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Tuesday
April 15, 1980

Highlights

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Highlights

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

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Presidential Documents

Title 3—

The President

Proclamation 4748 of April 11, 1980

Technical Amendments to Proclamation 4744

By the President of the United States of America

A Proclamation

By the authority vested in me as President by the Constitution and the laws of the United States, including Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862), and the Emergency Petroleum Allocation Act of 1973, as amended (15 U.S.C. 751 *et seq.*), Proclamation 4744 is hereby amended as follows:

Section 1–101. Section 1–104 of Proclamation 4744 is amended by renumbering paragraph (a)(2) as (a)(3), and by the addition of a new paragraph (a)(2) to read:

"(a) . . .

(2) With respect to the entry of gasoline subject to the payment of a fee, the Secretary shall refund fees paid or reduce fees owed by the amount of any additional levy which results in a reduction in entitlements obligations as set forth in Section 2–105(b) of this Proclamation and which is imposed and collected by Puerto Rico on such entries that are consumed in Puerto Rico; *provided,* that, with respect to each barrel, such refunds or reductions may not exceed the amount of the actual fee for the month in which the entry was made."

Sec. 1–102. Section 2–105(a) of Proclamation 4744 is amended by revising the phrase "paragraphs (b) and (c)" to read "paragraph (b)".

Sec. 1–103. Section 2–109 of Proclamation 4744 is amended to read:

"Sec. 2–109. Notwithstanding any provision to the contrary in the Energy Regulations:

"(a)(1) A person that is a refiner may add to its B_I^t factor for gasoline (its increased purchased product costs as described in Section 212.83 of the Energy Regulations) for use in determining any current month's prices an amount equal to $4.20 multiplied by the number of barrels of gasoline subject to the gasoline conservation fee which that refiner entered into the United States in the month two months prior to such month. Any increases in gasoline prices that are allowed as a result of such addition to the B_I^t factor shall not be made prior to May 15, 1980.

"(2) If, in any current month beginning with June 1980, the amount of gasoline conservation fees on gasoline paid by a refiner in the month immediately preceding that month was greater or less than an amount determined by multiplying $4.20 by the number of barrels of gasoline subject to the gasoline conservation fee which were entered into the United States by that refiner in the month three months prior to that month, the difference shall be added to or subtracted from, respectively, that refiner's B_I^t factor for use in determining that month's prices.

"(b)(1) A person that is a refiner may add to its A_I^t factor for gasoline (its increased crude oil costs as described in Section 212.83 of the Energy Regulations) for use in determining any current month's prices an amount equal to $4.20 multiplied by the number of barrels of that refiner's gasoline production in the month two months prior to that month. Any increases in gasoline prices

that are allowed as a result of such addition to the A_i^t factor shall not be made prior to May 15, 1980.

"(2) If, in any current month beginning with June 1980, the amount paid by a refiner for gasoline entitlements purchased in the month immediately preceding that particular month was greater or less than an amount determined by multiplying $4.20 by the number of barrels of that refiner's gasoline production in the month three months prior to that month, the difference shall be added to or subtracted from, respectively, that refiner's A_i^t factor for use in determining that month's prices.

"(3) The amount added to or subtracted from the A_i^t factor pursuant to this section shall not be subject to the "gasoline tilt" provision found in the last sentence of the first paragraph of Section 212.83(a)(2)(iii)(C) of the Energy Regulations."

Sec. 1–104. Section 3–103(a) of Proclamation 4744 is amended by revising the phrase "Section 3–103" to read "Section 3–102".

Sec. 1–105. Section 4–101 of Proclamation 4744 is amended by revising the phrase "April 14" to read "April 24".

IN WITNESS WHEREOF, I have hereunto set my hand this eleventh day of April, in the year of our Lord nineteen hundred and eighty, and of the Independence of the United States of America the two hundred and fourth.

Jimmy Carter

[FR Doc. 80–11617
Filed 4–14–80; 11:26 am]
Billing code 3195–01–M

Presidential Documents

Executive Order 12207 of April 12, 1980

Creating an Emergency Board to Investigate a Dispute Between the Port Authority Trans-Hudson Corporation and Certain of its Employees

A dispute exists between the Port Authority Trans-Hudson Corporation and certain of its employees represented by the Brotherhood of Railway Carmen of the United States and Canada.

This dispute has not heretofore been adjusted under the provisions of the Railway Labor Act, as amended; and

The dispute, in the judgment of the National Mediation Board, threatens substantially to interrupt interstate commerce to a degree such as to deprive a section of the country of essential transportation service:

NOW, THEREFORE, by the authority vested in me by Section 10 of the Railway Labor Act, as amended (45 U.S.C. 160), it is hereby ordered as follows:

1–101. *Establishment of Board.* There is established a board of three members to be appointed by the President to investigate this dispute. No member of the board shall be pecuniarily or otherwise interested in any organization of railroad employees or any carrier.

1–102. *Report.* The board shall report its finding to the President with respect to the dispute within 30 days from the date of this Order.

1–103. *Maintaining Conditions.* As provided by Section 10 of the Railway Labor Act, as amended, from this date and for 30 days after the board has made its report to the President, no change, except by agreement, shall be made by the Port Authority Trans-Hudson Corporation, or by its employees, in the conditions out of which the dispute arose.

Jimmy Carter

THE WHITE HOUSE,
April 12, 1980.

[FR Doc. 80–11618
Filed 4–14–80; 11:27 am]
Billing code 3195–01–M

Rules and Regulations

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DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

7 CFR Part 275

[Amdt. No. 160]

Food Stamp Program—Performance Reporting System

Correction

In FR Doc. 80-7491, appearing on page 15884, in the issue of Tuesday, March 11, 1980, make the following correction.

On page 15907, second column, in the first complete paragraph, the thirteenth line should have read: "may be the 6 months prior to the month of review or the 6 months prior to the month".

BILLING CODE 1505-01-M

DEPARTMENT OF ENERGY

10 CFR Part 205

Administrative Procedures and Sanctions; 1980 Interpretations of the General Counsel

AGENCY: Department of Energy.

ACTION: Notice of interpretations.

SUMMARY: Attached are interpretations issued by the Office of General Counsel of the Department of Energy under 10 CFR Part 205, Subpart F, during the period March 1, 1980 through March 31, 1980.

Appendix B identifies those requests for interpretation which have been dismissed during the same period.

FOR FURTHER INFORMATION CONTACT: Diane Stubbs, Office of General Counsel, Department of Energy, 1000 Independence Avenue, SW., Room 5E052, Washington, D.C. 20585, (202) 252-2931.

SUPPLEMENTARY INFORMATION: Interpretations issued pursuant to 10 CFR Part 205, Subpart F, are published in the **Federal Register** in accordance with the editorial and classification criteria set forth in 42 FR 7923 (February 8, 1977), as modified in 42 FR 46270 (September 15, 1977).

These interpretations depend for their authority on the accuracy of the factual statement used as a basis for the interpretation (10 CFR 205.84(a)(2)) and may be rescinded or modified at any time (§ 205.85(d)). Only the persons to whom interpretations are addressed and other persons upon whom interpretations are served are entitled to rely on them (§ 205.85(c)). An interpretation is modified by a subsequent amendment to the regulation or ruling interpreted thereby to the extent that the interpretation is inconsistent with the amended regulation or ruling (§ 205.85(e)). The interpretations published below are not subject to administrative appeal.

Issued in Washington, D.C., April 9, 1980.

Merrill F. Hathaway, Jr.,
Acting Assistant General Counsel for Interpretations and Rulings.

Appendix A.—*Interpretations*

Number	To	Date	Category	File No.
1980-5	Mobil Chemical Company	Mar. 25	Fuel Use Act	A-502
1980-6	Basin, Inc	Mar. 31	Price and Allocation.	A-465

Interpretation 1980-5

To: Mobil Chemical Company.
Regulations Interpreted: 10 CFR 500.2(a).
Code: GCW-FU—Fuel Use Act

Regulations; Definition of Alternate Fuel and Refinery; Waste Gas.

Facts

The Mobil Chemical Company (Mobil) owns and operates an ethylene plant (plant) which is part of that firm's Olefins/Aromatics Chemical Manufacturing Plant located at Beaumont, Texas. The plant processes naphtha, ethane, and propane as feedstocks and primarily produces ethylene, propylene, benzene, and toluene. The plant also produces, as an unavoidable residue from the effluents of the plant's thermal reactors, a waste gas which consists of approximately 98.9 percent hydrogen and methane and small amounts of ethylene, ethane, and oily polymers.

Mobil is presently considering a substantial capital investment to modernize the plant in order to reduce the consumption of petroleum feedstock, natural gas, and electric power. The modernization plan would include the installation of several new ethylene process furnances having a higher heat recovery efficiency than the furnances to be replaced. The existing electric cracked gas compressor of this system would be replaced by a steam-driven compressor. In addition, Mobil proposes to install a new high-pressure steam boiler in a parallel cracking system. These units would be "new major fuel-burning installations" (MFBI's), as defined in 10 CFR 500.2, and thus may be subject to the fuel use prohibitions set forth in 10 CFR Part 505.

Mobil's existing plant utilizes the waste gas supplemented by natural gas as a primary fuel source. The new process furnances and boiler would be fired on 100 percent waste gas. Natural gas would be used in this equipment in emergency situations only. The improved yield efficiency of this modernization plan would result in an estimated feedstock, fuel, and power savings equivalent to approximately 640,000 barrels of crude oil per year while producing additional ethylene.

Mobil contends that this waste gas qualifies as an "alternate fuel," as defined in 10 CFR 500.2(a), one of the regulations implementing the Powerplant and Industrial Fuel Use Act of 1978 (FUA), Pub. L. No. 95-620 (November 9, 1978).[1] Under FUA a new MFBI may not consume petroleum or natural gas as a primary energy source without an exemption from the Department of Energy (DOE). FUA encourages the use of alternate fuels in place of petroleum or natural gas. A new MFBI in a plant engaged in industrial operations may consume waste gas that qualifies as an alternate fuel without an exemption from DOE.

Issue

Does Mobil Chemical Corporation's Beaumont, Texas ethylene plant engage in "industrial operations" under paragraph (6) of the definition of alternate fuel in 10 CFR 500.2(a) so that waste gas may be consumed by a new MFBI at that plant as an alternate fuel under the regulations implementing the Powerplant and Industrial Fuel Use Act of 1978?

Interpretation

Pursuant to paragraph (6) of the definition of alternate fuel in 10 CFR 500.2(a) of the regulations[2] implementing the Powerplant and Industrial Fuel Use Act of 1978, Mobil Chemical Corporation's Beaumont, Texas ethylene plant engages in "industrial operations" so that a new MFBI at that plant may consume waste gas as an alternate fuel.

Section 505.2(a) of DOE's regulations pertaining to an MFBI provides:

[1] 42 U.S.C. § 8301 *et seq.*

[2] *See* 44 FR 28950 (May 17, 1979).

