initially for technical professionals and GS–13 through –15 employees and, if this phase is successful, subsequently for other groups of laboratory personnel. Specific proposed changes include the following:

1. Five levels of classification for professionals (scientists, engineers, and related GS–13 through –15 employees).
2. Broad pay bands within classification levels, with individual pay adjusted annually by placement into one of five basic incentive pay groups.
3. Development of general classification/performance standards.
4. Individual placement in incentive pay groups during a performance appraisal process based on Performance by Objectives.
5. Modification of reduction-in-force (RIF) procedures to emphasize performance while substantially retaining existing veterans' preference, tenure, and length-of-service factors.
6. Subsitution of streamlined procedures in those instances where an employee migrates from one classification level to another because of continued poor performance. In such instances, the employee's salary will remain constant.

Demonstration Elements

Classification Levels

The heart of the proposal is the grouping of the currently used nine-grade (GS –5, –7, –9, –11, –12, –13, –14, –15, and 16+) pay/classification system for professionals into five levels of classification. These levels incorporate expanded pay flexibility by including the intervening grade levels. The levels and comparable GS grades for each level are as follows:

Level I. Assistant Professional Members, GS–5 through GS–8.

Level II. Associate Professional Members, GS–9 through GS–11.

Level III. Professional Members, GS–12 through GS–13.

Level IV. Senior Professional Members, GS–14 through GS–15.

Level V. Professional Exceptional, GS–16 and above.

The fifth level will be added where necessary to accommodate GS–16 through Public Law-level candidates who are not offered or who decline Senior Executive Service (SES) membership.

Table 4 depicts these levels and useful pay overlaps between levels.

These broad pay levels will serve to enhance competitive recruitment of quality candidates, as well as to allow tangible performance-linked distinctions between existing employees. Classification of employees under such a pay system will be less burdensome and less susceptible to judgmental errors in precise grade placement. The system, in fact, incorporates a rank-in-*person* system with its inherent flexibilities while retaining through the broad groupings the overall benefit of rank-in-*job* distinctions that can reasonably be applied by supervisors and managers. To the extent that high grade adjustments are required at the completion of the project, the exit procedures discussed later in this proposal will be employed.

This project envisions four discrete career paths that are related to the current GS grade levels as shown in Table 5 (subject to change as project experience dictates). The current GS system will remain as pay anchor for the project.

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TABLE 4. Basic Professional Pay Levels and Classification Levels.

OLD SYSTEM	GS-5	GS-6	GS-7	GS-8	GS-9	GS-10	GS-11	GS-12	GS-13	GS-14	GS-15	GS 16	GS-17[1]	GS-18	PL[d]
NEW SYSTEM	LEVEL I ASSISTANT PROFESSIONAL MEMBER				LEVEL II ASSOCIATE PROFESSIONAL MEMBER			LEVEL III FULL PROFESSIONAL MEMBER		LEVEL IV SENIOR PROFESSIONAL MEMBER		LEVEL V PROFESSIONAL EXCEPTIONAL			
NEW PAY RANGE, DOLLARS[a]	11,243 TO 22,277[b]				17,035 TO 28,855[b]			24,703 TO 38,186		34,713 TO 53,081[c]		[c]			

[a] BASED ON OCTOBER 1979 PAY RATES.
[b] SUBJECT TO POSSIBLE CHANGE. (special rates)
[c] SUBJECT TO STATUTORY LIMITATIONS.
[d] PUBLIC LAW.

TABLE 5. Career Path Identification by Classification Level as Related to Current Grade Levels.

GS GRADE LEVEL	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16-PL[a]
CLERICAL CAREER PATH[b]																
TECHNICAL CAREER PATH[b]												IV		V[c]		
ADMINISTRATIVE CAREER PATH						I				II		III		IV		V[d]
PROFESSIONAL CAREER PATH						I				II		III		IV		V

[a] PUBLIC LAW
[b] LEVELS TO BE DETERMINED
[c] RESERVED FOR MANAGERIAL POSITIONS
[d] RESERVED FOR MANAGERIAL/EXPERT POSITIONS

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The initial phase will convert the professional population (primarily scientists and engineers and GS–13 through –15 employees of the two Centers) to appropriate career paths. As the project demonstrates its success, each participating Center may convert technician personnel below GS–13 to their career path, with subsequent conversion of the remaining two career paths in successive time frames. The technician career path is currently scheduled for conversion in August 1981.

The four separate career paths simplify personnel categorization and are reflective of private industry classification structures.

A Level V has been added in each career path primarily to provide flexibility in adapting the project to federal government-wide application and to special situations.

Classification/Performance/ Qualification Standards

The proposed classification levels for professionals will differentiate between broad groups of employees as follows:

Level I. Entrance and training positions.

Level II. Advanced training and specific task performance and development to full performance levels.

Level III. Journeyman performance-level positions and supervisors.

Level IV. Senior technical specialists, supervisors, and managers.

Level V. Individuals in GS–16 and higher positions not included in the Senior Executive Service.

These levels are sufficiently distinct that they can be easily understood by managers; correct placement will therefore be more certain.

The proposed classification system will be modeled on industry and university practices and will follow an abbreviated benchmark description approach, with classifiers and supervisors assigning incumbents' duties and responsibilities within the range of a benchmark level of difficulty. (Final classification judgments will be made with the advice of classfication specialists in the respective personnel organizations.) Position descriptions can to a large degree be standardized and presented in a side-by-side format that presents the position description along with a limited number of general performance expectations. These performance standards, matched to the level of difficulty, will in most cases be supplemented by individualized documented performance goals and expectations that will serve as the combined basis for incentive pay decisions.

Basic qualifications for each level will be determined by qualifications-rating determinations keyed to existing OPM X118 qualifications standards. References in these Z118 standards to the next lower "grade level" will be interpreted under the demonstration project as experience at the next lower classification level (i.e., broad pay band).

Incentive Groups

The pay system itself will feature incentive pay increases in lieu of step increases, comparability increases, within-level promotions, and most performance awards. Five incentive pay groups will be established, and pay for these groups will be fixed as follows. Employees who greatly exceed performance expectations will be given a basic incentive increase, plus an additional amount to be determined on the basis of funds available after disbursement of basic incentive increases to fully satisfactory performers. Two additional groups of employees who fully meet performance objectives will receive a basic incentive increase, plus a possible additional amount. Employees who meet objectives for acceptable performance in most respects will receive half the basic incentive increase, and employees who need improvement will not receive any increase. Figure 3 depicts these incentive pay groupings.

The obvious result of annual performance-related placement of employees in the proposed incentive pay groups for pay fixing purposes will be a migration of the least productive but adequate employees to the lower end of the pay band and rapid movement of high performers to the upper end of the pay band. This migration will be monitored by management and the evaluation staff to ensure that its rate is meaningful and to provide EEO data to enable measurement of EEO impact, as defined in the uniform guidelines.

Resources for incentive pay increases will include funds normally allocated for comparability increases, within-grade step increases, promotions within proposed levels and most performance awards (e.g., quality step increases and sustained superior performance awards). These resources, as increased annually, will compose the overall system control on manpower and will be adjusted to account for significant reductions or increases in manpower to meet mission requirements. Supplemental local managerial control mechanisms may include percentage distributions of the work force between basic employee classification levels and percentage distributions of adequate performers between incentive pay groupings. These allocations will be sufficiently flexible to allow alteration as demonstration experience dictates. After some experience with the project, both Centers will explore the possibility of a dollar salary increase in lieu of fixed percentage increases. If the evaluation mechanism shows that performance has increased significantly as a result of the experiment, both Centers will pursue the feasibility of allocating additional funds to reward the measured improvement in organizational effectiveness.

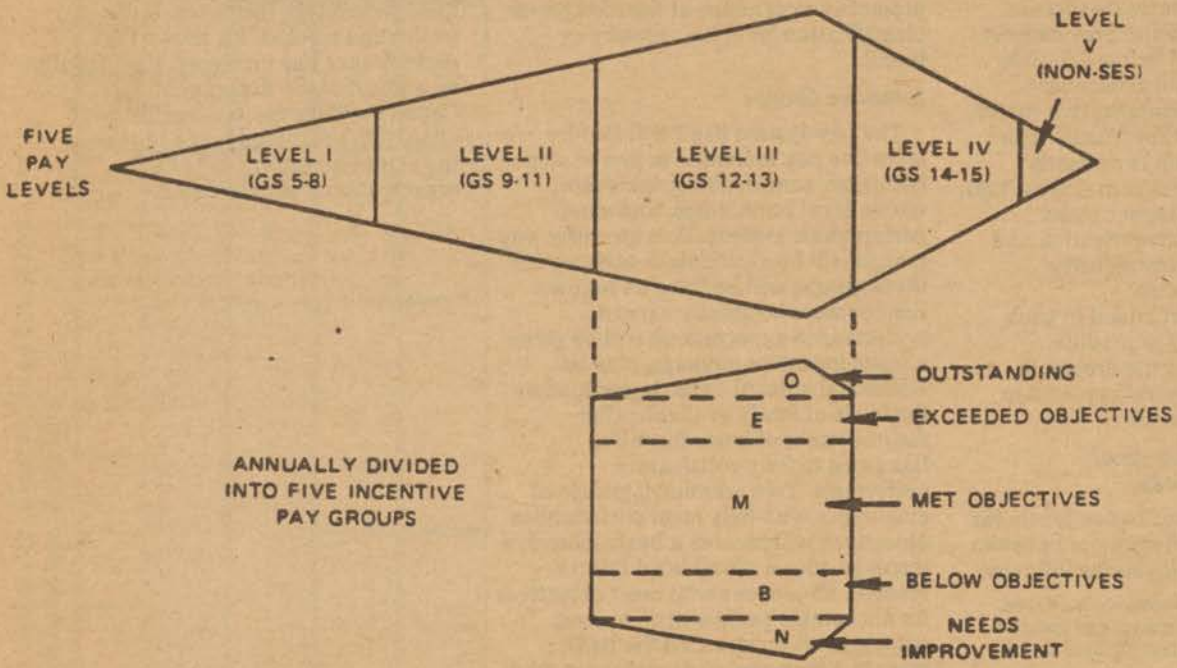


FIGURE 3. Incentive Pay Groupings Within Each Level.

A bonus approach will be used to recognize high performers who are not eligible for continuing pay increases because they are at the maximum salary rate for their classification level. The project will also explore the concept of establishing incentive pay increases based on organizational performance and will identify ways in which this can be accomplished without causing a negative impact on the block of funds dedicated to individual awards.

Performance Appraisal

Development of Performance Standards. The initial method to develop performance standards involves the use of a panel to develop broad standards for use by individual supervisors in their subsequent development of more specific and specialized standards for individual subordinates. A panel including both supervisors and employees (experts from specific occupational groups involved) will brainstorm on the tasks and attributes typically required in a position. These tasks and attributes will then be ranked in order of importance by the panel. From the resulting list of tasks and attributes, supervisors will choose appropriate tasks and attributes to formally develop individual performance standards. Both Centers will also explore industry performance standards systems for inclusion or modification to fit the standards for certain occupational groups.

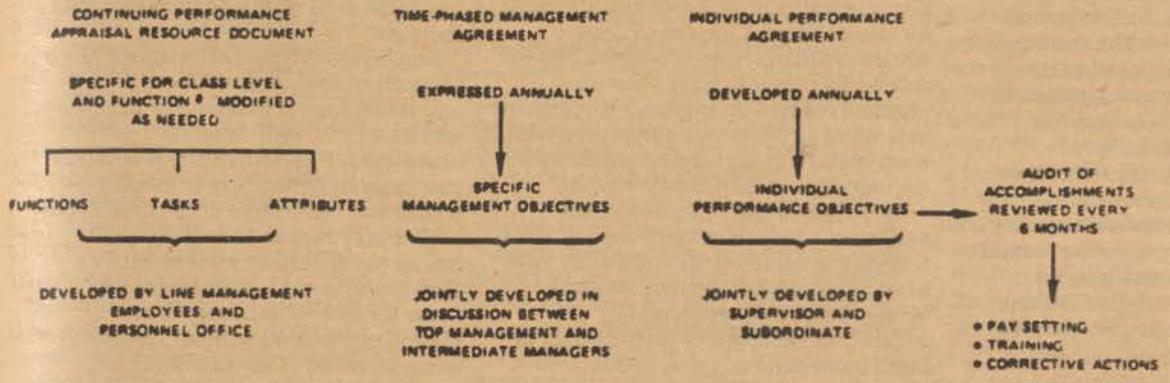
Initially, to ensure that teamwork and unit performance are encouraged while project simplicity is maintained, a critical performance element of "teamwork" will be a part of every individual rating. As the demonstration project develops, a separate method of unit recognition may well be considered, depending on the availability of funds. Under this method, unit performance, when appropriate, will be a separate weighting factor in the overall ratings of employees in exceptional units.

Performance by Objectives. The performance appraisal process will be initiated by circumstantially dictated needs (rather than a statutory requirement) to determine the compensation of employees. Both employee and supervisor will be more concerned over performance standards that affect employee pay; this additional concern will cause greater and more effective communication between the two. Under the concept of Performance by Objectives that will be used, the above broad standards will serve as a base for communication to establish mutually discussed objectives between supervisor and employee over specific expectations for the upcoming performance period. The objectives may be modified during the performance period to accomplish changes in work load planning, resource allocations, etc. Communication and written performance standards will move

increasingly in the direction of Performance by Objectives. Objectives that are understood by both supervisor and employee should be measurable to the extent possible and should provide for continuing improved performance to meet these objectives. The attributes initially developed will be keyed to areas where improvement is needed. Identification of these areas will aid in identification of training requirements used in developing individual training plans.

Organizational Objectives. A modified system of Management by Objectives, coupled with individual Performance by Objectives, will be tested. Overall management objectives will be communicated by means of discussions between top Center management and intermediate managers on performance expectations during the coming year. These overall expectations as translated for lower level implementation will be complemented by individual functional and task performance standards of a general nature. This system, as depicted in Figure 4, permits inputs from all management levels on the development of standards for individual professional performance of functions translated into specific tasks and on particular management objectives.