"Section 202(a) of the Act prohibits, unless an exemption has been granted under Subpart C or D of this Part, the use of petroleum or natural gas as a primary energy source in any new installation consisting of a boiler."

Sections 507.3(a) and 507.4(a) provide that an "alternate fuel," as defined in § 500.2(a), is excluded from the definitions of natural gas and petroleum and thus such an "alternate fuel" may be burned in a new MFBI without an exemption from DOE.

"Alternate fuel" is defined at § 500.2(a) in pertinent part as follows:[3]

"Alternate fuel" means electricity or any fuel, other than natural gas or petroleum. The term includes—

* * * * *

(6) *Waste gases from industrial operations. (For purposes of this subsection (6), the term "industrial" does not pertain to refineries.) (Emphasis added.)*

This regulation provides, therefore, that a waste gas from an industrial operation is an alternate fuel. Nowhere in the regulations set forth in 10 CFR Parts 500 *et seq.* are the terms "refinery" and "industrial operations" expressly defined. Absent such a definition, we conclude that in this context the term "refinery" generally has the same meaning as that term has in other relevant DOE regulations set forth in the Mandatory Petroleum Allocation Regulations, 10 CFR Part 211.[4] Every operation that does not take place at such a "refinery" is to be considered to be an industrial operation for purposes of paragraph (6) of the definition of alternate fuel in 10 CFR 500.2a.

Relevant terms in 10 CFR Part 211 are defined in § 211.51 as follows: [5]

"Crude oil" means a mixture of liquid hydrocarbons including lease condensate that exists in natural underground reservoirs and remains liquid at atmospheric pressure after passing through surface separating facilities.

"Refined petroleum product" means gasoline, kerosene, middle distillate (including Number 2 fuel oil), LPG, refined lubricating oils, or diesel fuels.

"Refineries" means those industrial plants, regardless of capacity, processing crude oil feedstock and manufacturing refined pertroleum products, except when such plant is a petrochemical plant.

"Petrochemical plant" means those industrial plants, regardless of capacity, that process petrochemical feedstocks and obtain at least thirty (30) percent conversion, by weight to petrochemicals . . . so long as the weight of hydrocarbon contained in the final petrochemical is equal to at least thirty (30) percent of the initial petrochemical feedstock fed to the plant under consideration.[6]

Since Mobil's ethylene plant in Beaumont, Texas, processes petrochemical feedstocks and obtains approximately 70 percent conversion, by weight, to the petrochemicals ethylene, propylene, benzene and toluene,[7] the plant qualifies under these definitions as a "petrochemical plant" and thus is not a "refinery."

For the reasons set forth above, we have determined that Mobil's ethylene plant at Beaumont, Texas, is engaged in industrial operations for the purposes of paragraph (6) of the definition of alternate fuel in 10 CFR 500.2(a) and, therefore, may burn its waste gas, consisting primarily of methane and hydrogen, as an alternate fuel in any new MFBI in that plant.

Issued in Washington, D.C., on March 28, 1980.

Thomas C. Newkirk,

Deputy General Counsel for Regulation.

Interpretation 1980–6

To: Basin, Inc.

Regulations and Statutes Interpreted: 10 CFR 205.202, 210.62, 211.63; EPAA §§ 2 (a) and (b), 4(b)(1).

Code: GCW–AI–Normal Business Practices; Supplier/Purchaser Relationship.

Facts

Basin, Inc. (Basin) is an independent firm located in Midland, Texas, which purchases domestic crude oil at the wellhead and gathers, transports, and sells the crude oil to refineries and other purchasers. Based on these activities, Basin is a reseller of crude oil as defined in 10 CFR 212.31, and is thereby subject to the general regulations set forth in Parts 205 and 210, the allocation regulations in Subpart C of Part 211, and the price regulations in Subpart L of Part 212. Basin currently maintains supplier/purchaser relationships pursuant to 10 CFR 211.63(b) with its purchasers of crude oil, and these firms or subsequent purchasers eventually refine the crude oil into motor gasoline and other finished products which are then marketed through normal distribution channels.

BTA Oil Producers (BTA), which supplies Basin with 4,000 barrels per day of crude oil of various regulatory tiers, has recently proposed to terminate its existing supplier/purchaser relationship with Basin in accordance with the requirements set forth in 10 CFR 211.63(d) and to enter into a new agreement that would provide for the sale by BTA to Basin of the same crude oil previously supplied. Although Basin would continue its present functions of collecting, storing, and transporting the crude oil, as a condition to continued receipt of the crude oil Basin would be required to resell the entire volume to a joint venture composed of BTA and Hill Petroleum Company (Hill), which would enter into a processing agreement with Erickson Refining Corporation (Erickson) to have the crude oil refined. According to the joint venture agreement between BTA and Hill, BTA would own a 60 percent interest in the venture.

Under the terms of the processing agreement with Erickson, the joint venture would retain title to the crude oil being refined and would receive refined petroleum products allocated to it based on assays of each crude oil shipment delivered to the refinery. Erickson would provide only refining services for which it would be paid a monetary fee, while the joint venture would have sole responsibility for the sale and transportation of the refined petroleum products to available markets.

Based on the foregoing facts, Basin has requested an interpretation concerning the permissibility of the arrangements proposed by BTA. In particular, Basin raises questions regarding the applicability of 10 CFR 210.62 to the above facts.[8]

Issue

Do the Mandatory Petroleum Price and Allocation Regulations, particularly 10 CFR 210.62, prohibit the sale of domestic crude oil by BTA to Basin on condition that Basin resell the crude oil to a joint venture composed of BTA and Hill?

Interpretation

For the reasons set forth below, the DOE has determined that the proposed sale of domestic crude oil by BTA to Basin on condition that Basin resell the crude oil to a joint venture composed of BTA and Hill is prohibited by § 210.62. The new arrangement

---

[3] The relevant statutory definition is set forth at § 103(a)(6) of FUA.

[4] This Interpretation does not imply that the Economic Regulatory Administration (ERA) of DOE could not adopt by rulemaking a different and broader definition of refinery for purposes of 10 CFR 500.2(a). It may be permissible for ERA to provide, for example, that certain petrochemical plants or gas processing plants (as defined in 10 CFR 211.51) are refineries. Such action would be consistent with the related definition of "refiner" in the Mandatory Petroleum Price Regulations, 10 CFR 212.31. *Cf. Mobil Oil v. FEA*, 566 F.2d 87 (TECA 1977).

[5] Certain of the terms referred to in these definitions, such as motor gasoline, middle distillate, and butanes, are also expressly defined in § 211.51. The inclusion of LPG as a "refined petroleum product" in § 211.51. does not affect the inclusion of "liquid petroleum gas" in the definition of natural gas at 10 CFR 507.2.

[6] The regulatory language deleted ("or other products that are converted to petrochemicals") is inappropriate to apply to paragraph (6) of the definition of alternate fuel in 10 CFR 500.2(a) because that regulation envisions determining whether or not a waste gas qualifies as an alternate fuel solely through an examination of the industrial or refining operations at a plant site. It is irrelevant to this determination that a plant's products may be used as a petrochemical feedstock by another plant.

Section 211.62 defines a refinery to include a petrochemical plant. We consider applying this definition to paragraph (6) of the definition of alternate fuel in § 500.2(a) inappropriate because of the narrow purpose of this inclusion, which is related strictly to the Buy/Sell and Entitlements programs. *See Monsanto Co.*, 2 FEA ¶83,028 (January 31, 1975).

[7] Section 211.51 defines "petrochemicals" in reference to the oil import regulations, 10 CFR 213.27(8), for purposes of determining what is a "petrochemical plant" and thus not a "refinery" under that section. For the purposes of applying these terms to determine what is an industrial operation under paragraph (6) of the definition of alternate fuel in 10 CFR 500.2(a), petrochemicals means olefins (including ethylene, propylene and butylenes), diolefins (including butadiene), aromatics (including benzene, toluene and xylenes), acetylene, and products derived thereform.

[8] Since Basin's request is resolved on the basis of the conditional sale of crude oil by BTA to Basin, we do not reach the other issues raised by Basin, including the permissibility of processing agreements under DOE regulations. *See Notice of Intent, Amendments Concerning Processing Agreements Involving Non-Refiners*, Docket No. ERA–R79–53, 45 FR 3060 (January 16, 1980).

proposed by BTA is an impermissible modification of normal business practices in that it fundamentally changes Basin's relationship with BTA, it was not customary in the sale of this crude oil, and it would frustrate important objectives of the Emergency Petroleum Allocation Act of 1973, as amended, Pub. L. No. 93-159 (November 27, 1973) (EPAA).[9] Consequently, the joint venture is not entitled to acquire such volumes of crude oil for processing and marketing under the facts presented inasmuch as this acquisition of crude oil would be improper under the applicable DOE regulations.

Producers of domestic crude oil are subject to allocation regulations set forth in Subpart C of Part 211, which require the maintenance of supplier/purchaser relationships. Those regulations generally freeze "all supplier/purchaser relationships in effect under contracts for sales, purchases and exchanges of domestic crude oil on January 1, 1976," or which are begun thereafter through a first sale that is exempt from this rule. 10 CFR 211.63(b).[10]

In addition to requiring the maintenance of supplier/purchaser relationships with respect to sales of domestic crude oil, the regulations affect relations between producers, resellers, and refiners of crude oil. Section 210.62(a) directs that suppliers of crude oil deal with their purchasers according to normal business practices and that no supplier "modify any normal business practice so as to result in the circumvention of any provision of this chapter." Section 210.62(b) prohibits any preference or sales treatment which frustrates or impairs the purposes of the price and allocation regulations or of the EPAA. Section 210.62(c) provides in relevant part:

Any practice which constitutes a means to obtain a price higher than is permitted by the regulations in this chapter *or to impose terms or conditions not customarily imposed upon the sale of an allocated product* is a violation of these regulations. (Emphasis added.)

Subsection (c) makes clear that the imposition of terms or conditions not customarily imposed upon the sale of an allocated product is also a violation of this regulation.

That BTA intends to sever its current supplier/purchaser relationship with Basin and to create a new one (see 10 CFR 211.63(b)(2)) does not relieve BTA of the requirement of Section 210.62 that the customary business practices established in the original relationship be continued. Actions that circumvent or contravene the requirements of any DOE regulation are broadly prohibited by Section 205.202, which supplements Subpart C of Part 211, and therefore the new relationship may not be substituted simply to avoid that obligation. Accordingly, the changes proposed by BTA are to be considered as modifications of its existing supplier/purchaser relationship with Basin.