In an example of this system, an employee's functions, tasks, and attributes might involve serving as a project leader, gaining project acceptance and funding from the Washington-level sponsor by the use of strong technical knowledge, demonstrating organizational skills, and generating capable oral and written communications. Measurement of these established general performance expectations could then be accomplished by having the employee meet general management objectives, such as enhancing Center impact in Navy command control and communications by obtaining Center tasking for a specific high-potential project.



* SUCH AS PROFESSIONAL MEMBER, ELECTRONICS ENGINEER (WEAPONS SYSTEMS).

FIGURE 4. Performance by Objectives System for Performance Appraisal.

Schedule and Mechanics of Appraisals and Incentive Groupings. The performance of employees and supervisors will be reviewed every 6 months. However, appraisals will be completed and pay will be adjusted annually. An employee whose performance, as judged against performance standards, is deemed unsatisfactory will be warned, and, if appropriate, adverse action will be taken. In Incentive Group N of employees and supervisors, performance will be judged as needing improvement (not low enough for adverse action but not high enough to fully meet objectives). Those performing in this category will receive no increase. Those with performance judged to be below objectives in some respects, to have met objectives, to have exceeded objectives, or to be outstanding will receive consideration for incentive increases and will be placed in Groups B, M, E, and O. The amount of increase to be received by individuals in these groups will be determined by individual supervisors and reviewed by high-level supervisors. Involvement of higher-level management will be used to ensure a broad-based equity among employees in separate work groups.

Review Process. All performance appraisals will be reviewed by at least the next higher level of management.

A corrective system exists to deal with problems that occur when individual performance objectives are not established at the outset of the rating period. A higher level of management will then revert to the general established functions, tasks, and attributes and will review the employee's performance against these factors. Overall judgments could still be made by this higher level of review for consistency with overall management objectives. This corrective system will insure that the neglected employee is treated equitably. Naturally, such a major oversight on the supervisor's part would be reflected in his or her performance appraisal and subsequent pay fixing and corrective actions.

The Technical Director or other appropriate level of management will be informed of all incentive pay issues, since these issues and their resolution could impact on the incentive pay of lower-level supervisors. The Personnel Department will be responsible for assisting and advising management in the performance appraisal system, evaluation techniques, dispute resolution, etc. A written performance review for each employee will be required from an appropriate level of supervision. The written review format will be as concise as possible, but sufficiently detailed to define critical job-related standards and objectives. Each performance evaluation will include supervisory comments to provide a written record of the extent to which employee performance meets, exceeds, or falls short of established standards and objectives.

Management Approach. While the performance appraisal system attempts to set specific standards communicated and understood by management, supervisor, and employee, it will still require judgments by those recommending and determining pay increases. Effective operation of this system will therefore require direct action in instances where supervisory personnel consistently exercise poor or detrimental judgments in the performance appraisal process. These poor supervisory judgments will be reflected in supervisors' pay determinations or in removal from their supervisory functions. The furtherance of this demonstration project by complete and equitable judgments of subordinates' performance will be a performance element for each supervisor. The use of high supervisory expectations will insure that supervisors will also be accountable for their increased flexibility in managing their personnel resources. The manager will, of course, also continue to be responsible for ensuring that EEO principles are followed in all personnel decisions.

Compensation

The basis for the demonstration project pay system is the General Schedule. Pay rates for the various levels of responsibility are directly keyed to this schedule. As long as GS grades exist, necessary linkages with comparable rates will be accomplished through this means. Subsequent adjustment of GS grades to locality rates, as proposed in the current Compensation Bill, will not disturb the demonstration project relationship with the GS grades. At a time when no GS system may exist, the broad levels of the demonstration project will readily serve for comparison of Bureau of Labor statistics with private enterprise pay to determine comparability. Various alternatives will be explored to maintain general equity between employees who meet objectives and their "satisfactory" counterparts in the GS pay system.

Incentive Group N, as described earlier, is a zero-increase category. This category is reserved for employees who need improvement in some respects. While these employees are not sufficiently deficient in performance to merit immediate adverse action (placement in a lower classification level or separation), they do not merit a pay increase. Employees in Groups O, E, M, and B will receive an increase in base pay, the amount of which will vary, depending on the incentive groups to which these employees are assigned. These employees may receive a bonus amount for membership in organizational elements that are rated Outstanding in performance, depending on the availability of award funds.

The "pay based upon performance" concept, when fully implemented, will result in a redistribution of current pay resources based upon individual and unit performance measured against predetermined standards. Properly developed individual standards and unit objectives that focus on mission requirements, invididual and organizational productivity, and management goals will insure that employee rewards are tied directly to greater efficiency and improved agency operations rather than to longevity or other artificial measures of worth.

The mechanics for accomplishing the redistribution of the funds pool will be as follows. The distribution of the pool of funds will be based on individual assignment to one of five individual incentive pay groups. Performance of individual employees will be appraised in August by their immediate supervisors against the performance standards established at the beginning of the rating period; employee performance will be reevaluated halfway through the period. Table 6 defines incentive groups and shows how the "individual incentive" portion of the pool will be distributed. If unit incentives are used, the "unit incentive" portion of the funds pool will be distributed in equal shares to all but Group N employees of unit identified by management as high-achieving organizations. This amount will be paid in the form of a bonus and will not become part of employee base pay for the purpose of computing the next year's increase.

Employees whose performance ratings place them in Incentive Group N or B will recieve no or limited pay increase and as a result will "migrate" downward. If incentive pay placement continues in Group N or B, employees who reach the bottom of the overlapping scale (they remain identified in the higher classification level as long as they are covered in that range) will cross the line into the next lower classification level without specific adverse action. This migration is necessary for an employee whose performance over a period of time has been deficient enough to merit the employee's placement in lower level duties/responsibilities where new opportunities for acceptable performance exist. Clearly the employee who has experienced several performance evaluations and who, in each case, has been given a year to demonstrate improvement has been provided equal or better "due process" than the obviously unsatisfactory employee who is accorded immediate performance-based action procedures and downgraded or removed after the required 30-day notice period. Further, it should be noted that in these instances the employee's pay will remain constant. The downward migration results from the need to comply with statutory pay levels. Performance-based action procedures will cover demotion between levels or removal where performance is clearly so unsatisfactory as to preclude even placement in Incentive Group N.

Table 6.—*Distribution of Individual Incentive Funds*

Incentive group	Performance	Pay adjustment rate, percent
O[1]	Outstanding—far exceeds standards for acceptable performance	x+y
E[1]	Exceeded objectives—exceeds standards for acceptable performance, but not sufficiently to warrant assignment to Incentive Group O.	x+w
M	Met objectives—fully meets standards for acceptable performance	x
B	Below objectives—does not fully meet standards for acceptable peformance.	x/2
N	Needs improvement—needs improvement for work to meet established standards.	O

x=Comparability Plus: a percentage increase based on the annual comparability increase plus average annual within-grade increases and within-level career promotions.
y=An additional share (based on percentage) of the remaining funds.
w=An additional share (based on percentage) of the remaining funds, somehwat smaller than Group O share.
Incentive Groups E, M, and B will be considered one group for RIF purposes.
[1]Funds for O and E ratings will be generated primarily from funds formerly devoted to quality step increases and sustained superior performance awards. This resource will be complemented by any funds made available as a result of N and B ratings.

Pay and Grade Retention. The CSRA provision of pay and grade retention is inconsistent with this performance-based demonstration project. (It is noted that these provisions to save grades and pay seem specifically designed around problems of the GS classification and RIF systems and the inflexibilities associated with these systems.) Consequently, pay and grade retention are neither desired nor required. Waiver of this provision is requested, although the option is requested of developing a pay retention system for certain actions such as (but not limited to) Upward Mobility and Application of New Classification Standards.

Promotions. Promotions from one classification level to the next will follow basic federal merit promotion practices either competitively or, where appropriate, as exceptions to merit promotion. At the time of promotion the promoted employee will be granted an increase of no less than 10% of basic compensation. This minimum increase is subject to review and change if equity with GS system counterparts is not attained. (Basic compensation is defined as the original base pay plus any *continuing* salary increase.) The only immediate constraints to this promotion policy will occur with promotions from Level IV to Level V; in such a case, the incumbent's current salary would be close enough to any statutory limit imposed on federal salaries to preclude awardng a full 10% increase.

Minimum time-in-grade requirements will be as follows: Level I—12 months for eligibility to Level II; Level II—12 months for eligibility to Level III; Level III—12 months for eligibility to Level IV; Level IV—Eligibility for Level V determined at agency level; Level V—Not established.

As is presently the case, each Center, depending on local determinations, can establish appropriate TIG guidelines that may exceed the above minimum TIG. Any exceptions to this minimum TIG will require competitive selection from an OPM or other authorized certificate-of-eligibles at a GS grade equating to the next higher demonstation project pay level.

Entry Into and Exit From the Project

Entry into the project will be best accomplished through a "full employee protection" approach that ensures each employee an initial place in the demonstration without loss of pay. An automatic conversion from current GS grade and step into the new level and pay will be accomplished.

Mechanisms will be explored that will protect an employee's entitlement to a higher rate than the limit on GS salaries at the time of entry; that is, employees currently at the statutory pay ceiling will receive adjustments at the point Congressional approval is given to revise the ceilings upward.

Automatic Conversion. Reasons for accomplishing this automatic conversion are the time constraints of the necessary start-up time and the need for extensive training of supervisors and managers in the pay for performance concept. Employees will enter the system at the same dollar salary they hold in the GS system at the time of entrance. This automatic entrance will result in employee placement without loss in pay in the demonstration pay level comparable to GS rate. Employees will automatically hold an initial rating placing them in Incentive Group M from entrance until October 1980. At the October 1980 rating, employees will either remain in Incentive Group M and receive an increase in an amount equivalent to the October GS comparability increase or be placed in Incentive Group O and receive an additional amount based upon current criteria for granting quality salary increases and sustained superior performance awards. At that time no employee will be placed in Incentive Group E, B, or N. By August 1980 performance standards for each employee are scheduled for completion; each employee will be advised and consulted on these standards for the next performance period August 1, 1980 through August 1, 1981). The first full demonstration project adjustments will occur on October 1, 1981, with placement in appropriate incentive groups based on standards implemented on August 1, 1980 and performance during the period August 1, 1980 to August 1, 1981. The period from August 1, to October 1, each year will permit time for supervisory review of ratings. Establishment of specific rates will be effective annually at the beginning of the first pay period on or after 1 October.

New Hires. Newly hired personnel entering the demonstration project will be employed at a level consistent with duties and responsibilities of the position and individual basic qualifications for the level, as determined by rating keyed to existing X118 qualifications standards. Each Center will determine in-hire pay rates within the classification level as related to market conditions reflected in Bureau of Labor statistics or other measures. Salaries of individual candidates will be based on academic qualifications, experience, and educational substitutions.

Candidates with similar qualifications as determined above will be paid equivalent starting salaries within each classification level.

Special Pay Rates. Special rate ranges will be translated from their GS base and used where such translated rates are advantageous and provide greater flexibility in the top rates of the level. Because of the *performance-related* pay practices of the demonstration project, special rate ranges will not be used to provide automatic increases for all employees within special rate range occupations.

The representative rate definition used in the General Schedule will be replaced by a "base grade" principle. The "base grade" is the GS grade most comparable to the demonstration project level and salary as determined by the most recent project event (i.e., project entrance, incentive pay determination, promotion, or demotion). In instances where the current salary is in the area between two overlapping GS grades, the base grade is either (1) the higher of the two overlapping GS grades if the current salary meets or exceeds Step 4 of the higher GS grade, or (2) the lower of the overlapping grades if the current salary is less than Step 4 of the higher GS grade.

Exit from the project, if necessary, will be a simple, straight-forward pay protection procedure using the "base grade principle." The employees exits at the dollar amount of salary currently received matched to the appropriate grade and step in the General Schedule. This placement will consititute the basis from which the existing employee competes in a RIF action or is transferred, reassigned, or terminated. Upon exit from the system, NWC an NOSC billets and grades will be adjusted in an equitable fashion to those of other Navy laboratories.

Where the above salary fixing would result in placement in normally unused even grades (GS–6, –8, or –10), placement will be at an appropriate two-grade-interval grade according to the above "base grade" rules.

Prior to exit of employees from the demonstration project, each employee will be converted back to the appropriate GS grade, using the base grade principle. An information sheet describing the demonstrating project and the conversion procedure will accompany the Official Personnel Folder (OPF) to the new employing office as a permanent record in this OPF. This same documentation exit procedure will be used for exiting employees in any necessary instance.

Reduction in Force

Major modifications are proposed, including limiting competitive areas to career fields (Professional, Administrative, Technical, and Clerical) and ranking personnel within each competitive level primarily on the basis of incentive pay groupings and secondarily on the basis of the normal elements of tenure, veterans' preference and service computation date. These modifications will substantially increase the probability of retaining the highest-performing individuals in their positions and will also increase the probability of displacement of the lowest performing individuals. For better understanding, a diagram of this system is provided in Figure 5.

The following specific characteristics will apply to the RIF process, as it is proposed for this demonstration project.

A competitive level will include all positions of the same career field (e.g., professional), the same difficulty level (e.g., Level III), having substantially the same duties and qualifications requirements (e.g., Electronics Engineer (Computer Hardware Design)).