The modification of the relationship between BTA and Basin is not a mere change without significance, but on the contrary is inherently significant in that it would eliminate a fundamental and essential aspect of Basin's business. Basin currently purchases the subject crude oil from BTA with a free and clear title and markets that oil to several purchasers with whom it has existing supplier/purchaser relationships pursuant to Section 211.63(b). BTA has not customarily designated Basin's purchasers but now proposes to impose the fundamental condition that all future supplies of crude oil be resold to the joint venture in which it is a participant. This modification of BTA's normal business practices would supplant Basin's crude oil resale operations with an arrangement designed solely to provide BTA with the economic benefits of obtaining refined petroleum products for resale through its participation in the joint venture. As set forth in the request for interpretation, the agreement proposed by BTA would impair competition fostered by DOE regulations in that it would totally eliminate any opportunity for Basin's current purchasers, subsequent purchasers, and any other potential purchasers, to obtain supplies of this crude oil from Basin.

The EPAA was enacted in response to the threat presented to the petroleum industry and to the national economy by shortages of domestic and imported crude oil, residual fuel oil, and refined petroleum products.[11] It was determined that such shortages were likely to lead to dislocations in the national distribution system and that regulatory authority was necessary to minimize the resulting impact.[12] Thus, while the overall objectives of the EPAA require the application of certain restrictions on the petroleum industry, it is also the purpose of that Act to preserve competition. Accordingly, the EPAA authorizes allocation and price regulations, and § 4(b)(1)(D) provides as a specific objective of those regulations:

(D) preservation of an economically sound and competitive petroleum industry, including the priority needs to restore and foster competition in the producing, refining, distribution, marketing, and petrochemical sectors of such industry, and to preserve the competitive viability of independent refiners, small refiners, nonbranded independent marketers, and branded independent marketers.

The EPAA further states that the regulations issued thereunder should provide for the allocation of crude oil to provide adequate supplies to refineries and to provide for equitable distribution of crude oil at equitable prices, in a manner designed to minimize "economic distortion, inflexibility, and unnecessary interference with market mechanisms."[13]

BTA's proposed arrangement therefore takes on added significance in light of the findings and objectives of the EPAA and the Mandatory Petroleum Price and Allocation Regulations which are intended to prevent the harmful effects of inadequate supplies of crude oil, residual fuel oil, and refined petroleum products. In the proposed arrangement, BTA seeks to exercise the leverage of its position as the owner of a supply of crude oil in order to modify its business relationship with Basin and to control subsequent distribution of that oil[14] as well as the products to be derived therefrom. Thus, the modification contravenes the purposes of the EPAA and the regulations and falls within the prohibitions of § 210.62.

As presented by Basin, BTA's proposal would result in discrimination among Basin's purchasers in violation of § 210.62(b) in that it would provide for dealing with one purchaser, the joint venture, on terms that preclude dealing with other purchasers. The proposed agreement would obligate Basin to extend an absolute preference to the joint venture through a condition imposed by BTA, while BTA itself would be a partner in that venture. The resulting arrangement would have the effect of frustrating or impairing the purposes of the EPAA and the DOE regulations as previously described.

Based on the foregoing analysis the proposed arrangement between BTA and Basin would significantly modify the applicable normal business practices because it would require that Basin eliminate its current purchasers, their subsequent purchasers, and other potential purchasers from the chain of supply of BTA's crude oil. The restraint that would be imposed on Basin, and the resulting barrier to other purchasers, would therefore violate Section 210.62 (a), (b) and (c). BTA may not sell its crude oil to Basin on condition that such crude oil be resold to a designated joint venture inasmuch as the first sale of that crude oil in this manner would not be in accordance with § 210.62.

Issued in Washington, D.C., on March 31, 1980.

Thomas C. Newkirk,

Deputy General Counsel for Regulation.

[9] 15 U.S.C. § 751 *et seq.* (1976).

[10] Pursuant to § 211.63(d), there are various methods by which a supplier/purchaser relationship may be terminated. Although Basin anticipates that all terminations of supplier/purchaser relationships for the crude oil to be supplied to the joint venture would be in compliance with § 211.63(d)(1)(i), it should be noted that the requirements of that subsection must be fully met. As set forth in *Arizona Fuels Corporation*, Interpretation 1979-18, 44 FR 60266 (October 19, 1979), consent to termination of a supplier/purchaser relationship by a purchaser under § 211.63(d)(1)(i) must be in writing, giving notice of the termination date, and all subsequent purchases of the crude oil involved must consent in writing to that termination. All such consents must be express and knowing.

[11] EPAA, § 2(a).

[12] EPAA, § 2(b).

[13] EPAA, § 4(b)(1) (E), (F) and (I).

[14] Possible anticompetitive effects of vertical restraints, such as limitations by a seller on its customer's choice of purchasers in the resale of a product, have been subjected to close scrutiny under the antitrust laws. *See, e.g., Continental T.V., Inc.* v. *G.T.E. Sylvania, Inc.*, 433 U.S. 36 (1977); *United States* v. *Arnold, Schwinn & Co.*, 388 U.S. 365 (1967); *United States* v. *Bausch & Lomb Optical Co.*, 321 U.S. 707 (1944).

Appendix B.—*Cases Dismissed*

File No.	Requester	Category	Date dismissed
A-525	American Car Rental Association	Price	Feb. 13.
A-463	San Jose Peace Officer's Association	Price and Allocation	Mar. 14.
A-284	Texaco, Inc.	Allocation	Mar. 10.

[FR Doc. 80-11411 Filed 4-14-80; 8:45 am]

BILLING CODE 6450-01-M

FEDERAL ELECTION COMMISSION

11 CFR Chapter I

[Notice 1980-14]

Presidential Election Campaign Fund; Presidential Primary Matching Fund

AGENCY: Federal Election Commission.

ACTION: Transmittal of Regulations to Congress.

SUMMARY: FEC regulations governing the administration of the Presidential Primary Matching Payment Account provided for in Chapter 96 of Title 26, United States Code have been revised. The revised regulations at 11 CFR Chapter I have been transmitted to Congress pursuant to 26 U.S.C. 9039(c). Under the following revisions, the Commission may suspend matching fund payments to a candidate who knowingly, willfully and substantially exceeds expenditure limitations, and that candidate would be prohibited from receiving any further payments. Current regulations provide that the Commission may suspend matching fund payments to a candidate who knowingly and willfully exceeds expenditure limitations, but payments to that candidate would be resumed if he or she repaid an amount equal to the excessive expenditure and paid or agreed to pay any civil or criminal penalties resulting from the violation.

EFFECTIVE DATE: Further action, including the announcement of an effective date, will be taken by the Commission after these regulations have been before Congress 30 legislative days in accordance with 26 U.S.C. 9039(c).

FOR FURTHER INFORMATION CONTACT: Patricia Ann Fiori, Assistant General Counsel, 1325 K Street NW., Washington, D.C. 20510 (202) 523-4143.

SUPPLEMENTARY INFORMATION: The Commission on November 5, 1979, published a Notice of Proposed Rulemaking (44 FR 5594). No comments were received on the proposed regulations.

Explanation and Justification of Revised Regulations Governing Suspension of Payments From the Presidential Primary Matching Fund

Under the proposed revisions to the Presidential Primary Matching Fund regulations, the Commission may suspend payments to a candidate who, after certification for matching funds, knowingly, willfully and substantially exceeds the expenditure limitations at 11 CFR 9035. A candidate whose payments are suspended will, under the proposed revisions, be ineligible to receive any further payments.

Regulations promulgated on May 7, 1979, provide that the Commission may suspend matching payments to a candidate who knowingly and willfully exceeds expenditure limitations after certification for public funds (11 CFR 9033.9).[1] However, such a candidate may re-establish eligibility by repaying an amount equal to the excessive expenditure and by paying or agreeing to pay any civil or criminal penalties resulting from the violation of the limitation. Under the proposed revisions, the Commission may suspend payments to a candidate only if he or she knowingly, willfully *and substantially* exceeds expenditure limitations. In addition, under the proposed revisions, a candidate will not be permitted to re-establish eligibility after payments have been suspended for exceeding expenditure limitations.

Statutory provisions at 26 USC 9033(b)(1) state that in order to receive matching funds, a candidate must certify to the Commission that the candidate and his or her authorized committees "will not incur qualified campaign expenses in excess of the limitations of such expenses under [26 USC] section 9035." A candidate who exceeds the expediture limitations of 26 USC 9035 after certifying that he or she will not exceed those limitations violates a basic condition of eligibility for matching funds and that candidate's eligibility for continued receipt of payments is thereby terminated. Such a result is consistent with the statutory provisions establishing the public financing system for presidential primary candidates, as well as with the legislative history of those provisions.

The statutory provisions governing entitlement to matching funds expressly provide that a candidate must establish his or her eligibility for those funds by meeting certain conditions. The conditions are set forth at 26 USC 9033, which provides that in order to be eligible for payments, a candidate must make certain agreements and certifications. Further, it is clear that the statute empowers the Commission to determine whether a candidate has established eligibility by meeting the specific conditions, and a candidate who does not meet those conditions is ineligible to receive matching funds. (See *Committee to Elect Lyndon LaRouche* v. *FEC.* Fed. Elec. Camp. Fin. Guide (CCH) ¶ 9091 (D.C.Cir. 1979), *cert. denied,* — US — (February 19, 1980)[No. 79-801]).

As a condition precedent to the receipt of federal matching funds, a candidate must, under 26 USC 9033(b)(1), certify that he or she will not exceed the expenditure limitations applicable to publicly financed candidates. While the statute does not specifically authorize the suspension of payments to a candidate who violates a condition of eligibility by exceeding expenditure limitations, the Commission's power to suspend is implied from its express authority to determine initial eligibility. Because eligibility is a continuing requirement, the power to determine initially whether eligibility has been established necessarily implies the authority to monitor eligibility. Section 9033 specifically sets forth conditions of eligibility. These conditions consist of a series of agreements and certifications which the candidate must make prior to receiving matching funds. Where a candidate fails to abide by an agreement or certification which relates to a requirement central to the Act—such as the expenditure limitations—that candidate is failing to fulfill the basic conditions for eligibility to continued receipt of matching payments. In such a situation, the Commission has the authority to revoke that candidate's eligibility.

Moreover, without the authority to suspend payments to a candidate who is violating the conditions of eligibility, the Commission would be unable to protect the integrity of the public financing system. Allowing candidates to exceed expenditure limitations while continuing to receive matching funds undermines the equal protection of the public financing system. A central concept of the statutory provisions establishing that system is equal treatment of all candidates. The candidate who abides by expenditure limitations would suffer a great disadvantage if another candidate were permitted to exceed those limitations and still receive public funds. To prevent this inequitable result,

[1] Current regulations at 11 CFR 9033.3 also provide that a candidate is ineligible for matching funds if he or she has knowingly, willfully and substantially exceeded the expenditure limitations prior to certification.

matching fund payments must be permanently suspended to any candidate who exceeds expenditure limitations.