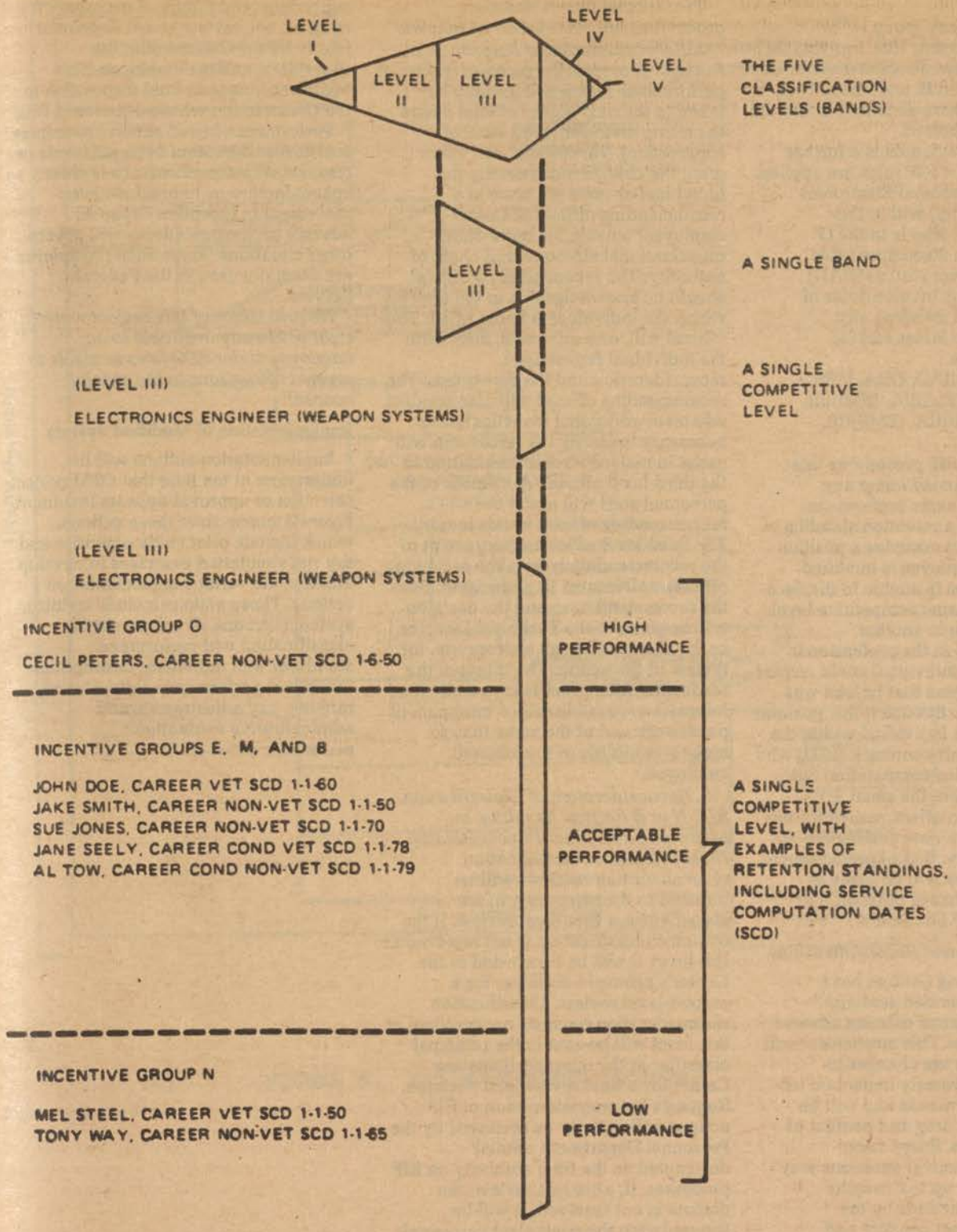
Competitive areas will be limited to career fields only. S&Es will compete only with other S&Es for retention. This added special feature will limit the disruption that results when, for instance, engineers are offered clerical, messenger, or laborer positions. This will also permit managers to reduce S&E work forces without affecting employees in the administrative, clerical, wage grade, or technical career paths when there is a requirement to reduce only the S&E work force.

Retention will still be based upon career status, veteran's preference, lenght of service, but it will depend primarily on the pay incentive grouping. Veteran's preference will also be modified to give retention recognition to 30% or greater compensable disabled veterans (called 30-compensable veterans), as recently enacted into legislation. A competitive level structure from highest to lowest retention standing would look as follows:

Incentive pay group	Career (I) or career conditional (II)	Veteran (A) or nonveteran (B)	30-compensable (D)
0	I	A	D
0	I	A	
0	I	B	
0	II	A	D
0	II	A	
0	II	B	
[EMB]	I	A	D
[EMB]	I	A	

Note.—Sequence repeats for Group E, M, and B competitive level structure; then for Group N.

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(R) **FIGURE 5. Categorization of Professionals for the Proposed RIF Process.**

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The incentive pay group is the primary displacement tool. Individuals in Group O always displace individuals in Group E, M, and B, and Group N. E, M, and B performers displace Ns and the lowest Ns are released.

The following example is a further illustration of how RIF rules are applied. A Level III professional Electronics Engineer (specialty) within this competitive level who is in the O grouping and is a 30-compensable veteran with career status (OIAD) would *displace* by inverse order of competitive level standing any:

1. OIAD with a lesser service computation date.
2. OIA, OIB, OIIAD, OIIA, OIIB.
3. [EMB]IAD, [EMB]IA, [EMB]IB, [EMB]IIAD, [EMB]IIA, [EMB]IIB.
4. NIAD, etc. . . .

Under normal RIF procedures this same individual could *bump* any individual in the same professional career field with a retention standing of OIA or lower who occupies a position for which the employee is qualified.

If this employee is unable to displace someone in the same competitive level or bump someone in another competitive level in the professional career field, this individual could *retreat* to a Level II position that he/she was promoted from or through if this position is occupied by an individual within the same retention subgrouping (OIAD) who has a lesser service computation date.

Succinctly stated, the usual RIF system remains in effect, except for the establishment of a new and higher retention category: that of performance. This new category will be likely to ensure the retention of outstanding individuals in RIF situations.

Adverse Actions and Reconsiderations

The participating Centers have available a "suspended sentence" procedure to enhance existing adverse action procedures. This mechanism will be used to encourage changes in behavior that adversely impact on job conduct or performance and will be useful in alcohol/drug and conflict of interest situations. Suspension, demotion, and removal decisions may be suspended for up to 6 months pending specific actions by the employee to correct conduct and performance. The penalty may be canceled if conduct or performance problems are resolved. The penalty be effected if the employee does not cooperate with Center efforts to bring about the needed changes. The organization's expectations will be provided to the employee in writing.

Two special reconsideration procedures are established as follows:

1. *Reconsideration of Performance Ratings.* A request for reconsideration of performance rating will initially be taken to the next higher official above the rating reviewer (third level of supervision). This official can either grant the change requested by the individual or refer the issue to a recommending official (a Center employee) outside the immediate organizational structure and chain of authority. The recommending official should be knowledgeable in the area on which the individual is being rated. This official will, as a minimum, meet with the individual requesting reconsideration and the supervisor. The recommending official will also conduct whatever additional investigation is necessary to clarify the issues and will assist in making a recommendation to the third-level official. A member of the personnel staff will assist the recommending official in this inquiry. The third-level official, after receipt of the recommendation from the reviewing official, will issue a final decision. Both the recommendation and the decision will be given to the Technical Director or the Commander, as appropriate, for review of the action. The intent of the reconsideration process is to make it as informal as possible with a minimum of paperwork and at the same time to make it equitable to the affected employee.

2. *Reconsideration of Classification, RIF, N or B Ratings Resulting in Migration, and Other Project-Related Dissatisfactions.* Classification reconsideration requests will be directed to the supervisor of the classifier for a first-level review. If the disputed classification is not resolved at this level, it will be forwarded to the Center's principal classifier for a second-level review. Classification reconsideration requests not resolved at this level will be sent to the principal classifier at the other participating Center for a final review and decision. Requests for reconsideration of RIF actions will initially be reviewed by the Personnel Department official designated as the final authority on RIF processes. If, after this review, the dispute is not resolved, it will be forwarded to the equivalent personnel specialist at the other participating Center for final review and decision. N or B ratings that result in a migration to a lower classification level and other dissatisfactions related to the demonstration project will be presented for resolution (a) to the immediate supervisor, (b) to the second-level supervisor, and finally, if necessary (c) to an ad hoc review board appointed jointly by the Commander, the supervisor, and the employee. This board recommends final disposition to the Commander, whose decision is final.

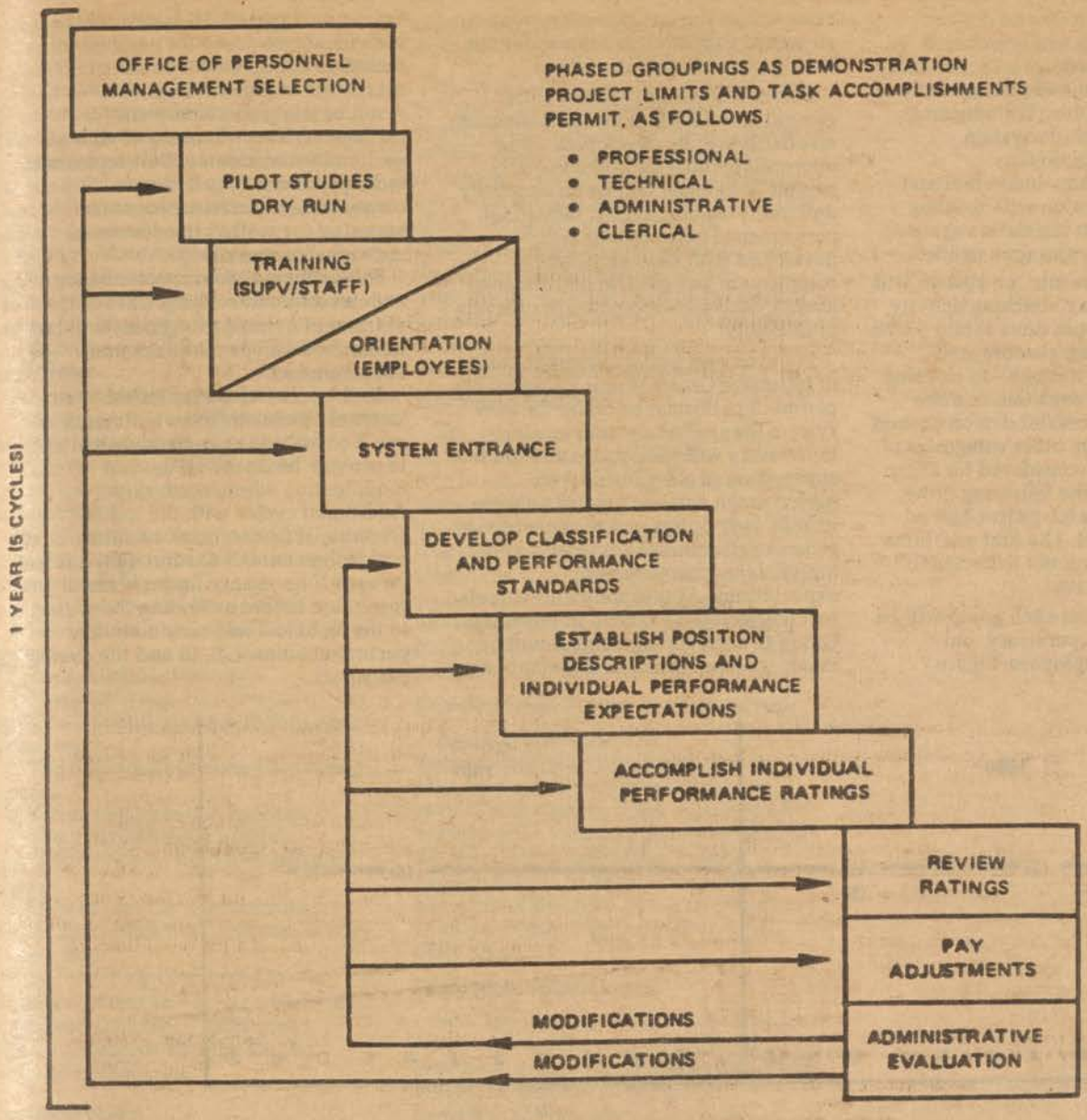
Performance-based action procedures will govern demotion between levels or removal where performance is clearly so unsatisfactory as to preclude even placement in Incentive Group N; adverse action procedures will govern other situations where such procedures are normally used in the Federal Service.

No provisions of this project waive a right or remedy available to an employee under EEO laws or rights to present allegations to the special counsel.

Implementation of Modified System

Implementation actions will be undertaken at the time that OPM project selection or approval appears imminent. Figure 6 summarizes these actions, which include pilot study activities and dry run simulation exercises to develop and test the various implementation actions. These actions include training, system entrance, development of classification and performance standards and individual descriptions, individual performance ratings, group ranking, pay adjustments, and administrative evaluation.

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(R) **FIGURE 6. Implementation Actions.**

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Using the pilot study and dry run results, the training and orientation phase will focus initially on supervisory and staff personnel and subsequently on employee participants. Training and orientation will include system description and functions, implementation plans, individual and group roles, interaction with existing and planned reform legislation systems, and special skills training as needed.

Initially, entrance into the system will be a mechanical pay matching activity as spelled out in a previous section, with professionals, administrators, and technicians GS–13 through –15 entering and proceeding through one or more cycles. After a successful demonstration with the base group, other categories of employees will be considered for entry into the project in the following order: Technical and Administrative below GS–13, and Clerical. The first additions to the base group are not expected to occur until August 1981.