Finally, permanent suspension of matching fund payments to a candidate who has knowingly, willfully and substantially exceeded expenditure limitations is consistent with the legislative history of the public financing system for presidential candidates. The legislative history of the matching fund system indicates that the primary purpose of that legislation was to curb "abuses by special interest groups and big money . . . in connection with campaigns to the office of President".[2] Congress sought to further this purpose by "drastically reducing the amounts which may be expended by the candidate".[3] It would thus run counter to the very purpose of the public financing statute to allow candidates who knowingly, willfully and substantially exceed expenditure limitations to subsequently receive public funds. Such an outcome would permit a candidate to make vast amounts of campaign expenditures, and nevertheless receive matching payments, thereby defeating the basic purpose underlying the enactment of public financing.

11 CFR 9033.9 is amended to read as follows:

PART 9033—ELIGIBILITY

* * * * *

§ 9033.9 Suspension of payments.

(a) If the Commission has reason to believe that a candidate or his or her authorized committee(s) has knowingly, willfully and substantially failed to comply with the disclosure requirements of 2 USC 434 and 11 CFR Part 104, or that a candidate has knowingly, willfully and substantially exceeded the expenditure limitations at 11 CFR 9035, the Commission may make an initial determination to suspend payments to that candidate.

(b) The Commission shall notify the candidate of its initial determination, giving the legal and factual reasons for the determination and advising the candidate of the evidence upon which its initial determination is based. The candidate shall be given an opportunity within 20 days of the Commission's notice to comply with the above cited provisions or to submit written legal or factual materials to demonstrate that he or she is not in violation of those provisions.

[2] H.R. Rep. No. 93-1239, 94th Cong., 2nd Sess. 13 (1974).

[3] S. Rep. No. 93-689, 94th Cong., 2nd Sess. 5 (1974).

(c) The Commission shall consider any written, legal or factual materials submitted by the candidate in making its final determination. Such materials may be submitted by counsel if the candidate so desires.

(d) Suspension of payments to a candidate will occur upon a final determination to suspend payments by the Commission. Such final determination shall be accompanied by a written statement of reasons for the Commission's action. This statement shall explain the reasons underlying the Commission's determination and shall summarize the results of any investigation upon which the determination is based.

(e)(1) a candidate whose payments have been suspended for failure to comply with reporting requirements may become entitled to receive payments if he or she subsequently files the required reports and pays or agrees to pay any civil or criminal penalties resulting from failure to comply.

(2) a candidate whose payments are suspended for exceeding expenditure limitations shall not be entitled to receive further matching payments under 11 CFR 9034.1.

Dated: April 9, 1980.

Robert O. Tiernan,

Chairman, Federal Election Commission.

[FR Doc. 80-11404 Filed 4-14-80; 8:45 am]

BILLING CODE 6715-01-M

FEDERAL RESERVE SYSTEM

12 CFR Part 205

[Reg. E; Docket No. R-0272]

Electronic Fund Transfers; Definitions and Rules of Construction Documentation of Transfers

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board is adopting in final form amendments to § 205.9 of Regulation E (Electronic Fund Transfers) to (1) exempt deposits of cash, checks, drafts, and similar paper instruments at electronic terminals from the requirement that the terminal location be disclosed on the periodic statement, (2) provide that institutions may disclose the charges for account maintenance *or* the charges for electronic fund transfers on periodic statements, (3) permit financial institutions operating certain cash-dispensing terminals to mail a terminal receipt on the next business day following the day the transfer was initiated, until financial institutions replace those terminals, and (4) delay until August 10, 1980, the requirements that the terminal location and name of any third party to or from whom funds were transferred be disclosed on the periodic statement. These amendments are intended to facilitate compliance with the requirements of Regulation E, while not diminishing the consumer protections that it provides. The Board is also issuing an analysis of the economic impact of the amendments adopted at this time.

EFFECTIVE DATE: May 10, 1980.

FOR FURTHER INFORMATION CONTACT: Regarding the regulation: Dolores S. Smith, Section Chief, or Lynne B. Barr, Senior Attorney (202-452-2412), Division of Consumer and Community Affairs, Board of Governors of the Federal Reserve System, Washington, D.C. 20551. Regarding the economic impact analysis: Frederick J. Schroeder, Economist (202-452-2584), Division of Research and Statistics, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

SUPPLEMENTARY INFORMATION: (1) *Sections 205.2(g) and 205.9(b)(1)(iv)—Definition of electronic fund transfer and disclosure of terminal location.* The Board has been asked to reconsider its opinion that deposits of cash, checks, drafts, or similar paper instruments at electronic terminals are encompassed by the definition of "electronic fund transfer" in § 205.2(g), and that the requirements of the Act and regulation apply to them. Commenters contended that such transfers are not initiated electronically and should therefore be excluded. Commenters also stated that operational problems make it difficult and costly to treat deposits at ATMs and other terminals as electronic fund transfers.

The Board believes that the protections provided by the Act, particularly error resolution procedures, should be given to consumers using this type of service. It remains the Board's opinion that deposits at terminals are electronic fund transfers within the meaning of the Act. This view is supported by the Report of the Senate Committee on Banking, Housing and Urban Affairs (Report No. 95-915) which states that "automated teller machine transactions, such as cash withdrawals or deposits" are encompassed within the definition.

Certain specific operational problems were raised by the commenters. First, concern was expressed that all accounts held at a financial institution will be subject to the regulatory requirements (such as initial disclosures, documentation requirements, and error

resolution) because it is possible for a consumer to deposit money to accounts for which there is no EFT agreement. It is the Board's opinion that a deposit by a consumer at an electronic terminal does not make an account subject to the requirements of Regulation E, absent an agreement (by encoding accounts on the access device, marketing the deposit service, or specific agreement) between the consumer and the financial institution to permit deposits to the account. The Board's position on this issue is similar to that taken with respect to which accounts are subject to the requirements of § 205.9(b) (see 45 FR 8250). Institutions may limit the accounts to which deposits may be made by consumers and thus limit their exposure. Institutions may also limit the permissible dollar amount of deposits, provided disclosure is made pursuant to § 205.7(a).

Another concern of financial institutions relates to the difficulty of processing these deposits. It is the Board's understanding that deposits at terminals, because the amount of the deposit must be verified and availability of the funds determined, are generally processed with other deposits rather than with other terminal transfers, and that the terminal location is generally not captured. After the effective date of the regulation, the financial institution would have to capture and store the terminal location for disclosure on the periodic statement. In order to do so, according to commenters, institutions would have to verify and manually process ATM deposits separately from, not only other ATM transfers, but also other deposits. The Board is concerned that these increased processing steps and costs would result in loss of depository services to consumers and interfere with the development of such EFT services; it has therefore adopted an amendment to § 205.9(b)(1)(iv) exempting deposits at terminals from the requirement that the terminal location be disclosed on the periodic statement. It should be noted that the Board considers this an interim exemption that will become unnecessary as methods to process these transfers electronically become readily available to financial institutions.

The Board believes that this amendment will not decrease the significant consumer protections provided to consumers by the error resolution and other requirements of the regulation, which remain in effect as to deposits at electronic terminals. If a consumer requests additional information about a deposit within the time periods prescribed in § 205.11(b), for example, the institution must comply with the error resolution requirements.

This amendment and the one discussed in section (2) below are being adopted without an opportunity for further public comment on the specific wording because the Board believes that there has been ample opportunity for comment on the issues, and because a prompt resolution is necessary in view of the time remaining until the effective date of the regulation. Accordingly, the expanded rulemaking procedures set forth in the Board's policy statement of January 15, 1979 (44 FR 3957), will not be followed in connection with these two amendments.

One commenter asked whether section 906(f), which provides that any documentation provided pursuant to the Act constitutes *prima facie* proof of payment to another person, would apply to terminal receipts for deposits at terminals. The Board believes that section 906(f) does not apply to deposits to the consumer's account, since no payment is being made to another person. If a deposit is made to another person's account, and, because of an agreement between the consumer making the deposit and the financial institution as to deposits to *that* account, the other person's account is subject to Regulation E, the receipt would constitute *prima facie* proof of payment.

Financial institutions have asked what their responsibility will be under the regulation when the amount of a deposit as verified by the institution is more or less than the amount entered by the consumer into the terminal. Although financial institutions may wish to notify consumers immediately of any discrepancy, the Board believes that a financial institution is not required by the regulation to notify the consumer of the different amount until the periodic statement is sent. The statement should reflect the proper amount, or, depending on the institution's system, a correction of the erroneous amount. The financial institution must, of course, comply with the error resolution procedures when an error in a deposit is alleged by the consumer.

Financial institutions also expressed concern about potential consumer fraud. Financial institutions are concerned that they will be unable to resolve error allegations within the 10-business-day period prescribed by § 205.11, and will have to provisionally recredit the consumer's account for the amount alleged to be in error during the investigation. The Board believes that a financial institution completes its investigation responsibilities under § 205.11 by examining the questioned deposit, verifying the amount, and reporting to the consumer in accordance with the regulation's requirements.

The Board has also been asked whether cash payments made at electronic terminals are subject to the Act. It is the Board's opinion that such payments are not electronic fund transfers because they do not debit or credit an "account" as that term is defined in the Act.

(2) *Section 205.9(b)(3)—Charges for electronic fund transfers.* The Board has adopted an amendment to § 205.9(b)(3) to permit a financial institution to disclose on periodic statements the total charges (a) for electronic fund transfers or the right to make transfers, *or* (b) for account maintenance assessed against the account during the statement period. This amendment comports with the statutory language. It permits disclosure on the periodic statement of the total charges assessed against the account during the statement period, including any transaction charges. No change has been made to § 205.7(a)(5), however, and financial institutions must separately disclose the EFT charges, including transaction charges, when the initial disclosures are made. The amendment is being adopted in response to comments on the final regulation that raised significant operational obstacles to separate disclosure of EFT and non-EFT charges, particularly for accounts where the charges are identical for electronic and paper transfers. The Board believes that the amendment more closely approximates the congressional intent with respect to such charges, will not reduce the information given to the consumer (who will be told what the separate EFT charges are in the initial disclosures required by § 205.7), and will result in cost savings to financial institutions.

The Board does not believe that overdraft or stop payment charges are EFT charges or charges for the right to make electronic fund transfers. They need not be disclosed under §§ 205.7(a) or 205.9(b).

(3) *Section 205.9(f)—Receipt requirements for certain cash-dispensing terminals.* Section 205.9(a) of the regulation, which becomes effective May 10, 1980, provides that a financial institution must make a written receipt available to the consumer at the time any transfer is initiated at an electronic terminal. It came to the Board's attention that some financial institutions operate cash-dispensing electronic terminals that are incapable of generating a receipt to the consumer at the time the transfer is initiated. In response to concerns that financial

institutions would take these terminals out of service on May 10 because of non-compliance and that a valuable service would thus be unavailable to consumers, the Board proposed an amendment to Regulation E to permit financial institutions with such terminals until January 1, 1981, to replace the terminals, provided that in the interim the financial institution mails or delivers a receipt to the consumer on the next business day after the transfer was initiated (45 FR 8268, February 6, 1980). The proposed deferral of the effective date was intended to give financial institutions adequate opportunity to replace existing terminals.