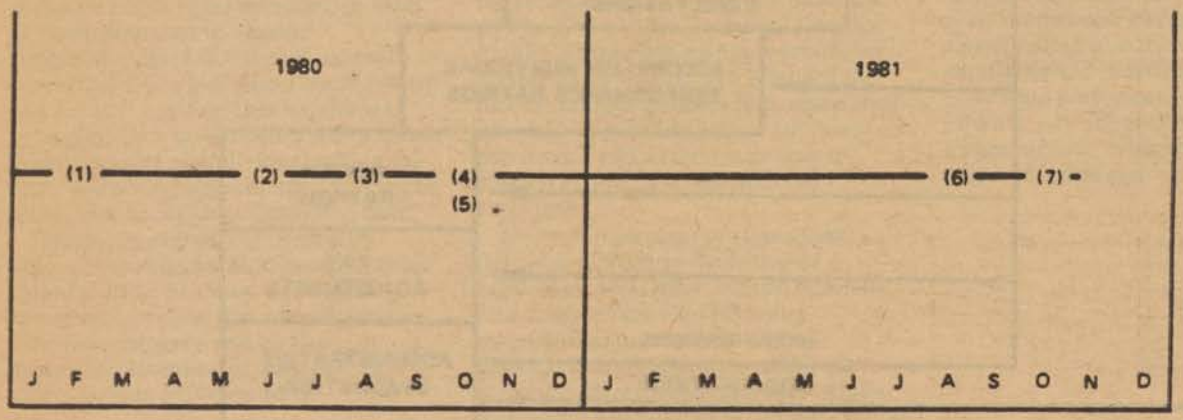
Implementation for each group will be simultaneous for supervisory and nonsupervisory employees. Figure 7 summarizes the initial implementation steps and expected milestones for the first implementation increment.

Before mechanical system entry, general classification and performance standards will be developed, using appropriate industry and university models. Emphasis will be on simplicity and utility. Subsequently, individual performance expectations will be developed with each employee to complement any general performance standards associated with group levels of difficulty.

Following an initial automatic rating in Incentive Group M and a reasonable period of performance under the new system (as spelled out previously), individuals will participate with their supervisors in a review of their performance and accomplishments in light of their duties and responsibilities, general performance standards, and individual accomplishment expectations. At this point, individuals will tentatively be placed in Incentive Group O or M and agreement will be reached on performance expectations for the next period. High-performing individuals proposed for assignment to Incentive Group O will be screened for placement in Incentive Group O as a result of joint supervisory and managerial forced ranking of all high performing candidates. Development of these processes may include consideration of unit performance appraisal, as well as the discussed individual appraisals.

Following individual performance reviews and unit ranking, final placement in incentive groups will be authorized and pay adjustments accomplished.

Each cycle will be subjected to an internal administrative verification to see if objectives are accomplished and to provide feedback for system modification where necessary. Additional cycles with the initial grouping of professional, administrator, and technician GS–13s through –15s will be used if necessary for problem resolution before extending the system to the technical and administrative personnel below GS–13 and the clerical personnel.



(1) DEVELOP PERFORMANCE AND CLASSIFICATION STANDARDS
(2) ENTER PROJECT
(3) COMMUNICATE STANDARDS
(4) COMPUTE INCREASE FOR O AND M RATINGS
(5) MAKE TRIAL APPLICATION OF INCENTIVE PAY
(6) COMPLETE ALL RATINGS
(7) MAKE INCENTIVE PAY ADJUSTMENTS FOR ALL FIVE INCENTIVE GROUPS

FIGURE 7. Schedule for Initial Implementation Steps.

Training

The key to the success or failure of the proposed demonstration project will be the training provided for all involved. This training will not only provide the necessary knowledges and skills to carry out the proposed changes, but will also lead to commitment to the program on the part of all participants.

Training at the beginning of implementation and throughout the 5-year demonstration will involve three segments of the organization.

1. Supervisors of demonstration employees.
2. Demonstration employees.
3. Administrative staff responsible for assisting managers in effecting the changeover and operation of the new system (generally personnel professionals).

The elements to be covered in the orientation portion of this training will include the following:

1. A description of the system.
2. How persons are entered into the system.
3. Pay adjustment process.
4. Familiarization with the new position descriptions and performance objectives.
5. The individual performance rating process.
6. The reconsideration process.
7. The demonstration project administrative and formal evaluation process.
8. How to exit the demonstration project and return to the present system, if necessary.
9. Instruction and practice in the objective-setting skills that will be used in the Performance by Objectives process. Intensive training will be provided in this area.

Line Supervisors

Since the essence of the proposal is a "management-centered personnel administration process" with "increased personnel management authority (for) the line supervisor," it will be of critical importance to provide the necessary knowledges and skills to managers and line supervisors. The training for line managers will include detailed information on the policies and procedures of the new system. Also included in the training will be skills training in performance appraisal, objective-setting, and discussion of objectives with employees. As a minimum, a 16-hour class in Personnel Resource Management that includes both the procedural aspects and the skills training will be necessary for all supervisors involved.

Employees

Not only will the nonsupervisory employees need to be informed and oriented to the new system, but they will also need skills training in order for the system to succeed. Few employees spend much time on personal objective-setting when there is no pressure or incentive to do so; employees therefore may lack the necessary objective-setting skills. Consequently training in objective-setting will be necessary for the employees as well as for the supervisors. At least eight to 12 hours of training that will combine orientation to the new system and training in objective-setting are proposed.

Administrative Staff

The administrative staff (generally personnel specialists) will play a key role in assisting, training, and coaching managers and employees in implementing the new system. This staff will also need experience in preparing standards and applying them. As a minimum, a 24-hour workshop is foreseen as necessary to provide the required knowledges and skills to this group.

Demonstration Project Evaluation Plan

A comprenhensive and methodologically rigorous evaluation plan for the proposed demonstration project is necessary if the objective of assessing the merits of generalization of the results throughout the Federal Government is to be met. Essential elements of this plan are set forth below in as much detail as is possible at this early stage.

Evaluation Effort Phases

Because this experiment will include major modifications in core federal personnel practices, an evaluation effort that is inclusive must occur. An overview of that effort is provided below.

Formative Phase

The initial phase, which is already under way and which will accelerate once Office of Personnel Management project selection decisions are made, is the evaluation effort that is intended to aid in structuring the experiment. During this phase the following efforts will be undertaken:

1. Identification and description of the experimental and control groups that are to be the subjects of the demonstration project.
2. Establishment of a set of pre-project data and criteria that will provide the baseline for the experiment (these will include goal-oriented data and criteria, goal-free data, and selected environmental factors).
3. Assistance in further refinement of the "treatments" that are intended to be administereed to the experimental

groups. Current personnel management practices of the public sector, private industry, and universities will be surveyed for insights into treatment options (such management practices might include the performance evaluation processes employed by companies like Southern Railway and Honeywell Inc. and the incentive pay systems in use for faculty compensation at selected universities). In addition, existing literature will be reviewed and an analysis of recent DOD and GAO studies of Project REFLEX will be scrutinized for insights.

4. Establishment of recommendations on the training that will be required for Center managers and employees as a corollary to the experiment.

Experimental Phase

Once the experiment is under way, performance monitoring evaluation efforts will be conducted. Data will be continuously collected on a wide range of measures, and periodic reports will be issued, indicating the extent of experimental treatments and effects. Measures of inputs, processes, and outputs will be recorded. Instruments will be periodically administered to collect reactive data from individuals within the experimental and control groups and from external actors such as the sponsors of the Centers' work and the users of their outputs. Interim reports on the evaluation effort will be issued to Office of Personnel Management, Director of Navy Laboratories, Assistant Deputy Chief of Naval Operations (OP–14), and management of each participating laboratory.

Summative Phase

Upon conclusion of the experimental period, an assesment of the impacts of the experiment will be undertaken. Every effort will be made to establish cause-and-effect relationships. Pre- and post-data for the experimental and control groups will be studied in light of changes in the external environment, which will have been monitored during this time frame. The degree to which the experiment has proved effective and efficient in meeting the stated goals and objectives will be assessed. In addition every effort will be made to gauge the goal-free effects of the experiment. Anticipated and *unanticipated* effects (positive and negative) will be examined in this post-project phase. Separate final project reports will be issued by the internal and external evaluation teams.

Evaluation Philosophy

Management scientists have provided a generic formula. They hold that: P is a function of $U + C$ where P equals perfomance, U uncontrollable variables, and C controllable variables.

The underlying argument of the proposed demonstration model is that the performance of Navy Laboratories can be substantially improved if core personnel management processes can become more controllable by goal-oriented line managers. In the present situation, these personnel management processes are viewed as uncontrollables or constraints.

Behavioral scientists offer a slightly different formula. They argue that by manipulating independent variables (supervisory practices), one initially affects "intervening" variables (employee satisfaction, longer time frame), "end result" variables (productivity, goal accomplishment, effectiveness).

Independent→Dependent (Intervening)→Dependent (End Results).

Both of the above formulas are pertinent to the methodology to be chosen for this experiment. Together they suggest the need for an inclusive data collection effort that encompasses controllable and uncontrollable variables, short-run measures of a "reactive" type, and longer-run measures of the impact of the experiment on goal accomplishment of the overall organization. Multiple criteria for evaluation of the experiment are a necessity.

Evaluation Measures and Criteria
Measures

Evaluation literature draws a distinction between reactive research and measures and nonreactive or "unobtrusive" research and measures. The former refer to methods of research that involve researcher-researchee interactions in which reactions are given to questionnaires and interviews. People report their perceptions in response to questions posed them. For example, they might be asked their perceptions of the effectiveness of a Center or of pay equity. Certain biases are built into these measures, for example, the questions asked or not asked and the manner in which the questions are asked.

Unobtrusive measures, on the other hand, do not rely on people's reactions; they are collected from impersonal sources, such as existing records and reports. These measures are also biased in that they are dependent on previous judgments on what records should be kept and what reports should be written.

A strong argument can be made that exclusive reliance on either reactive or nonreactive measures is hazardous. For that reason, the evaluation design will incorporate both types of measures during each of the evaluation phases.

Evaluative Criteria

Evaluative criteria will be deduced from the goals and objectives stated for this experiment. As discussed earlier, multiple criteria will be developed. Some will be quantitative (cost-effectiveness), others more qualitative (perceived effectiveness, equity). Many specific criteria will be measured through use of previously validated instruments (such as organizational health inventories, the OPM Attitude Survey, an organizational commitment questionnaire, and Likert's and Herzberg's job satisfaction instruments). New data collection methods may be required for some criteria.

Evaluation Design Logic

The basic assumption of the demonstration project is that the performance of Navy laboratories can be improved substantially by implementing the proposed changes in personnel management processes. The proposed changes will place emphasis on a higher degree of involvement in and control of the personnel management processes by line managers.

The proposed demonstration project involves four major changes in existing personnel management processes: (1) A revised classification structure; (2) a revised system for determining the pay of individuals; (3) a new performance appraisal method; [1] and (4) suspended penalties for adverse actions. Indivually and in combination, these changes are expected to positively affect a cluster of personnel subsystem performance variables, supervisor and employee job satisfaction along a number of dimensions, performance of individuals and of organizational units, and overall laboratory performance.

Project Variables

Figure 2, which shows the conceptual evaluation schematic of the proposed major change sand goals, is repeated here for reader convenience.

The proposed major changes of the project are in the following areas: 1. Classification structure; 2. Pay system; 3. Performance appraisal system; [2] 4. Adverse actions.

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[1] The revised performance appraisal method will discriminate among workers in terms of level of performance. These discriminations will be factors in the proposed RIF process.

[2] Encompasses modified RIF criteria.

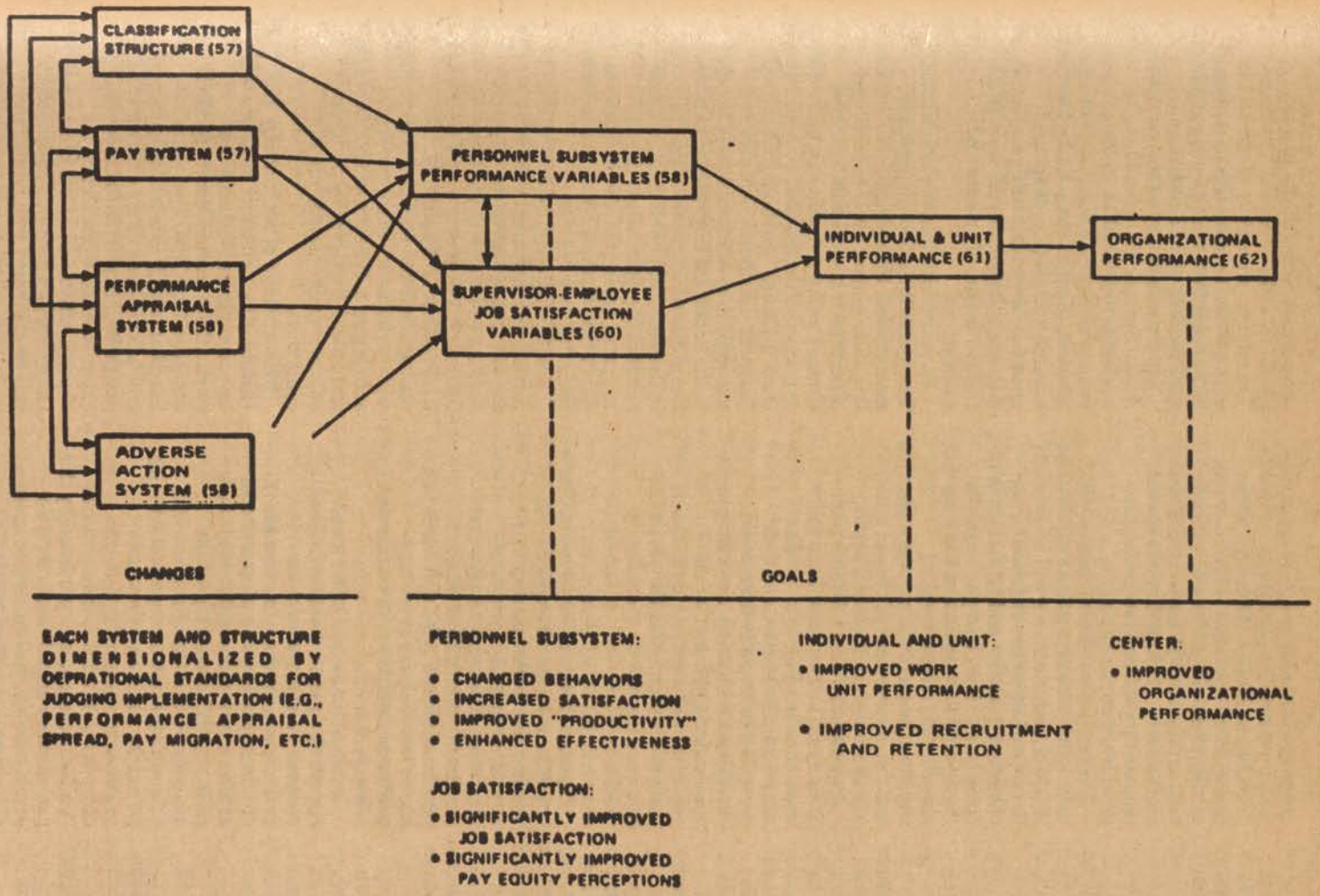


FIGURE 2. General Evaluation Schematic for Demonstration Project. The relationships between implementation of the planned changes and variables to be evauated are shown. Numbers in parentheses refer to corresponding pages in this proposal for further discussion.

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Dimensions of the classification structure and the pay and performance appraisal systems will be converted to variable status and used in combination to measure variance in implementation at the level of *organizational units.*

Personnel subsystem performance variables that are expected to be positively affected by the changes include productivity of the personnel subsystem, recruitment success, turnover (under normal and RIF conditions), and line management and employee satisfaction with the personnel processes.

Supervisor and employee job satisfaction are expected to be significantly increased by the implementation of the revised personnel management technologies noted above. Overall job satisfaction, perceived pay equity, and motivation are expected to be significantly greater among supervisors and employees who perform at satisfactory or superior levels than among personnel needing performance improvement.

It is expected that *organizational unit performance* will be dependent upon *individual performance* and will vary in relation to the extent that the proposed personnel processes are implemented by unit line managers, with *personnel subsystem performance variables* and *supervisor-employee job satisfaction* serving as important intervening variables.

It is expected that *Center performance* will vary in relation to the extent that revised *personnel management technologies* are implemeted in the organization with *personnel subsystem performance, supervisor-employee job satisfaction,* and *individual and organizational unit performance* functioning as important intervening variables.

Implementation Measures

The measures of implementation will be congruent with the methods and procedures developed to guide decisions on such major changes as classification, pay allocation, and performance appraisal (e.g., the algorithm that will be constructed for pay setting so that administrators will be able to monitor and control the allocation of pay).

Fundamentally, the extent of implementation of a change in a personnel process will be measured by the degree to which each of its major dimensions is actually achieved. The dimension is in effect a goal. For example, the performance appraisal system is intended to increase the extent to which supervisors discriminate between levels of performance. Thus, for this dimension, implementation will be measured statistically by the extent to which supervisors produce an equitable "evaluation spread." Similarly, when performance appraisal is linked to pay setting, it should produce direct and visible relationships between pay and performance. High performers should migrate upward and low performers downward on the pay scale.

The implementation measures will have either face or content validity. Two levels of such measures will be used: (1) Records of behaviors required by the change in question, and (2) measures of consequences, such as pay migration, that should flow automatically from the change. The measurement of implementation of the proposed changes and the achievement of project goals (dimensions) are discussed below.

Implementation of Classification Structure. The key question in this evaluation is whether or not line supervisors have allocated their personnel to levels in the revised classification structure according to the standards established by the implementation project staff. The method of determining the answer to this question will be to conduct a validation check and use a ratio of correct to incorrect allocations.

Implementation of Pay System. The question to be examined in the case is whether pay increases vary in accordance with performance appraisals. The hypothesis is that implementation of the changed personnel technologies will result in a higher increase in pay for high performers and lower or no increase in lower performers.

Implementation of Performance Appraisal System. The questions of concern for evaluation of the performance appraisal system are (1) did the supervisors develop task and attribute performance standards that meet project criteria; (2) did the supervisors develop objectives with subordinates that meet project criteria; (3) did the supervisors evaluate performance according to these objectives; (4) what is the statistical "performance spread" produced by the performance appraisals; and (5) do employees feel that the performance objectives and ratings are equitable?

Data required to these questions will be collected for each performance appraisal cycle by reviewing centrally maintained records (copies of performance objectives and performance appraisal reports) and by querying individual supervisors and subordinates.

In the event that a RIF occurs in either Center during the experimental period, data will be acquired to allow a comparison of the effects of the proposed and present RIF processes. The relative proportion of workers in each performance category that would be bumped from their positions under each process will be determined.

Implementation of a Revised Adverse Action System. The question to be answered in evaluation of the adverse actions structure is whether or not the planned, changed methods for handling adverse actions (e.g., suspended penalties) are in fact being employed; if they are being employed, what is the relative degree of success and satisfaction?

Personnel Subsystem Performance. The planned changes in personnel management technologies will increase line management's role in personnel processes. It is expected that these changes will also result in a basic shift in personnel department activities away from "policing" functions and toward "support" functions. This shift is not expected to result in less need for staff in the Personnel Department (it is more likely that an increased need will occur in the short run) but it is expected to result in changes in how time is allocated among functional activities (labor distribution) and in productivity and efficiency of effort.

Baseline data will be collected and periodic measurement will be done over the life of the experiment on *specific variables* of concern. These are as follows: 1. The productivity/efficiency of the Personnel Departments. 2. Line management and employee satisfaction with performance of the personnel subsystem. 3. Recruitment effectiveness and cost. 4. Turnover by performance category under normal and RIF conditions.

Measurement of productivity and efficiency for personnel functions will be accomplished by using the productivity measurement approach developed by OPM. This sampling-based approach to work measurement will be employed in the experimental and control laboratories before the experiment is begun, during the experiment, and after it is completed. Data acquired from this methodology will be combined with output and budgetary data that will be acquired from existing data sources.

Briefly, the OPM methodology employs detailed categories for the following personnel functions: Staffing, position classification, employee and labor relations, employee development, and general administration and other. A distinction is made between direct and indirect labor, and data are gathered by random sampling. The methodology produces a labor distribution by

personnel function. This distribution by function can be related to personnel function cost data and personnel output data.

It is planned that sampling will be conducted thoughout the 5-year term of the project. Training of supervisors and baseline data collection was initiated in September 1979.

Specific measures derivable from the above methodology will include the following: 1. Cost/functional output (e.g., positions allocated). 2. Percent of time distribution by function. 3. Functional activity/cost. 4. Correlation of productivity and unit cost measure with perceived effectiveness.

Perceived personnel subsystem effectiveness will be measured using data from the OPM Attitude Survey, which is discussed below.

An additional goal of the personnel subsystem is to increase the effectiveness of *recruiting*. Both effectiveness and cost are expected to be affected by the experiment. The enhanced flexibility in setting starting salaries and in classification should permit more timely offers and higher starting salaries for qualified candidates. The impact of the proposed changes upon recruiting will be measured by comparing results at the control and experimental Centers.

The following data will be required from experimental and control Centers: 1. Recruitment interviews, offers, and acceptance by year. 2. Post hiring evaluations by year (experimental Centers only). 3. Recruiter's evaluation of quality (experimental Centers only). 4. Reasons for declinations (experimental Centers only).

Other goals within the personnel subsystem are related to *employee turnover*. The planned changes intended to reward performance are hypothesized to aid in the retention of high performers and stimulate turnover by lower performers. Turnover data will be acquired by performance category, grade level, occupational category, etc.

Job Satisfaction and Commitment. It is expected that the proposed changes in classification, pay, performance appraisal, and appeals, in conjunction with associated changes in personnel subsystem performance variables, will result in improved supervisor and employee satisfaction and attitudes as measured along several dimensions.

An existing OPM attitude survey (the "A" Survey) will be administered in both the experimental and the control laboratories before, during, and after the experiment. OPM is planning a factor analysis and Alpha score analysis of its survey data to dimensionalize the instrument. A preliminary analysis of this instrument shows that data on the following dimensions may be obtained. 1. Satisfaction with performance appraisal methods. 2. Perceived quality of organizational climate. 3. Perceived pay equity. 4. Motivation. 5. Authority relationships. 6. Supervisory effectiveness. 7. Personal satisfaction. 8. Perceived organizational performance. 9. Personnel procedures and policies.

A sampling design for administering this instrument was completed in August 1979. Ideally, samples will be drawn by OPM, and Westinghouse Learning Corporation will be employed to administer the instrument and produce a computer tape. A computer program for analysis of the tape will be prepared at USC, where the data will be analyzed. These analyzed data will be made available to the evaluation teams of the two Centers, and an independent interpretation of the data will be made by the external evaluation team.

Individual and Unit Performance. It is expected that unit performance will vary as a function of the extent to which the unit implements the changes involved in the experiment. One reason for expecting higher unit performance is that individual work effort and performance hypothesis will be tested in the context of models that explicitly recognize the two-way causation between merit pay and level of performance. Other reasons for expecting higher unit performance are (1) attrition will increase among low performing workers, (2) greater flexibility in the recuitment process will lead to an improved quality of new hires, and (3) employee satisfaction and attitudes and organizational climate will improve, as discussed above.

Unit performance measures will be developed and administered cyclically in coordination with individual performance appraisals and pay determination staging. Unit performance measures will be generated from second-level supervisory evaluations, using instruments and procedures selected by the project staff. These measures will be independent of the rater's evaluation of the unit supervisor's performance.

Comparisons across units will be based on the extent to which unit performance improves or declines in relationship to an "idealized" performance target developed by the evaluating second-level supervisor.

Center Organizational Performance. Performance of the two participating Centers is expected to vary in relation to all other variable clusters specified in the research design. Independent evaluations of the performance of the experimental and control organizations will be obtained for purposes of longitudinal and control analyses.

A form of multi-attribute utility analysis will be employed for these evaluations. Selection, weighting, and measuring of organizational performance attributes will be accomplished by the process described below:

1. A group of evaluators competent to appraise the performance of the participating Centers will be identified and asked to serve.

2. Candidate performance attributes will be identified by the USC staff from a perusal of prior laboratory studies.

3. The candidate attributes will be reviewed with the group of evaluators and modified in accordance with these evaluators' judgments.

4. The selected performance attributes will be weighted on the basis of pooled subjective judgments, using guidelines designed to provide a subjectively established ratio scale.

5. The relative weights of the attributes will be normalized.

6. Measurement procedures for each attribute will be agreed upon by the evaluators.

7. Utility functions for each attribute will be decided upon by the evaluators.

8. Measurements will then be made; the evaluators will make these measurements where subjective judgment is required, or they will be accomplished mechanically if appropriate for particular attributes.

9. Weighted measures will then be aggregated across attributes for each Center.

10. Comparisons can then be made with possible idealized scores, both by attribute and by total.

11. Comparisons can also be made longitudinally for a given Center or between experimental and control laboratories over time.

Control

Given the evaluation design described above, cross-laboratory controls are possible for (1) employee satisfaction and attitude measures, and (3) organizational performance measures. Longitudinal and pre- and post-experiment measures will be employed for the other variables.

Additional Evaluation Data

In addition to the above-mentioned measures and data, there will be an ongoing monitoring of existing records and reports on the laboratories. Unobtrusive measures will be kept on such basic considerations as the profile of the science and engineering work force of the laboratories, including EEO profiles to enable measurement of EEO

impact as defined in the uniform guidelines.

The Evaluation Teams

Formulation of the design for evaluation of the demonstration project has taken place through an interactive process between personnel responsible for implementation of the project and participants on the external and internal evaluation teams.

External evaluation team participants are members of the faculty of the School of Public Administration, University of Southern California. The faculty members include a Professor of Research Methodology, two Professors of Public Administration with specializations in Personnel Administration, an Associate Professor with a specialty in Research and Development Administration, and two Associate Professors with degrees in Economics.

Internal teams will be employed at each of the two experimental Centers. Each team will be led by a senior Center employee with a technical background who is thoroughly familiar with the objectives of the demonstration project. Other team members will be drawn primarily from the Personnel Departments and Central Staffs on the basis of their relevant expertise.

The external evaluation team will be responsible to OPM. This team will oversee the collection of reactive data through interviews, the administration of the "A" Survey, and conduct of the work sampling of the personnel subsystems. It will also be responsible for acquisition of the data for evaluating laboratory performance. Data analysis responsibilities will include analyzing both the reactive data mentioned above and data collected by internal team members on all of the other variables described above.

The internal teams will take the lead in collecting regularly recurring data that result from implementing the planned changes in personnel technologies. They will also collect data available from existing records and reports.

All data collected by the external and internal teams will be shared in ways that protect the privacy of individual respondents. Separate analyses will be conducted and interpretive reports will be written by the external and internal teams. Independence of the external evaluation will be assured by having that team report directly to OPM. Figure 8 diagrams the relationships of OPM and the evaluation teams.

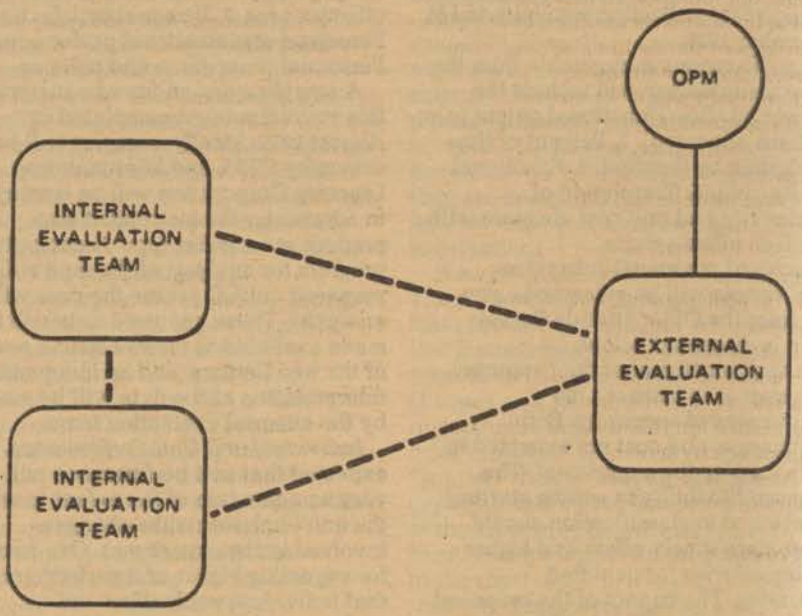


FIGURE 8. Relationships of Evaluation Teams and Office of Personnel Management.