The vast majority of the comments favored some delay in the May 10 effective date of the requirement that a receipt be made immediately available. However, most financial institutions operating the terminals in question argued that the seven-month extension would be an insufficient period in which to make the capital expenditure necessary to replace the affected terminals. These institutions argued that no loss in consumer protection would occur as a result of a permanent "grandfathering" of such terminals, because the consumer would receive the required information in the mail shortly after the transfer has taken place. In fact, these commenters argued, the possibility of detecting unauthorized use of an access device would be enhanced by the practice of mailing the receipt to the consumer on the next business day.

The Board has adopted an amendment (§ 205.9(f)) that will permit financial institutions operating certain cash-dispensing terminals to mail or deliver a written terminal receipt to the consumer on the next business day after the transfer is initiated. The amendment applies to terminals that (a) do not permit transfers other than cash withdrawals, (b) cannot make a receipt available to the consumer at the time the transfer is initiated, (c) cannot be modified to provide a receipt at that time, and (d) were purchased or ordered prior to February 6, 1980, the date the final regulation was published (45 FR 8264). The Board considered but rejected requests that it totally exempt such cash dispensers from the receipt requirement.

This is a permanent exception as to terminals purchased or ordered by the financial institution before February 6, 1980. There is no specific date by which these terminals must be replaced. Section 904 of the Act permits the Board to "provide for such adjustments and exceptions for any class of electronic fund transfers, as in the judgment of the Board are necessary or proper to effectuate the purposes" of the Act. The amendment adopted by the Board will permit financial institutions to phase out these terminals in an orderly and cost-effective manner, and to continue providing what appears to be a beneficial service to consumers. The Board believes that the consumer protection provided by the receipt requirement will not be significantly changed by the amendment.

The Board believes that the amendment permits financial institutions to reinstall their present cash-dispensers in new locations. It should be noted that the exception may only be used by the financial institution that presently owns or operates the terminals; terminals sold to other financial institutions will not remain within the exception.

(4) *Section 205.9(g)—Delayed effective date for certain periodic statement requirements.* The Board has adopted an amendment (§ 205.9(g)) which provides that a financial institution's failure to describe an electronic fund transfer in accordance with certain periodic statement requirements shall not constitute a violation of the Act or regulation as to any transfer that occurs before August 10, 1980. These requirements relate to § 205.9(b)(1)(iv), which requires disclosure of the terminal location for each transfer, and § 205.9(b)(1)(v), which requires disclosure on the statement of the name of any third party to or from whom funds were transferred.

The Board proposed the delay in the effective date of these portions of the regulation because it had become aware that financial institutions were expecting to experience serious difficulty in complying with these two requirements by May 10. The Board issued the final portions of Regulation E on February 6, 1980, slightly more than three months before the effective date of the regulation. The Board was concerned that rushed compliance efforts to meet the deadline and non-compliance after that date would result in substantial costs to financial institutions.

The comments received by the Board, with one exception, favored the adoption of a delayed effective date. Financial institutions responded to a request for specific estimates of costs that would be incurred if they had to comply by May 10, and subsequent reductions in those costs should the delay be adopted. Their estimates are discussed in detail in section (5) below. Significant obstacles to compliance by May 10 cited by commenters included the necessary modifications in computer software; redesign, reprinting, and distribution of statement forms; training of personnel; and the pretesting of new statement programs and formats.

The Board has determined, based on the comments received and its own analysis, that a brief delay in the effective date of these two periodic statement requirements will result in cost savings to financial institutions and will not result in a significant reduction in the consumer protections afforded by the Act.

The Board considered, but rejected, suggestions to delay the effective date for a longer period and to extend the delay to other requirements. Most financial institutions commented that this brief delay, limited to the two most difficult provisions in the documentation requirements, was adequate.

The Board wishes to insure that consumers enjoy the major protections of the Act and regulation during the three-month delay. Consequently, a requirement previously stated in the Federal Register has been incorporated into the regulation. Where applicable, financial institutions must, upon the consumer's request and without cost, provide the consumer with evidence of proof of payment to another person (as provided by section 906(f) of the Act). The Board reiterates that financial institutions must treat any request for additional information from the consumer as to an incompletely identified transfer as an "error" under § 205.11(a) and comply with the error resolution procedures.

(5) *Economic impact analysis.* Section 904(a)(2) of the Act requires the Board to prepare an analysis of the economic impact of the regulation that the Board issues to implement the Act. The following economic analysis accompanies sections of the regulation that are being issued in final form.[1]

The analysis must consider the costs and benefits of the regulation to suppliers and users of electronic fund transfer (EFT) services, the extent to which additional documentation, reports, records, or other paperwork would be required, the effects of the regulation on competition in the provision of electronic fund transfer services among large and small financial institutions, and the effects of the regulation on the availability of EFT services to different classes of consumers, particularly low-income consumers.

[1] The analysis presented here is to be read in conjunction with the economic impact analysis that accompany the Board's final rules at 44 FR 18474 (March 28, 1979), at 44 FR 33838 (June 13, 1979), at 45 FR 46433 (August 8, 1979), at 44 FR 59468 (October 15, 1979), and at 45 FR 8259 (February 6, 1980).

The regulation in part reiterates provisions of the statute and in part amplifies the statute. Therefore, the economic analysis considers impacts of both the regulation and the statute, and throughout the analysis a distinction will be made between costs and benefits of the regulation and those of the statute. *The following analysis assumes that the regulation and the Act have no relevant economic impact if they are less restrictive than current industry practices or state law. In this case, the regulation will not affect costs, benefits, competition, or availability and will not inhibit the market mechanism. The following analysis of the regulation and the Act is relevant only if their provisions are more constraining than those provisions under which institutions would otherwise operate.*

Section 205.9(b)(1)(iv) is amended so that deposits of cash, checks, drafts, or similar paper instruments at electronic terminals are not subject to the terminal location documentation requirement. Commenters pointed out that deposits made at electronic terminals are usually processed in the same way as deposits made at night depositories, at lobby drop boxes, and through the mail. Many financial institutions do not segregate deposits made at electronic terminals from other deposits and have no way of identifying at which electronic terminal a deposit was made. Costly changes in operating procedures and separate manual processing would be necessary to capture terminal location information for such deposits. The amendment is expected to reduce compliance costs and prevent the elimination of terminal deposit services by some institutions that could not comply in the absence of the amendment. Consumers will continue to receive receipts for deposits at electronic terminals and be protected by the error resolution procedures and other provisions of the Act and regulation.

Section 205.9(b)(3) is amended to provide that financial institutions may show on the periodic statement the total amount of all fees or charges assessed against the account during the statement period. Total fees or charges assessed only for EFTs or the right to make such transfers need not be reported separately, as had been previously required. Commenters pointed out that most data processing systems are not now capable of segregating the information needed to compute charges associated only with electronic transfers. Reprogramming accounting systems would be very expensive. Furthermore, many institutions assess fees or charges for service packages that include EFT services, so that isolation of changes related only to EFT would not be possible. This amendment is expected to reduce compliance costs substantially. Consumers will continue to be assured to receiving documentation of account fees and charges so that they can use that information to shop for the best of the different types of accounts available in the market.

Section 205.9(f) grants financial institutions a permanent exemption from the § 205.9(a) terminal documentation requirements for certain cash dispensers. A recent survey of all insured commercial banks revealed that the number of cash dispensers in operation was 623 in 1974, 437 in 1976, and 395 in 1979; and that the number of automated teller machines in operation was 1476 in 1974, 3032 in 1976, and 6215 in 1979.[2] It is apparent that the number of cash dispensers in use at commercial banks has declined in absolute terms and as a percentage of all automated retail banking machines. Similar trends in equipment use are expected to be obtain for other types of financial institutions.

In response to its request for information, the Board received comments from 11 financial institutions that were each operating at least one cash dispenser incapable of issuing receipts to consumers. All of these commenters requested a delay of the effective date or a permanent exemption from the requirements under consideration. Commenters cited customer satisfaction with existing cash dispensers, some of which have been in place for over 10 years, and the high costs associated with abandoning or replacing cash dispensers. Costs of replacing a non-complying machine were estimated to range from $20,000 to $50,000, depending on the type of replacement equipment, in addition to site preparation, reprogramming, and card base replacement costs. Furthermore, given the long lead times required to order and secure delivery of new equipment, some financial institutions could not replace non-complying machines by May 10, 1980.

This information, together with the realization that the stock of existing cash dispensers is declining as machines are retired and replaced with machines capable of issuing receipts when transfers are made, leads the Board to grant a permanent exemption from the § 205.9(a) documentation requirements for cash dispensers that were purchased or ordered prior to February 6, 1980. While the number of financial institutions and consumers affected by the exemption is relatively small, the impact of the exemption on them will be significant and provide a net benefit.

Consumers will retain the documentation protections afforded by the Act because of the provision that financial institutions must mail or deliver, on the business day following the transfer, a written receipt detailing the required transfer information. At the same time, financial institutions will not be forced to abandon cash-dispenser service or replace existing service with more costly service. The costs of any premature abandonment or replacement would be passed on to consumers to some degree.

Although the requirement to mail or deliver a written transaction document will increase the paperwork and record-keeping burden of institutions that do not now provide that service for cash-dispenser transactions, the burden will be much smaller than that imposed by the Act were the regulatory exception not granted. Without the exemption, equipment replacement costs and costs of civil liabilities for noncompliance would be greater. The exemption will provide greater relief from the statutory compliance burden for small financial institutions because they are less able than larger institutions to bear fixed costs associated with meeting the Act's compliance deadline.

The exemption is expected to have some influence on the availability of EFT services to different income classes of consumers. Certain of the affected cash dispensers are the only form of EFT service offered in the low-income rural areas they serve, and the exemption will permit the continued operation of those machines. Furthermore, some low-income consumers might be priced out of the market for EFT services if higher transaction charges were imposed because of cash dispenser replacement.

Section 205.9(g) delays until August 10, 1980, the effective date of two periodic statement requirements, §§ 205.9(b)(1) (iv) and (v). The delay applies to all financial institutions. Commenters provided compliance cost estimates that demonstrate that documentation of terminal locations and of third-party names are among the most burdensome requirements of the Act. Most commenters indicated that they would have to incur substantial system development costs in order to capture the necessary information and reproduce it on periodic statements.

[2] David A. Walker, "An Analysis of Financial and Structural Characteristics of Banks with Retail EFT Machines," Working Paper No. 79-1. Washington, D.C.: Federal Deposit Insurance Corporation, 1979, p. 3.

Some institutions and contract processors stated that the necessary reprogramming efforts could not be completed by May 10, 1980, regardless of cost, because sufficient human resources are not available and because new systems require time for field testing and modification. Rushed compliance efforts would probably require much greater expenditures and more costly revisions than efforts directed toward an August 10, 1980, or later compliance deadline. Many commenters were unable to provide estimates of cost savings from the three-month delay. For the 25 commenters that gave cost estimates, the delay was expected to save a total of over $1 million.