Costs

Efforts will be made to obtain congressional funding for this demonstration project. If congressional funding is not available, the costs associated with the project will be borne by the Department of the Navy and the two participating Centers, with funding provided out of normal activity training and administrative over head funds. Major costs will be in evaluation and in implementation, including Personnel Department costs for training and rewriting standards and costs associated with the development of the demonstration project, such as for travel, research, etc. The total cost of the project for the 5-year period is estimated to be $2,700,000 (in fiscal year 1979 dollars). Table 7 summarizes demonstration project costs.

Table 7.—*Demonstration Project Costs Summarized. All Costs Based on Fiscal Year 1979 Dollars*

Type of cost	Cost to participating organization, thousands of dollars		Total, thousands of dollars
	NOSC	NWC	
Project development	75	75	150
Training	300	475	775
Standards development	150	200	350
Evaluation:			
Internal	450	625	1,075
USC	75	75	150
USC (OPM)			200
Total	1,050	1,450	2,700

Authorities Lacking and Waivers of Law and Regulation Required

Aspects of Project for Which Specific Authorities Are Lacking

Authorities for a number of specific aspects not included in present Civil Service laws and regulations are needed to implement the demonstration project. These include the following:

1. Establishment of broad classification standards for employees and of classification authority for this new system.

2. Creation of broad pay bands within classification levels.

3. Establishment of four separate career paths for Federal white collar workers: professional, technician, administrative, and clerical.

4. Individual placement of demonstration project employees in incentive pay groups during a performance appraisal process based on Performance by Objectives.

5. Addition of performance as the primary determinant for retention in a RIF.

6. Provision for exclusion from existing procedures the downward migration between classification levels for failure to receive pay increases. In these cases, the actual salary of the employees will not be reduced.

7. Use of suspended penalty in certain adverse actions.

8. Establishment and implementation of control techniques that are not currently in the law. The law (5 U.S.C. 5401 (a)(D)) states that merit pay shall regulate the costs of merit pay by establishing control techniques.

9. Provision for establishment of a performance appraisal plan (subject to OPM approval) that follows the basic concepts of 5 U.S.C. 43, but is not necessarily identical to Chapter 43, or OPM regulations established under 5 U.S.C. 4305.

Waivers of Law and Regulations Required

Provisions of Civil Service law or regulation that must be waived in order for this demonstration project not to be prohibited are included in Table 8. No Civil Service rule will be affected by the demonstration project.

Table 8.—*Provisions of Laws or Regulations That Require Waiving* [1]

[Additional waivers may be required because of laws passed or rules and regulations established during the course of the project]

Law	Regulation
* * *	
Sec. 3502. Order of retention for RIF	Sec. 300.601 through .605. Time-in-grade restrictions. Sec. 351.401. Determination of retention standing. Sec. 351.402 (a) through (d). Competitive area. Sec. 351.403(a). Competitive level. Sec. 351.404(a). Retention register. Sec. 351.501. Tenure groups and subgroups, competitive service. Sec. 351.502. Tenure groups and subgroups, excepted service. Sec. 351.504. Performance ratings. Sec. 351.901 through .903. RIF appeals.
Sec. 4303. Only insofar as it applies to the downward movement between classification levels because of failure to receive pay increases.	Part 432. Only insofar as it applies to the downward movement between classification levels because of failure to receive pay increases.
Sec 5101.(1)B and (2). Classification of positions. Sec. 5102. Definitions; application. Sec. 5104. Basis for grading positions. Sec. 5105 through 5107. Related to classification. Sec. 5108. Classification of positions at GS–16, –17, and –18. Sec. 5112(b). Employee and agency requests for classification appeals. Sec. 5114. Reports; positions in GS–16, –17, and –18	Sec. 511.101 and .201 through .203. Classification under the general schedule. Sec. 511.601 through .612. Classification appeals.
Sec. 5303. Higher minimum rates for selected professions. Sec. 5331 through 5336. GS pay rates and step increases. 5361 through 5366. Grade and pay retention. Sec. 5371. Scientific and professional positions. Sec. 5401 through 5402. Merit pay (new law) (CSRA–1978)	Sec. 530.305 through .307. Administration of special salary rates. Sec. 531.201 and .202. Rates of basic pay. Sec. 531.203 (a) and (b). Sec. 531.204. Special provisions. Sec. 531.205. Pay conversion rules. Sec. 531.301 through .305. Adjustment of rates payable to supervisors. Sec. 531.401 through .413. Within-grade increases. Sec. 531.501 through .517. Salary retention.
* * *	* * *
	Part 771. Agency grievance system.

[1] Waiver required only to the extent that this project conflicts with pertinent provisions of law or regulation.

Appendix A—Generalized Description of Project Participants

Responsibilities and Capabilities of Navy Laboratories

Both NWC and NOSC are major research and development field activities of the Naval Material Command and are under the direct command of the Chief of Naval Material (CNM). The Director of Navy Laboratories serves as a focal point for the management of these and other CNM-commanded laboratories.

The laboratories were established as a result of the need perceived during World War II for permanent ordnance research and development facilities. Today's Navy laboratories maintain the capability to carry a development all the way from initial concept formulation through advanced and engineering development to Fleet introduction and support of in-service use. This full-spectrum capability encompasses a wide variety of essential tasks, ranging from basic research to the support of specialized equipment to the creation of new technical options for the Fleet. The broad capabilities of each laboratory are focused on specific responsibilities that are delegated through assigned product areas within an assigned mission.

Although these missions encompass very different areas of expertise, all CNM laboratories have certain special characteristics in common that influence day-to-day operations as well as corporate planning. These include the following:

1. The scope of effort encompasses the full spectrum of Navy research, development, test, and evaluation (RDT&E).

2. Civilian scientific and technical employees work in cooperation with naval personnel to meet Fleet needs.

3. Work is accomplished within rigid constraints on manpower ceilings and grade levels.

4. Funding is managed through the Navy Industrial Funding accounting system.

The laboratories also share significant areas of responsibility that directly affect the responsibilities that must be placed on managers and scientific and technical employees. These responsibilities include the following:

1. Maintain an understanding of the operational and support problems and opportunities facing the Fleet and the Fleet marine forces.

2. Keep abreast of relevant scientific and technical developments of other Navy and DOD laboratories, other service RDT&E activities, universities, and industry.

3. Conduct in-house technology base programs that are complementary to outside activities and tailored to enable the Navy to exploit in a highly discriminating, objective, efficient, and timely way the relevant work of others.

4. Seek new applications of science and technology to Navy and Marine Corps problems; advance the art of branches of science and technology that are of unique or particular importance to the Navy and the Marine Corps.

5. Develop and evaluate new weapon systems concepts to enhance the effectiveness of the Navy and the Marine Corps; prove the feasibility of critical components; build and demonstrate prototypes of such systems.

6. Act as project manager or provide technical direction during the development phase for the acquisition process of new systems, when directed.

7. Provide support, as requested, to Systems Commands and project managers during both the formative stages and the actual design, development, test, and evaluation of new advanced developments, engineering developments, and operational system developments.

8. Act as technical advisors and consultants on matters within their areas of specialty to Navy and Marine Corps Bureaus and Commands and to the operating forces.

9. Maintain and provide the technical knowledge, skills, and facilities to provide prompt, direct assistance to the Fleet, and to support, modify, and improve equipments in use by the Navy and the Marine Corps.

Naval Ocean Systems Center Brief—Mission

The mission of NOSC is to be the principal Navy RDT&E center for command control, communications, ocean surveillance, surface and air launched undersea weapon systems, and supporting technologies.

Personnel

Table A–1 shows personnel data for NOSC, including groupings of scientists and engineers by discipline and by general schedule level (grade).

Funding

NOSC's funding for fiscal year 1978 was $198.3 million, with primary support coming from the Center's major sponsors—Naval Sea Systems Command, Naval Electronic Systems Command, and Director of Navy Laboratories. RDT&E funding by type included approximately 18% for exploratory development, 17% for advanced development, and 17% for operational systems development. Another large funding category was about 17% for operations and maintenance, Navy.

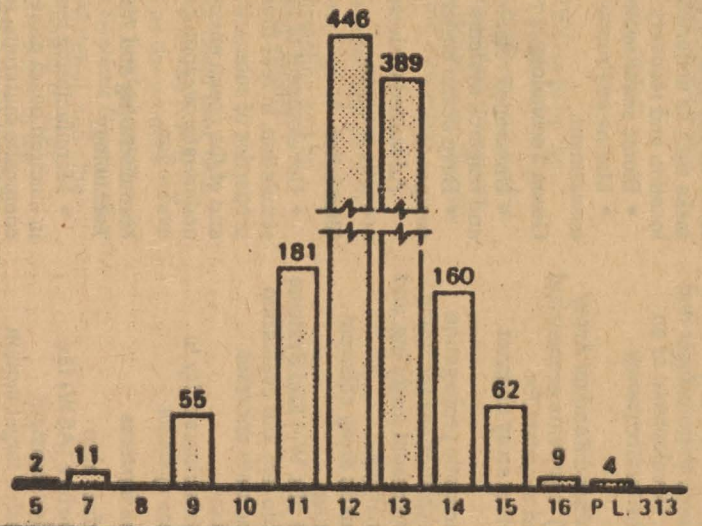
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TABLE A-1. NOSC Personnel Data. Extracted from NOSC Laboratory Management Brief of 30 September 1978.

ON BOARD

MILITARY	CIVILIAN	FTP	TPTI*	UNGRADED (FTP)
278	2549	2493	56	72

SCIENTISTS AND ENGINEERS BY GRADE



GRADED (FTP)
2421

ADMINISTRATIVE	342***
TECHNICIANS	401
SCIENTISTS AND ENGINEERS	1319

ELECTRONICS ENGINEER	683
PHYSICIST	240
MECHANICAL ENGINEER	93
MATHEMATICIAN	79
GENERAL ENGINEER	62
OCEANOGRAPHER	21
OPERATIONS RESEARCH ANAL	62
BIOLOGIST	15
PSYCHOLOGIST	17
CHEMIST	12
OTHER SCIENTISTS	22
OTHER ENGINEERS	13

DEGREES · ALL FTP PERSONNEL

	PhD	DVM	MS/MA	BS/BA
SCIENTISTS & ENGRS.	179	1	460	658
OTHER CIVIL SERVICE	5		61	159
MILITARY OFFICERS	1	3**	28	28
TOTAL	185	4	549	845

CIVILIAN CEILING(FTP)..... 2558

MILITARY ALLOWANCE:
OFFICER 64 ..... ENLISTED 257

*Temporary, part-time, intermittent (summer and cooperative education employees excluded)
**On loan from the Air Force
***Clerical personnel not included

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Facilities

The primary facilities for NOSC are located at San Diego, Calif.; with a laboratory at Kaneohe Bay, Oahu, Hawaii; sea ranges at San Clemente Island, Calif.; and a test range at Morris Dam, Calif. Other activities are located at La Posta, Calif.; Lake Pend Oreille, Idaho; and Cape Prince of Wales, Alaska. Future building plans include an $8.8 million ocean surveillance facility in San Diego.

Program Work

The following excerpt from the NOSC Laboratory Management Brief summarizes program work.

Command Control and Communications (C^3)

- Tactical C^3/1 Land-Based Test Site to ensure system interoperability.
- Integrated Shipboard Data Multiplex System (SDMS).
- Optical communications systems.
- Tri-service communications, navigation, and identification (CNI) system, Joint Tactical Information Distribution System (JTIDS).
- AN/USC–34 Link 11 System providing real-time communications capability for Naval Tactical Data System (NTDS).
- AN/UYQ–21 modular display suite development and evaluation.
- Advanced command and control technology development.
- VERDIN/Enhanced VERDIN, for improving submarine communications.
- Provision of a timely and reliable communication capability with the Fleet Ballistic Missile Submarine.
- System engineering to define Navy satellite requirements.
- Secure voice conferencing to ensure world-wide military command effectiveness.
- Timely and reliable minimum essential communications in electronic countermeasures (ECM) environment (low probability of interception/anti-jam—LPI/AJ) to allow successful tactical combat at sea.
- Procedures, techniques, subsystems, and control necessary to improve utilization and management of existing Navy communication assets.
- Advanced Command Control (C^2) Architectural Test Bed (ACCAT) for evaluating C^2 concepts and technology.
- Assessment of Navy Command and Control System (NCCS) performance supporting the Naval Electronic Systems Command, PME–108, in assembling a development plan for NCCS improvement and test and evaluation of its major components (NCCS system engineering, test, and evaluation).
- Theoretical and experimental research and development of efficient blue-green lasers for enhanced capability in unique underwater applications.

Ocean Surveillance

- Electromagnetic/electro-optic (EM/EO) satellite sensor and information exchange systems and surface terminals.
- Multisensor correlation and multisource integration.
- Integrated Undersea Surveillance System (IUSS).
- Advanced undersea surveillance sensors and data acquisition systems such as towed arrays, deployable arrays, fixed distributed systems, and active systems.
- Development of surveillance/intelligence data handling systems.
- Ocean surveillance system analysis and evaluation.
- Test and evaluation of major surveillance systems and advanced sonar signal processing, and research on surveillance-oriented display systems.
- Applied research in transducer and array technology. Development of an array to exploit the midfrequency regime.
- Sonobuoy Thinned Random Array Program (STRAP) to provide geometrical array stability and a system for dynamically locating array element positions.
- Long-range acoustic propagation and performance predictions including acoustic and environment modeling, and acoustic signal analysis.
- Multiple acoustic array coherent real-time processing.
- Development of a Wet End Systems Test Bed to provide test and evaluation capability for candidate undersea surveillance systems.
- Assessment of vulnerability to enemy surveillance systems.

Undersea Weapon Systems

- Advance surface ship antisubmarine warfare (ASW) fire control systems development incorporating passive target motion analysis (TMA).
- Applied research in torpedo propulsion, guidance and control, detection and classification, fire control, hydrodynamics, and hydroacoustics.
- Development of lightweight torpedoes, including MK–46 Near-Term Improvement Program (NEARTIP) (Lead Lab) and Advanced Lightweight Torpedo (ALWT) (Lead Lab).
- Adaptive Line Cancellor and Enchancer/Platform Noise Monitoring System (ALICE/PNMS).
- Undersea launch test program for cruise missiles.
- Advanced sonar systems development (SQQ–23, SQS–56, BQS–15, AN/SQQ–23A, AN/SQS–23B, AN/SQS–56).
- Submarine target model validation.

Marine Sciences

- Physical, chemical, and biological oceanography, meteorology, and sea floor geology.
- Underwater sound propagation, including acoustic and environmental modeling and acoustic signal analysis.
- Theoretical and experimental investigation of tropospheric, ionospheric, and magnetospheric effects on electromagnetic/electro-optic (EM/EO) propagation, including predictions of system performance.
- Geophysical studies in the Arctic Ocean and adjoining ice covered seas. The Arctic Submarine Laboratory provides technical support to Fleet under-ice operations.
- Marine biosciences and marine mammal systems for performing Navy tasks such as underwater object location and recovery (Lead Lab).
- Bionic sonar systems development.
- Marine environmental quality assessment.

Ocean Technology

- Unmanned remote undersea work and research systems.
- Deep ocean materials and components.
- Advanced undersea optical and acoustic sensors.

Simulation

- Development of techniques for simulation, in real-time, of the acoustic properties of submarines and targets, and of the ocean environment for underwater weapon design and evaluation.

Manufacturing and Automatic Testing Technology

- Manufacturing technology programs in electron beam projection techniques, composite materials, microwave tubes, fiber optics, torpedo propellers, and compute aided design of integrated circuits.
- Coordination of the Navy-wide RDT&E program in testing technology (Lead Lab).

Electronic Devices, Components and Subsystems

- Utilization of materials for electronic and EO devices to increase performance and reliability of electronic components.

- Development of EO devices for communications, surveillance, and weapon delivery.
- Application of industrial Large-Scale Integration/Very Large-Scale Integration (LSI/VLSI) and optics technology to signal and information processing.
- Application of fiber optics technology to underseas systems including unmanned vehicles.
- Characterization and evaluation of solid-state emitters and detectors for use in high performance military systems.
- Development of microwave devices for use in radar and communication systems.
- Shipboard radar performance assessment—Environmental/Weapons Effect Prediction System (E/WEPS).

NOSC uses systems analysis, simulation, and modeling as basic tools to identify problems, evaluate alternative solutions, and bring a systems approach to individual tasks. These techniques are applied to studies of total systems and warfare situations. They contribute to the formulation of new concepts to meet future Navy needs.

Naval Weapons Center Brief

Mission

The mission of NWC is to be the principal Navy RDT&E center for air warfare systems (except antisubmarine warfare systems) and missile weapon systems, and the national range/facility for parachute test and evaluation.

Personnel

Table A–2 shows personnel data for NWC, including groupings of scientists and engineers by discipline and by general schedule level (grade).

Funding

NWC's funding for fiscal year 1978 was $243.0 million, with the Naval Air Systems Command as the primary funding source. Other funding came from the Naval Sea Systems Command, the Chief of Naval Materiel, and other Navy commands. Funding by type included approximately 52% in the various R&D categories; other funding includes 14% for weapon procurement plus lesser percentages for a variety of categories.

Facilities

The major facilities of NWC are located on over a million acres of desert land in California's upper Mojave Desert. These include laboratories and shops for basic and applied R&D, a computer complex, and an array of instrumented air and surface ranges. Planned construction includes new facilities for parachute test work, a Range Operations Center Complex, and a Weapon System Support Facility.

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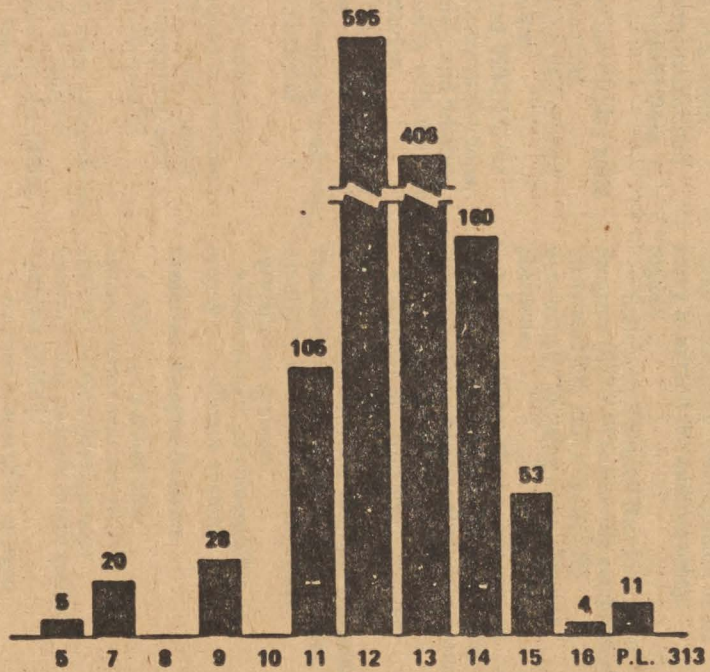
TABLE A-2. NWC Personnel Data. Extracted from NWC Laboratory Management Brief of 30 September 1978.

ON BOARD:	TOTAL MILITARY	TOTAL CIVILIAN	FTP*	TPTI**	FTP* UNGRADED
	476	3,976	3,932	44	748

FTP* GRADED 3,184

ADMINISTRATIVE	1,087
TECHNICIANS	710
SCIENTISTS AND ENGINEERS	1,387

ELECTRONIC ENG	418
PHYSICIST	207
GENERAL ENG	190
MECHANICAL ENG	196
MATHEMATICIAN AND STATISTICIAN	96
CHEMIST	53
AEROSPACE ENG	81
OTHER ENG	61
OTHER SCIENTIFIC	85



SCIENTISTS AND ENGINEERS BY GRADE

CIVILIAN CEILING
3,969

MILITARY ALLOWANCE
OFFICER 52 ENLISTED 461

*FTP - Full-time permanent
**TPTI - Temporary, part-time, intermittent (summer employees excluded)

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Program Work

The following excerpt from the NWC Laboratory Management Brief summarizes program work.

Air-Launched Weapon Systems:

—Sidewinder AIM–9D/G/H*—In-service engineering.

—Sidewinder AIM–9L*—Production support for USN and USAF.

—Sidewinder AIM–9M*—Product improvement of AIM–9L.

—Sparrow AIM–7F*—Production, in-service support.

—Sparrow AIM–7M*—Product improvement of AIM–7F.

—Phoenix—Production, in-service support, and product improvement for the fuzing system.

—AMRAAM—Navy laboratory support to the Air Force SPO at ADTC Eglin.

—AIAAM—Assist NAVAIR and USAF in concept formulation.

—Walleye*—Product improvement for data link and extended range.

—Harpoon—Production, in-service support, and product improvement.

—Supersonic Tactical Missile*—Technology demonstration of propulsion, seeker, warhead, and guidance systems.

—Rockeye,* FAE,* APAM,* Bigeye*—Development and support.

—Gator—Navy lead laboratory support to Eglin AFATL.

—Night Attack/Maverick*—Development of weapon system.

Tactical Aircraft Systems:

—Aircraft Survivability*—A–7, A–4, F–14, F–18, AV–8B, LAMPS.

—A–7E Weapon System Program*—Operational software, weapons integration.

—A–6E Operational Computer Program*—Overall computer program.

—F/A–18 Weapons Systems Program*—Integration of weapons and software.

—A–4/AV–8B Angular Rate Bombing System*—Development and production support.

Defense Suppression:

—Shrike*—In-service engineering, and product improvement.

—Standard ARM*—In-service support.

—HARM*—Full-scale development.

—ERASE*—Development of technology and subsystems for anti-radiation systems.

—ALR–67*—Full-spectrum assistance to NAVAIR for development of the threat warning receiver.

—EWTES*—Electronic Warfare Threat Environment Simulator.

Surface-Launched Missiles:

—ASMD/Point Defense—Advanced missile technology.

—Seasparrow RIM–7M*—Adaptation AIM–7F to ship-launched role.

—Standard Missile—Fleet support and product improvement for fuzing and propulsion systems.

—Chaparral*—Production and field support, product improvement.

—SLU–FAE*—Development for the Army.

Test and Evaluation:*

—Conduct developmental and operational tests using ranges and T&E facilities.

—Develop and use surface and airborne electronic threat simulations.

—Develop and use airborne and land naval targets.

—Provide Trident propulsion support.

—Perform as lead activity for the Navy's secure telemetry effort.

Technology Base (Research):*

—Support of target sensing, warning, guidance, control, CM and CCM systems.

—Development of propellants and study of propulsion systems.

—Characterize high-explosive, warhead, and terminal effects.

—Solution of materials problems.

Technology Base (Weapons & Components):*

—Advanced development on component programs.

—Support validation and full-scale development of components.

—Strike Warfare Weaponry and Missile Propulsion Block Programs.

—CNM Executive Agent for Navy fuze development.

*Indicates lead laboratory responsibility.

[FR Doc. 79–37228 Filed 12–3–79; 8:45 am]

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federal register

Tuesday
December 4, 1979

Part V

Civil Aeronautics Board

Consumer Protection for Super Bowl Charter Participants

CIVIL AERONAUTICS BOARD

14 CFR Part 380

[SPDR-75; Special Regulations Docket: 37183; Dated: November 30, 1979]

Public Charters; Consumer Protections for Super Bowl Charter Participants

AGENCY: Civil Aeronautics Board.

ACTION: Notice of proposed rulemaking.

SUMMARY: The CAB proposes that charter operators marketing charters to the NFL Super Bowl be required to file with the CAB proof of possession of game tickets or the contract for the game tickets before they are permitted to advertise or accept money for the charter. Consumers promised tickets would be entitled to a refund of the total charter price if they were not provided. This action is taken at the CAB's own initiative because of problems consumers have experienced with past Super Bowl charters.

DATES: Comments by: December 20, 1979.

Comments and other relevant information received after this date will be considered by the Board only to the extent practicable.

Requests to be put on the Service List by: December 10, 1979.

The Docket Section prepares the Service List and sends it to each person listed, who then serves his comments on others on the list.

ADDRESSES: Twenty copies of comments should be sent to Docket 37183, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428. Individuals may submit their views as consumers without filing multiple copies. Copies may be examined in Room 711, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. as soon as they are received.

FOR FURTHER INFORMATION CONTACT: David Schaffer, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428; 202-673-5442.

SUPPLEMENTARY INFORMATION: Charters to Super Bowl football games have become a recurring source of concern to the Board. In the past, charter operators have advertised and sold charters to the Super Bowl promising game tickets as part of the ground package, when in fact they did not have either physical possession of, or binding commitments for, any tickets. In several instances, charter operators were unable to secure game tickets for people who had purchased seats on the charter. As a result many consumers were unable to attend the football game—often their sole reason for purchasing the charter transportation. Moreover, since the operators often intended to purchase the necessary tickets shortly before the game, participants often learned that they would not be provided with tickets only after they had flown on the charter to the city hosting the game.

To prevent recurrence of this problem, the Board on October 3, 1978, distributed a letter to the airline industry entitled "Charter flights to Super Bowl football games." This letter stated that we would consider it an unfair and deceptive practice for charter operators to advertise charters that held out tickets to the game as part of the package unless the operator had submitted written verification to the Board that it had a binding commitment from the holder of the tickets to furnish the necessary number. To further the policy of the industry-letter, the Board is instituting this rulemaking proceeding to consider what steps it should take to ensure that consumers who but seats on a charter to the city hosting the Super Bowl actually receive game tickets when that is part of the charter package.

We propose that each charter operator be required to file written proof, as part of its charter prospectus, or an amendment to it, that it possesses, or has a written contract for, a substantial number of game tickets before it may advertise a Super Bowl charter. We further propose that no charter operator be permitted to accept money until it has filed written proof that it possesses, or has a written contract for, enough game tickets for all participants entitled to receive one. If the operator has physical possession of the tickets, a signed statement to that effect will be sufficient. If the operator is not in possession but has a signed contract to receive game tickets, a copy of that contract shall be submitted as proof.

Representatives of the National Football League (NFL) have informed the Board that only the NFL office and the NFL teams are assured of receiving Super Bowl tickets. The contract that the operator submits must therefore include one of these entities as a party. If the operator intended to obtain the tickets from a third party, not part of the NFL, it would be required to submit as proof both its contract with that third party and the party's contract with the NFL office or team. An operator that advertised or accepted money for a Super Bowl charter without filing proof that it either had, or had a right to, the number of game tickets specified above would be engaged in an unfair and deceptive practice in violation of section 411 of the Federal Aviation Act. Under this proposal, it would also be in violation of § 380.18a of the Board's rules.

The proposed rule distinguishes between the advertising of a Super Bowl charter and the acceptance of money for seats on it. To advertise the charter, the operator need only submit proof that it has enough tickets or rights to them for a substantial number of potential customers. It need not obtain, prior to advertising, a sufficient number of game tickets to cover all participants in the program. Before payment could be accepted from a customer, however, the operator would have to submit proof that it had enough game tickets or rights to provide one to each participant entitled to receive it.

We are proposing a less stringent requirement for advertising because participants of past Super Bowl charters have often obtained their tickets from sources other than charter operators. Many season ticket holders, for instance, are able to get game tickets directly from their team. Requiring operators to have enough tickets for all the seats on their charter before advertising it may therefore by unnecessary.

We are not proposing at this time a specific percentage of seats for which the operator must have tickets before advertising the charter. Comments are specifically requested on whether "substantial" should be more narrowly defined, or what percentage should be used.