Other costs are associated with the terminal location and third-party name documentation requirements. These include costs of the addition of data storage capacity to handle the increased volume of transaction information, costs of retraining employees who use the new systems, and costs of discarding obsolete periodic statement forms and other supplies. The more time financial institutions and processors have in which to comply, the more efficiently resources can be allocated.

In consideration of the cost estimates furnished by commenters, the Board is extending the compliance deadline 3 months beyond the effective date of the Act. This regulatory provision is expected to yield a significant cost savings to financial institutions as a group and, for many individual institutions, prevent either widespread curtailments of EFT services or extensive violation of the statutory documentation requirements in case services are not curtailed. No significant loss of consumer benefits is expected, because consumers will have access to all information, proof of payments, and error resolution procedures required by law.

Although financial institutions will be spared substantial costs by the extension, commenters stated that many institutions, most of them small, will not be in compliance by August 10, 1980. Commenters anticipated that these institutions may have to suspend consumer EFT services, some of which have been successfully offered for many years, in order to protect themselves from civil liability under the Act. Even if compliance could be achieved soon after August 10, 1980, any disruption, however short, in EFT services would harm these institutions by causing loss of service with consequent loss of customers, by necessitating mailings of explanations to customers, and by requiring the use of managerial resources for discontinuing and later reinstating services. For many small financial institutions there will be little opportunity to control the process because they rely on outside processors, many of which cannot complete program modifications and client retraining by August 10, 1980. Low-income customers who have only savings accounts and who use EFT services will be adversely affected by the Act to the extent that their institutions will not be able to document the names of third-party payors or payees on periodic statements.

The delay in the effective date will reduce paperwork and documentation costs for those institutions that, in the absence of a delay, would continue to offer EFT services and would seek to comply by manually inserting transfer documentation into periodic statements.

(6) Pursuant to the authority granted in 15 U.S.C.A. 1693b, the Board hereby amends 12 CFR Part 205, effective May 10, 1980, by adding a footnote to paragraph (b)(1)(iv), amending paragraph (b)(3), and adding paragraphs (f) and (g) to § 205.9, to read as follows:

§ 205.9 Documentation of transfers.

* * * * *

(b) *Periodic statements.* * * *

(1) * * *

(iv) For each transfer initiated by the consumer at an electronic terminal,[48]

* * *

* * * * * *

(3) The total amount of any fees or charges, other than a finance charge under 12 CFR 226.7(b)(1)(iv), assessed against the account during the statement period for electronic fund transfers or the right to make such transfers, or for account maintenance.

* * * * *

(f) *Receipt requirements for certain cash-dispensing terminals.* The failure of a financial institution to comply with the requirement of paragraph (a) of this section that a receipt be made available to the consumer at the time an electronic fund transfer is initiated at an electronic terminal shall not constitute a violation of the Act or this regulation, provided

(1) The transfer occurs at an electronic terminal that

(i) Does not permit transfers other than cash withdrawals by the consumer,

(ii) Cannot make a receipt available to the consumer at the time the transfer is initiated,

(iii) Cannot be modified to provide a receipt at that time, and

(iv) Was purchased or ordered by the financial institution prior to February 6, 1980; and

(2) The financial institution mails or delivers a written receipt to the consumer that complies with the other requirements of paragraph (a) of this section on the next business day following the transfer.

(g) *Delayed effective date for certain periodic statement requirements.* The failure of a financial institution to describe an electronic fund transfer in accordance with the requirements of paragraphs (b)(1) (iv) and (v) of this section shall not constitute a violation of the Act or this regulation unless the transfer occurs on or after August 10, 1980, if, when a transfer involves a payment to another person, the financial institution, upon the consumer's request, and without charge, promptly provides the consumer with proof that such a payment was made.

* * * * *

By order of the Board of Governors, April 10, 1980.

Theodore E. Allison,

Secretary of the Board.

[FR Doc. 80-11400 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

[48] A financial institution need not identify the terminal location for deposits of cash, checks, drafts, or similar paper instruments at electronic terminals.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social Security Administration

20 CFR Part 404

[Regulations No. 4]

Federal Old-Age, Survivors, and Disability Insurance

AGENCY: Social Security Administration, HEW.

ACTION: Final rule.

SUMMARY: The Department of Health, Education, and Welfare (HEW) is revising its regulations to make them clearer and easier for the public to use. As part of this effort, we are revising completely Subpart B of 20 CFR Part 404. Subpart B contains the rules for determining the insured status of a worker and crediting quarters of coverage (QCs) for purposes of old-age, disability, dependents', and survivors' insurance benefits under title II of the Social Security Act. We have completely reorganized these regulations and rewritten the rules in simpler, briefer language. We have not changed the substance of our current rules, but have removed outdated and rarely used provisions.

DATES: The final rule is effective April 15, 1980.

FOR FURTHER INFORMATION CONTACT: Dave Smith, Legal Assistant, Office of Regulations, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235, telephone (301) 594–7336.

SUPPLEMENTARY INFORMATION: We have rewritten this subpart as part of HEW's "Operation Common Sense," a Department-wide effort to review, simplify, and reduce HEW's regulations. This subpart is important because insured status is a basic factor in determining if benefits are payable to a worker or to others based on that worker's earnings record. Whether a worker has insured status depends on the number of quarters of coverage (QCs) credited to him or her.

We published our proposed revision of Subpart B in the **Federal Register** in a Notice of Proposed Rulemaking (NPRM) on July 11, 1979 (44 FR 40526) with a 60-day comment period. We did not receive any comments. However, we felt we could improve the presentation of the subpart by further reorganizing the material, reversing the order of the discussion of insured status and QCs. We also made some refinements in language. These changes do not affect the substance of the rules.

In these final regulations we also included an appendix which shows the QC amount for each year after 1978. We explain in the regulations that the adjusted amount is published the preceding year on or before November 1 as a Notice in the **Federal Register.** We also updated the cross-references to material in Subpart D of 20 CFR Part 404 to reflect the recodification of that subpart published at 44 FR 34479 (June 15, 1979).

In both the NPRM and final regulations we have added a provision to the former regulations and deleted some provisions from the former regulations.

Added Provision

We have added a provision in § 404.110(d)(2) (§ 404.120(d)(2) in the NPRM) on crediting QCs for fully insured status based on wages paid before 1951. This provision reflects the amendment made to section 215(d)(1)(C) of the Social Security Act by section 142(b) of Pub. L. 92–603, enacted October 30, 1972. The amendment provides that total wages before 1951 include wages considered paid to a person before 1951 under section 231 of the Act (relating to benefits in case of certain persons interned in the United States during World War II). These wage credits may affect a person's current eligibility or benefit amount.

Deleted Provisions

Former § 404.103(d)(1)(x) contained conditions about crediting QCs based on wages paid in a year before 1951 equal to $3,000. We removed these conditions since they were taken out of the law by the Social Security Amendments of 1960 (section 206 of Pub. L. 86–778) and no longer apply.

Former § 404.113a concerned transitional insured status and applied only to certain claimants who attained age 72 before 1969 and are not fully insured. We removed this section from the regulations because we rarely use it, but we will apply this provision in appropriate cases.

Former § 404.115(b)(1) explained when disability insured status must be met for disability insurance benefits payable for months before January 1973. We removed this provision because it is outdated.

Former §§ 404.115(b)(2)(ii), 404.116(b)(3)(ii), and 404.116(d)(3)(ii) set out the conditions under which an application for a period of disability or disability insurance benefits filed before October 1972 was treated in the same way as an application filed after September 1972 for applying certain rules dealing with disability insured status. We removed these provisions because they are outdated.

Former § 404.120(a) permitted us to grant QCs based on a worker's railroad compensation for purposes of establishing a period of disability even though that compensation may not be used for other purposes under title II of the Social Security Act. The authority for this provision was contained in section 5(k)(1) of the Railroad Retirement Act (RRA) of 1937, but was deleted by the RRA of 1974 (section 18 of Pub. L. 93–445). We contacted the Railroad Retirement Board about a technical amendment to the RRA that would reinstate the deleted material. Until this material is reinstated, however, the provision in former § 404.120(a) no longer applies; therefore, we removed it.

Accordingly, the final rule is adopted as set forth below.

(Catalog of Federal Domestic Assistance Program Nos. 13.802 Social Security-Disability Insurance; 13.803 Social Security-Retirement Insurance; and 13.805 Social Security-Survivors Insurance.)

Dated: February 22, 1980.

William J. Driver,

Commissioner of Social Security.

Approved: April 9, 1980.

Patricia Roberts Harris,

Secretary of Health, Education, and Welfare.

Subpart B of Part 404 of Chapter III of Title 20 of the Code of Federal Regulations is revised to read as follows:

Subpart B—Insured Status and Quarters of Coverage

General

Fully Insured Status

Currently Insured Status

Disability Insured Status

Quarters of Coverage

Authority: Secs. 205, 212, 213, 214, 216, 217, 223, and 1102 of the Social Security Act, 53 Stat. 1368, 64 Stat. 504 and 505, 68 Stat. 1080, 64 Stat. 512, 70 Stat. 815, and 49 Stat. 647; sec. 5 of Reorganization Plan No. 1 of 1953, 67 Stat. 631, 42 U.S.C. 405, 412, 413, 414, 416, 417, 423, and 1302; 5 U.S.C. Appendix.

Subpart B—Insured Status and Quarters of Coverage

General

§ 404.101 Introduction.

(a) *Insured status.* This subpart explains what we mean when we say that a person has insured status under the social security program. It also describes how a person may become fully insured, currently insured or insured for disability benefits. Your insured status is a basic factor in determining if you are entitled to old-age or disability insurance benefits or to a period of disability. It is also a basic factor in determining if dependents' or survivors' insurance benefits or a lump-sum death payment are payable based on your earnings record. If you are neither fully nor currently insured, no benefits are payable based on your earnings. (Subpart D of this part describes these benefits and the kind of insured status required for each.) In §§ 404.110–404.120 we tell how we determine if you are fully or currently insured. The rules for determining if you are insured for purposes of establishing a period of disability or becoming entitled to disability insurance benefits are in §§ 404.130–404.133. Whether you have the required insured status depends on the number of quarters of coverage (QCs) you have acquired.

(b) *QCs.* This subpart also sets out our rules on crediting you with QCs. QCs are used in determining insured status. In general, you are credited with QCs based on the wages you are paid and the self-employment income you derive during certain periods. (See Subpart K of this part for a definition of "wages" and "self-employment income".) Our rules on how and when you acquire a QC are contained in §§ 404.140–404.146.

§ 404.102 Definitions.

For the purpose of this subpart—

"Act" means the Social Security Act, as amended.

"Age" means how many years old you are. You reach a particular age on the day before your birthday. For example, if your sixty-second birthday is on July 1, 1979, you became age 62 on June 30, 1979.

"Quarter" or "calendar quarter" means a period of three calendar months ending March 31, June 30, September 30, or December 31 of any year.