We propose that the *sale* of seats for a Super Bowl charter be allowed only if the operator has a game ticket or contract right to one for each participant in the charter program who is supposed to receive one. A statement certifying that the operator is in possession of enough tickets or a contract demonstrating the right to receive the required amount would have to be submitted to the Board before the operator could accept money for the charter. If the operator accepts money but never supplies game tickets, the participant would be entitled to a full refund even after the flight departure. Although this differs from the Board's general practice on post-departure major changes, it is a reasonable requirement in the case of Super Bowl charters because attending the game is the only reason that the consumer is participating in the charter.

In order to lessen the chance of disappointment in the transaction between travel agents and prospective participants, the proposal would require operators to state, in descriptive

materials sent to travel agents, when the agent may accept money for a Super Bowl charter. Agents may accept money in only two situations. Money could be accepted after the agent contacts the charter operator and reserves a game ticket for a participant. If such a reservation is made, the operator must hold that ticket for that participant unless the participant voluntarily withdraws from the charter.

Second, if the agent contacts the operator and discovers that the operator does not have a game ticket for the prospective participant, the agent may still accept money if the customer checked the box on the operator-participant contract authorizing the operator to retain the money while attempting to obtain more game tickets. Since may operators do not obtain tickets until shortly before the game, this procedure enhances the possiblility that a consumer, willing to put his money down, will eventually receive a ticket to the game. This is the same procedure that is now employed in § 380.31(b) to aid consumers in the charter overbooking situation.

A consumer who does not deal with a travel agent but mails his contract and money directly to the operator would also have the option of electing to have the operator seek tickets under § 380.31. If the participant so authorizes the operator by checking that space, the operator may retain the payment while trying to obtain additional game tickets. Within 3 days after the payment is received or before the flight departs, whichever occurs first, the participant would have to be informed by the operator of the present lack of tickets and that others are being sought. If the participant does not check the box and there are no more game tickets, the operator would have to return all the money within 3 days. The 3-day period begins on the day after the charter operator receives the money.

Under the Public Charter rules, we allow 7 days for the operator to give notice to the participant that the charter has been oversold. That period may be too long in the case of Super Bowl charters. The game tickets do not usually go on sale until 10 days or two weeks before the game. To ensure that the consumer receives timely notice of the operator's shortage of game tickets, it seems reasonable to establish a 3-day period for giving notice to the participant of the operator's lack of tickets. Comments, however, are specifically requested on this aspect of the proposal.

While the operator is seeking additional tickets, or before it has obtained any tickets, it would not be precluded from accepting and retaining payments for the charter if game tickets were not held out as being part of the transaction. It is important that participants that are not being guaranteed game tickets be informed of that fact. Toward this end, we propose to require that an operator, lacking a game ticket for a participant on a charter to the city hosting the Super Bowl, include a paragraph in that person's operator-participant contract stating that the operator will not provide tickets to the Super Bowl as part of the charter package. This statement would have to be treated the same as the other important provisions of the contract that presently must be printed so as to contrast with the rest of the contract by the use of bold-faced type, capital letters, or a type size that is at least 50 percent larger than that used for the rest of the contract.

The authority for this rulemaking is section 411 of the Federal Aviation act. That section prohibits unfair and deceptive practices by air carriers. Charter operators are indirect air carriers under the Act and therefore are covered by this prohibition. This notice proposes a filing requirement in order to better enforce section 411. But even while final action on this rulemaking is pending, an operator may not advertise a Super Bowl Charter unless it has enough game tickets to cover a substantial number of seats on the flight and may not accept money for the charter unless it has enough game tickets for all those entitled to one under the terms of the sale. For an operator to do otherwise would, in the Board's view, be a violation of section 411 of the Act independent of the violation of any filing requirement that the Board may adopt in the future. This policy has already been stated in our 1978 industry-letter, and now by PS–90, issued simultaneously, which we are incorporating into our rules. Although the proposed filing requirement applies only to charter operators, the policy stated in PS–90 is applicable to both charter and scheduled service tour operators. Filing or additional requirements on scheduled service tour operators are not being proposed here but will be considered in the context of Docket 34997, *Consumer Protections for Members of Scheduled Service Tour Groups*, SPDR–71, 44 FR 43481, July 25, 1979.

Although the main source of complaints in this area has been Super Bowl charters, the Board is concerned about the possibility of consumers being misled in a similar way by other special-event-type charters. We will consider extending this approach in the future to other events to which admission is limited, but will take no rulemaking action beyond what is specifically proposed here until we provide further opportunity for comment.

Because we find it important to have a rule in effect before the 1980 Super Bowl, only 20 days can be allowed for comments. We propose to make the rule effective 5 days after issuance.

Accordingly, the Civil Aeronautics Board proposed to amend 14 CFR Part 380, *Public Charters*, as follows:

1. Subpart B of the Table of Contents would be amended by adding a new § 380.18a, to read:

Subpart B—General Conditions and Limitations

* * * * *

380.18a Super Bowl Charters.

* * * * *

§ 380.2 [Amended]

2. Section 380.2 would be amended by adding the following definition in alphabetical order:

* * * * *

"Super Bowl charter" means a charter that is represented by its charter operator as including tickets to the National Football League's Super Bowl game as part of its ground package.

* * * * *

3. A new § 380.18a would be added, to read:

§ 380.18a Super Bowl charters.

(a) No charter operator shall advertise a Super Bowl charter unless the operator has submitted written verification to the Board as specified in § 380.28(a)(4), of one of the following:

(1) That it is in physical possession of enough Super Bowl game tickets to provide such tickets for a substantial number of seats on the charter;

(2) That the National Football League (NFL) office or an NFL team has entered into a written contract to furnish to the operator enough Super Bowl game tickets to provide such tickets for a substantial number of seats on the charter; or

(3) That a person that has a written contract for Super Bowl tickets from the NFL office or an NFL team has entered into a written contract to furnish to the charter operator enough Super Bowl game tickets for a substantial number of seats on the charter.

(b) Except as provided by § 380.31(c), no charter operator shall accept money for seats on a Super Bowl charter, or authorize a travel agent to accept such money, unless the operator has submitted written verification to the Board that it is in physical possession of, or has a written contract with the

NFL office, an NFL team, or a person that has entered into a written contract with the NFL office or an NFL team for, enough Super Bowl game tickets to provide one to every charter participant that is to receive such a ticket under the terms of its operator-participant contract.

(c) Any descriptive material for a Super Bowl charter sent to a travel agent by a charter operator shall state that the agent must not accept any money for that charter from a prospective participant unless either (1) the participant elects to have the operator seek tickets under § 380.31(c), or (2) the agent contacts the charter operator and makes a specific and confirmed reservation of a game ticket for that participant. Once such a reservation is made, the charter operator must hold that reservation for that participant unless the participant voluntarily withdraws from the charter.

4. Section 380.28 would be amended by adding a new paragraph (a)(4) to read:

§ 380.28 Charter prospectus.

(a) * * *

(4) From a Super Bowl charter operator, the written verification required by § 380.18a of this part. This shall be as applicable, either a signed statement that the operator has the game tickets, or a copy of the contract with the person who is to supply them. If the supplier of the tickets is not the National Football League or a member team, the supplier's contract with one of those entities must also be submitted.

* * * * *

5. In § 380.31, paragraphs (b) (c) and (e) would be amended to read:

§ 380.31 General requirements for operator-participant contracts.

* * * * *

(b) The contract form may include a space that participants may check to authorize the charter operator to retain their money while attempting to make other arrangements for them if there is no space available on the flight, on specific alternative flights they have requested or, in the case of Super Bowl charters, if the operator does not have possession of or a right to any more game tickets.

(c) If there is no space available on the flight or specific alternative flights requested by the participant, or in the case of Super Bowl charters, if the operator does not have either possession of or written contracts for any more game tickets, the operator shall return all the participant's money within 7 days (3 days for Super Bowl charters) after receiving it unless the participant, in accordance with paragraph (b) of this section, has authorized the operator to retain the payments while the operator attempts to make other arrangements, or in the case of Super Bowl Charters, attempts to obtain more game tickets, for the participant. If the operator retains the payments while attempting to make other arrangements or obtain game tickets for the participant, it shall notify the participant of the fact within 7 days (3 days for Super Bowl charters) after receiving the payments but in no event later than the departure. For the purpose of the time periods in this paragraph, receipt of money by a travel agent on behalf of a charter operator will not be considered as receipt by the operator.

(d) * * *

(e) The contract form shall be printed in 7-point or larger type. The statements required by paragraphs (a), (f), (h), (l), (r), (s), and (y) of § 380.32 shall be printed so as to contrast with the rest of the contract by the use of bold-faced type, capital letters, or a type size that is at least 50 percent larger than that used for the rest of the contract.

* * * * *

6. Section 380.32 would be amended by revising paragraph (s) and adding a new paragraph (y) to read:

§ 380.32 Specific requirements for operator-participant contracts.

* * * * *

(s) That upon a post-departure notification of a major change, the participant may reject the substituted hotel or the changed date, origin, or destination of a flight leg and be sent, within 14 days after the return date named in the contract, a refund of the portion of his payment allocable to the hotel accommodations or air transportation not provided. For Super Bowl charters only; that if game tickets are not supplied when promised by the operator-participant contract, the participant must be sent, within 14 days after the return date named in the contract, a refund of the total charter price.

* * * * *

(y) For charters to the city hosting the National Football League's Super Bowl, whether the operator will provide tickets to the Super Bowl game as part of the ground package.

7. Section 380.33 would be amended by adding a new paragraph (a)(5) to read:

§ 380.33 Major changes in itinerary or price; refunds.

(a) * * *

(5) A failure to provide the participant with tickets to the National Football League's Super Bowl game when the participant was supposed to receive one under the terms of the operator-participant contract.

* * * * *

(Secs. 204 and 411 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 769, 49 U.S.C. 1324, 1381)

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37338 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

CIVIL AERONAUTICS BOARD

14 CFR Part 399

[Reg. PS-90; Policy Statement Amendment No. 67 to Part 399; Docket 37183]

Statements of General Policy; Consumer Protection Provisions for Participants of Super Bowl Charters

AGENCY: Civil Aeronautics Board.

ACTION: Final rule.

SUMMMARY: In SPDR-75, issued today, the CAB proposes consumer protection provisions for participants of Super Bowl charters. While that rulemaking is in progress, the CAB will consider advertising or selling seats on a tour that purports to include tickets to the Super Bowl game as part of its ground package to be an unfair and deceptive practice unless the tour operator actually has possession of, or a binding written committment for, tickets to the game. The Board is amending its regulations to reflect this policy.

DATES: Effective: November 30, 1979. Adopted: November 30, 1979.

FOR FURTHER INFORMATION: David Schaffer, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428; 202-673-5442.

SUPPLEMENTARY INFORMATION: A full discussion of the issues involved is contained in SPDR-75, issued today.

Since this is a statement of policy and should be in effect before operators begin marketing their charters for this year's Super Bowl, the Board finds that notice and public procedure are unnecessary, impracticable and contrary to the public interest and that there is good cause for an immediate effective date.

Accordingly, the Civil Aeronautics Board amends 14 CFR Part 399, *Statements of General Policy* as follows:

1. Subpart G of the Table of Contents is amended by adding a new § 399.87, to read:

Subpart G—Policies Relating to Enforcement

* * * * *

§ 399.87 Super Bowl tours.

2. A new § 399.87 is added to Subpart G, to read:

§ 399.87 Super Bowl tours.

(a) A Super Bowl tour is a tour operated on either scheduled or charter service that is represented by its operator as including tickets to the National Football League's Super Bowl game as part of its ground package.

(b) The Board considers the advertising of a Super Bowl tour to be an unfair and deceptive practice within the meaning of section 411 of the Act unless one of the following is true:

(1) The tour operator is in physical possession of enough Super Bowl game tickets to provide such tickets for a substantial number of seats on the tour;

(2) The National Football League (NFL) office or an NFL team has made a binding written commitment in writing to furnish the operator with enough Super Bowl game tickets to provide such tickets for substantial number of seats on the tour; or

(3) A person that has a binding commitment from the NFL office or an NFL team for Super Bowl tickets has made a binding written commitment to furnish the tour operator with enough tickets for a substantial number of seats on the tour.

(c) The Board considers it to be an unfair and deceptive practice within the meaning of section 411 of the Act for a tour operator to accept money for a Super Bowl tour unless the operator is in physicial possession of, or has a binding written commitment from the NFL office, an NFL team, or a person with a binding written commitment from the NFL office or an NFL team for, enough Super Bowl game tickets for each tour participant that is supposed to receive one under the terms of the sale.

(Secs. 204 and 411 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 769, 49 U.S.C. 1324, 1381)

By the Civil Aeronautics Board.

Phyllis T. Kaylor,

Secretary.

[FR Doc. 79-37339 Filed 12-3-79; 8:45 am]

BILLING CODE 6320-01-M

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Federal Register

Vol. 44, No. 234

Tuesday, December 4, 1979

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AGENCY PUBLICATION ON ASSIGNED DAYS OF THE WEEK

The following agencies have agreed to publish all documents on two assigned days of the week (Monday/Thursday or Tuesday/Friday).

This is a voluntary program. (See OFR NOTICE FR 32914, August 6, 1976.)

Monday	Tuesday	Wednesday	Thursday	Friday
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Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408

***NOTE: As of July 2, 1979, all agencies in the Department of Transportation, will publish on the Monday/Thursday schedule.**

REMINDERS

The items in this list were editorially compiled as an aid to **Federal Register** users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.

Rules Going Into Effect Today

CIVIL AERONAUTICS BOARD

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FEDERAL COMMUNICATIONS COMMISSION

62285 10–30–79 / FM broadcast stations; channel assignment to Murfreesboro, Ark.

62285 10–30–79 / FM broadcast stations; channel assigned to Osage City, Kans.

62286 10–30–79 / FM broadcast stations; channel assigned to Duncan, Okla.

HOUSING AND URBAN DEVELOPMENT DEPARTMENT

Office of Assistant Secretary for Housing—Federal Housing Commissioner—

62200 10–29–79 / Housing assistance payments; existing housing (Section 8); mobile home spaces; fair market rents

List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

Last Listing **November 30, 1979**

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(Revised as of July 1, 1979)

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