"We," "our," or "us" means the Social Security Administration.

"You" or "your" means the worker whose insured status is being considered.

Fully Insured Status

§ 404.110 How we determine fully insured status.

(a) *General.* We describe how we determine the number of quarters of coverage (QCs) you need to be fully insured in paragraphs (b), (c), and (d) of this section. The table in § 404.115 may be used to determine the number of QCs you need to be fully insured under paragraph (b) of this section. We also consider certain World War II veterans to have died fully insured (see § 404.111).

(b) *How many QCs you need to be fully insured.* (1) You need at least 6 QCs but not more than 40 QCs to be fully insured. A person who died before 1951 with at least 6 QCs is fully insured.

(2) You are fully insured for old-age insurance benefits if you have one QC (whenever acquired) for each calendar year elapsing after 1950 or, if later, after the year in which you became age 21, and before the year you reach retirement age, that is, before—

(i) The year you became age 62, if you are a woman;

(ii) The year you became age 62, if you are a man who becomes age 62 after 1974;

(iii) The year 1975, if you are a man who became age 62 in 1973 or 1974; or

(iv) The year you became age 65, if you are a man who became age 62 before 1973.

(3) A person who is otherwise eligible for survivor's benefits and who files an application will be entitled to benefits based on your earnings if you die fully insured. You will be fully insured if you had one QC (whenever acquired) for each calendar year elapsing after 1950 or, if later, after the year you became age 21, and before the earlier of the following years:

(i) The year you die; or

(ii) The year you reach retirement age as shown in paragraph (b)(2) of this section.

(c) *How a period of disability affects the number of QCs you need.* In determining the number of elapsed years under paragraph (b) of this section, we do not count as an elapsed year any year which is wholly or partly in a period of disability we established for you. For example, if we established a period of disability for you from December 5, 1975 through January 31, 1977, the three years, 1975, 1976 and 1977, would not be counted as elapsed years.

(d) *How we credit QCs for fully insured status based on your total wages before 1951.*

(1) *General.* For purposes of paragraph (b) of this section, we may use the following rule in crediting QCs based on your wages before 1951 instead of the rule in § 404.141(b)(1). We may consider you to have one QC for each $400 of your total wages before 1951, as defined in paragraph (d)(2) of this section, if—

(i) You have at least 7 elapsed years as determined under paragraph (b)(2) or (b)(3) of this section; and

(ii) The number of QCs determined under this paragraph plus the number of QCs credited to you for periods after 1950 make you fully insured.

(2) *What are total wages before 1951.* For purposes of paragraph (d)(1) of this section, your total wages before 1951 include—

(i) Remuneration credited to you before 1951 on the records of the Secretary;

(ii) Wages considered paid to you before 1951 under section 217 of the Act (relating to benefits in case of veterans);

(iii) Compensation under the Railroad Retirement Act of 1937 before 1951 that can be credited to you under title II of the Social Security Act; and

(iv) Wages considered paid to you before 1951 under section 231 of the Act (relating to benefits in case of certain persons interned in the United States during World War II).

(e) *When your fully insured status begins.* You are fully insured as of the first day of the calendar quarter in which you acquire the last needed QC (see § 404.145).

§ 404.111 When we consider a person fully insured based on World War II active military or naval service.

We consider that a person, who was not otherwise fully insured, died fully insured if—

(a) The person was in the active military or naval service of the United States during World War II;

(b) The person died within three years after separation from service and before July 27, 1954; and

(c) The conditions in § 404.1315 and § 404.1316 that permit us to consider the person fully insured are met.

§ 404.115 Table for determining the quarters of coverage you need to be fully insured.

(a) *General.* You may use the following table to determine the number of quarters of coverage (QCs) you need to be fully insured under § 404.110. Paragraphs (b) and (c) of this section tell you how to use this table.

Worker who reaches retirement age as described in § 404.110(b)(2)			Worker who dies before reaching retirement age as described in § 404.110(b)(2)		
Col. I	Col. II[1]		Col. III[2]	Col. IV[3]	Col. V[4]
Date of birth	Men	Women	Year of death		Age in year of death
Jan. 1, 1893 or earlier	6	6	[5]1957	6	[6]28
Jan. 2, 1893 to Jan. 1, 1894	7	6	1958	7	29
Jan. 2, 1894 to Jan. 1, 1895	8	6	1959	8	30
Jan. 2, 1895 to Jan. 1, 1896	9	6	1960	9	31
Jan. 2, 1896 to Jan. 1, 1897	10	7	1961	10	32
Jan. 2, 1897 to Jan. 1, 1898	11	8	1962	11	33
Jan. 2, 1898 to Jan. 1, 1899	12	9	1963	12	34
Jan. 2, 1899 to Jan. 1, 1900	13	10	1964	13	35
Jan. 2, 1900 to Jan. 1, 1901	14	11	1965	14	36
Jan. 2, 1901 to Jan. 1, 1902	15	12	1966	15	37
Jan. 2, 1902 to Jan. 1, 1903	16	13	1967	16	38
Jan. 2, 1903 to Jan. 1, 1904	17	14	1968	17	39
Jan. 2, 1904 to Jan. 1, 1905	18	15	1969	18	40
Jan. 2, 1905 to Jan. 1, 1906	19	16	1970	19	41
Jan. 2, 1906 to Jan. 1, 1907	20	17	1971	20	42
Jan. 2, 1907 to Jan. 1, 1908	21	18	1972	21	43
Jan. 2, 1908 to Jan. 1, 1909	22	19	1973	22	44
Jan. 2, 1909 to Jan. 1, 1910	23	20	1974	23	45
Jan. 2, 1910 to Jan. 1, 1911	24	21	1975	24	46
Jan. 2, 1911 to Jan. 1, 1912	24	22	1976	25	47
Jan. 2, 1912 to Jan. 1, 1913	24	23	1977	26	48
Jan. 2, 1913 to Jan. 1, 1914	24	24	1978	27	49
Jan. 2, 1914 to Jan. 1, 1915	25	25	1979	28	50
Jan. 2, 1915 to Jan. 1, 1916	26	26	1980	29	51
Jan. 2, 1916 to Jan. 1, 1917	27	27	1981	30	52
Jan. 2, 1917 to Jan. 1, 1918	28	28	1982	31	53
Jan. 2, 1918 to Jan. 1, 1919	29	29	1983	32	54
Jan. 2, 1919 to Jan. 1, 1920	30	30	1984	33	55
Jan. 2, 1920 to Jan. 1, 1921	31	31	1985	34	56
Jan. 2, 1921 to Jan. 1, 1922	32	32	1986	35	57
Jan. 2, 1922 to Jan. 1, 1923	33	33	1987	36	58
Jan. 2, 1923 to Jan. 1, 1924	34	34	1988	37	59
Jan. 2, 1924 to Jan. 1, 1925	35	35	1989	38	60
Jan. 2, 1925 to Jan. 1, 1926	36	36	1990	39	61
Jan. 2, 1926 to Jan. 1, 1927	37	37	1991	40	62
Jan. 2, 1927 to Jan. 1, 1928	38	38			
Jan. 2, 1928 to Jan. 1, 1929	39	39			
Jan. 2, 1929 or later	40	40			

[1] Number of QCs required for fully insured status; living worker or worker who dies after reaching retirement age.
[2] Worker born before Jan. 2, 1930 who dies before reaching retirement age.
[3] Number of QCs required for fully insured status.
[4] Worker born Jan. 2, 1930 or later, who dies before reaching retirement age.
[5] Or earlier.
[6] Or younger.
[7] Or later.

(b) *Number of QCs you need.* The QCs you need for fully insured status are in column II opposite your date of birth in column I. If a worker dies before reaching retirement age as described in § 404.110(b)(2), the QCs needed for fully insured status are shown in column IV opposite—

(1) The year of death in column III, if the worker was born before January 2, 1930; or

(2) The age in the year of death in column V, if the worker was born after January 1, 1930.

(c) *How a period of disability affects the number of QCs you need.* If you had a period of disability established for you, it affects the number of QCs you need to be fully insured (see § 404.110(c)). For each year which is wholly or partly in a period of disability, subtract one QC from the number of QCs shown in the appropriate line and column of the table as explained in paragraph (b) of this section.

Currently Insured Status

§ 404.120 How we determine currently insured status.

(a) *What the period is for determining currently insured status.* You are currently insured if you have at least 6 quarters of coverage (QCs) during the 13-quarter period ending with the quarter in which you—

(1) Die;

(2) Most recently became entitled to disability insurance benefits; or

(3) Became entitled to old-age insurance benefits.

(b) *What quarters are not counted as part of the 13-quarter period.* We do not count as part of the 13-quarter period any quarter all or part of which is included in a period of disability established for you, except that the first and last quarters of the period of disability may be counted if they are QCs (see § 404.146(d)).

Disability Insured Status

§ 404.130 How we determine disability insured status.

(a) *General.* We have three different rules for determining if you are insured for purposes of establishing a period of disability or becoming entitled to disability insurance benefits. To have disability insured status, you must meet one of these rules and you must be fully insured (see § 404.132 which tells when the period ends for determining the number of quarters of coverage (QCs) you need to be fully insured).

(b) *Rule I—You meet the 20/40 requirement.* You are insured in a quarter for purposes of establishing a period of disability or becoming entitled to disability insurance benefits if in that quarter—

(1) You are fully insured; and

(2) You have at least 20 QCs in the 40-quarter period (see paragraph (e) of this section) ending with that quarter.

(c) *Rule II—You become disabled before age 31.* You are insured in a quarter for purposes of establishing a period of disability or becoming entitled to disability insurance benefits if in that quarter—

(1) You have not become (or would not become) age 31;

(2) You are fully insured; and

(3) You have QCs in at least one-half of the quarters during the period ending with that quarter and beginning with the quarter after the quarter you became age 21; however—

(i) If the number of quarters during this period is an odd number, we reduce the number by one; and

(ii) If the period has less than 12 quarters, you must have at least 6 QCs in the 12-quarter period ending with that quarter.

(d) *Rule III—You are statutorily blind.* You are insured in a quarter for purposes of establishing a period of disability or becoming entitled to disability insurance benefits if in that quarter—

(1) You are disabled by blindness as defined in § 404.1501(b)(1)(ii); and

(2) You are fully insured.

(e) *How we determine the 40-quarter or other period.* In determining the 40-quarter period or other period in paragraph (b) or (c) of this section, we do not count any quarter all or part of which is in a prior period of disability established for you, unless the quarter is the first or last quarter of this period and the quarter is a QC.

§ 404.131 When you must have disability insured status.

(a) *For a period of disability.* To establish a period of disability, you must

have disability insured status in the quarter in which you become disabled or in a later quarter in which you are disabled.

(b) *For disability insurance benefits.* (1) To become entitled to disability insurance benefits, you must have disability insured status in the first full month that you are disabled as described in § 404.1501(a), or if later—

(i) The 17th month (if you have to serve a waiting period described in § 404.315(d)) before the month in which you file an application for disability insurance benefits; or

(ii) The 12th month (if you do not have to serve a waiting period) before the month in which you file an application for disability insurance benefits.

(2) If you do not have disability insured status in a month specified in paragraph (b)(1) of this section, you will be insured for disability insurance benefits beginning with the first month after that month in which you do meet the insured status requirement and you also meet all other requirements for disability insurance benefits described in § 404.315.

§ 404.132 How we determine fully insured status for a period of disability or disability insurance benefits.

In determining if you are fully insured for purposes of paragraph (b), (c), or (d) of § 404.130 on disability insured status, we use the fully insured status requirements in § 404.110, but apply the following rules in determining when the period of elapsed years ends:

(a) If you are a woman, or a man born after January 1, 1913, the period of elapsed years in § 404.110(b) used in determining the number of quarters of coverage (QCs) you need to be fully insured ends as of the earlier of—

(1) The year you become age 62; or

(2) The year in which—

(i) Your period of disability begins;

(ii) Your waiting period begins (see § 404.315(d)); or

(iii) You become entitled to disability insurance benefits (if you do not have to serve a waiting period).

(b) If you are a man born before January 2, 1913, the period of elapsed years in § 404.110(b) used in determining the number of QCs you need to be fully insured ends as of the earlier of—

(1) The year 1975; or

(2) The year specified in paragraph (a)(2) of this section.

§ 404.133 When we give you quarters of coverage based on military service to establish a period of disability.

For purposes of establishing a period of disability only, we give you quarters of coverage (QCs) for your military service before 1957 (see Subpart N of this part). We do this even though we may not use that military service for other purposes of title II of the Act because a periodic benefit is payable from another Federal agency based in whole or in part on the same period of military service.

Quarters of Coverage

§ 404.140 What is a quarter of coverage.

(a) *General.* A quarter of coverage (QC) is the basic unit of social security coverage used in determining a worker's insured status. We credit you with QCs based on your earnings covered under social security.

(b) *How we credit QCs based on earnings before 1978 (General).* Before 1978, wages were generally reported on a quarterly basis and self-employment income was reported on an annual basis. For the most part, we credit QCs for calendar years before 1978 based on your quarterly earnings. For these years, as explained in § 404.141, we generally credit you with a QC for each calendar quarter in which you were paid at least $50 in wages or were credited with at least $100 of self-employment income. Section 404.142 tells how self-employment income derived in a taxable year beginning before 1978 is credited to specific calendar quarters for purposes of § 404.141.

(c) *How we credit QCs based on earnings after 1977 (General).* After 1977, both wages and self-employment income are generally reported on an annual basis. For calendar years after 1977, as explained in § 404.143, we generally credit you with a QC for each part of your total covered earnings in a calendar year that equals the amount required for a QC in that year. Section 404.143 also tells how the amount required for a QC will be increased in the future as average wages increase. Section 404.144 tells how self-employment income derived in a taxable year beginning after 1977 is credited to specific calendar years for purposes of § 404.143.

(d) *When a QC is acquired and when a calendar quarter is not a QC (general).* Section 404.145 tells when a QC is acquired and § 404.146 tells when a calendar quarter cannot be a QC. These rules apply when we credit QCs under § 404.141 or § 404.143.

§ 404.141 How we credit quarters of coverage for calendar years before 1978.

(a) *General.* The rules in this section tell how we credit calendar quarters as quarters of coverage (QCs) for calendar years before 1978. We credit you with a QC for a calendar quarter based on the amount of wages you were paid and self-employment income you derived during certain periods. The rules in paragraphs (b), (c), and (d) of this section are subject to the limitations in § 404.146, which tells when a calendar quarter cannot be a QC.

(b) *How we credit QCs based on wages paid in, or self-employment income credited to, a calendar quarter.* We credit you with a QC for a calendar quarter in which—

(1) You were paid wages of $50 or more (see paragraph (c) of this section for an exception relating to wages paid for agricultural labor); or

(2) You were credited (under § 404.142) with self-employment income of $100 or more.

(c) *How we credit QCs based on wages paid for agricultural labor in a calendar year after 1954.*

(1) We credit QCs based on wages for agricultural labor depending on the amount of wages paid during a calendar year for that work. If you were paid wages for agricultural labor in a calendar year after 1954 and before 1978, we credit you with QCs for calendar quarters in that year which are not otherwise QCs according to the following table.

(2) When we assign QCs to calendar quarters in a year as shown in the table in paragraph (c)(1) of this section, you might not meet (or might not meet as early in the year as otherwise possible) the requirements to be fully or currently insured, to be entitled to a computation or recomputation of your primary insurance amount, or to establish a period of disability. If this happens, we assign the QCs to different quarters in that year than those shown in the table if this assignment permits you to meet these requirements (or meet them earlier in the year). We can only reassign QCs for purposes of meeting these requirements.

(d) *How we credit QCs based on wages paid or self-employment income derived in a year.*

(1) If you were paid wages in a calendar year after 1950 and before 1978 at least equal to the annual wage limitation in effect for that year as described in § 404.1027(a), we credit you with a QC for each quarter in that calendar year. If you were paid at least $3,000 wages in a calendar year before 1951, we credit you with a QC for each quarter in that calendar year.

(2) If you derived self-employment income (or derived self-employment income and also were paid wages) during a taxable year beginning after 1950 and before 1978 at least equal to the self-employment income and wage limitation in effect for that year as described in § 404.1068(b), we credit you

with a QC for each calendar quarter wholly or partly in that taxable year.

§ 404.142 How we credit self-employment income to calendar quarters for taxable years beginning before 1978.

In crediting quarters of coverage under § 404.141(b)(2), we credit any self-employment income you derived during a taxable year that began before 1978 to calendar quarters as follows:

(a) If your taxable year was a calendar year, we credit your self-employment income equally to each quarter of that calendar year.

(b) If your taxable year was not a calendar year (that is, it began on a date other than January 1, or was less than a calendar year), we credit your self-employment income equally—

(1) To the calendar quarter in which your taxable year ended; and

(2) To each of the next three or fewer preceding quarters that were wholly or partly in your taxable year.

§ 404.143 How we credit quarters of coverage for calendar years after 1977.

(a) *Crediting quarters of coverage (QCs).* For calendar years after 1977, we credit you with a QC for each part of the total wages paid and self-employment income credited (under § 404.144) to you in a calendar year that equals the amount required for a QC in that year. For example, if the total of your wages and self-employment income for a calendar year is more than twice, but less than 3 times, the amount required for a QC in that year, we credit you with only 2 QCs for the year. The rules for crediting QCs in this section are subject to the limitations in § 404.146, which tells when a calendar quarter cannot be a QC. In addition, we cannot credit you with more than four QCs for any calendar year. The amount of wages and self-employment income that you must have for each QC is—

(1) $250 for calendar year 1978; and

(2) For each calendar year after 1978, an amount determined by the Secretary for that year (on the basis of a formula in section 213(d)(2) of the Act which reflects national increases in average wages). The amount determined by the Secretary is published in the **Federal Register** on or before November 1 of the preceding year and included in the appendix to this subpart.

(b) *Assigning QCs.* We assign a QC credited under paragraph (a) of this section to a specific calendar quarter in the calendar year only if the assignment is necessary to—

(1) Give you fully or currently insured status;

(2) Entitle you to a computation or recomputation of your primary insurance amount; or

(3) Permit you to establish a period of disability.

§ 404.144 How we credit self-employment income to calendar years for taxable years beginning after 1977.

In crediting quarters of coverage under § 404.143(a), we credit self-employment income you derived during a taxable year that begins after 1977 to calendar years as follows:

(a) If your taxable year is a calendar year or begins and ends within the same calendar year, we credit your self-employment income to that calendar year.

(b) If your taxable year begins in one calendar year and ends in the following calendar year, we allocate proportionately your self-employment income to the two calendar years on the basis of the number of months in each calendar year which are included completely within your taxable year. We consider the calendar month in which your taxable year ends as included completely within your taxable year.

Example. For the taxable year beginning May 15, 1978, and ending May 14, 1979, your self-employment income is $1200. We credit 7/12 ($700) of your self-employment income to calendar year 1978 and 5/12 ($500) of your self-employment income to calendar year 1979.

§ 404.145 When you acquire a quarter of coverage.

If we credit you with a quarter of coverage (QC) for a calendar quarter under paragraph (b), (c), or (d) of § 404.141 for calendar years before 1978 or assign it to a specific calendar quarter under paragraph (b) of § 404.143 for calendar years after 1977, you acquire the QC as of the first day of the calendar quarter.

§ 404.146 When a calendar quarter cannot be a quarter of coverage.

This section applies when we credit you with quarters of coverage (QCs) under § 404.141 for calendar years before 1978 and under § 404.143 for calendar years after 1977. We cannot credit you with a QC for—

(a) A calendar quarter that has not begun;

(b) A calendar quarter that begins after the quarter of your death;

(c) A calendar quarter that has already been counted as a QC; or

(d) A calendar quarter that is included in a period of disability established for you, unless—

(1) The quarter is the first or the last quarter of this period; or

(2) The period of disability is not taken into consideration (see § 404.320(a)).

Appendix—Quarter of Coverage Amounts for Calendar Years After 1978

This appendix shows the amount determined by the Secretary that is needed for a quarter of coverage for each year after 1978 as explained in 404.143. We publish the amount as a Notice in the **Federal Register** on or before November 1 of the preceding year. The amounts determined by the Secretary are as follows:

Calendar year:	*Amount Needed*
1979	$260
1980	$290

[FR Doc. 11384 Filed 4-14-80; 8:45 am]

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Food and Drug Administration

21 CFR Part 178

[Docket No. 79F-0243]

Indirect Food Additives: Adjuvants, Production Aids and Sanitizers; Dodecylbenzenesulfonic Acid and Isopropyl Alcohol

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This document amends the food additive regulations to provide for the safe use of dodecylbenzenesulfonic acid and isopropyl alcohol as components of sanitizing solutions. The agency is taking this action in response to a petition filed by Pennwalt Corp.

DATES: Effective April 15, 1980; objections by May 15, 1980.

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 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 August 24, 1979 (44 FR 49792) that a petition (FAP 9H3429) had been filed by Pennwalt Corp., Three Parkway, Philadelphia, PA 19102, proposing that the food additive regulations be amended to provide for the safe use of dodecylbenzenesulfonic acid and isopropyl alcohol as components of sanitizing solutions for use on food-processing equipment and utensils and

on glass bottles and other glass containters intended for holding milk.

Having evaluated the data in the petition and other relevant material, the Food and Drug Administration concludes that the food additive regulations should be amended 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), Part 178 is amended in § 178.1010 by revising paragraphs (b)(7) and (c)(5) to read as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS AND SANITIZERS

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(7) An aqueous solution containing dodecylbenzenesulfonic acid and either isopropyl alcohol or polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800). In addition to use on food-processing equipment and utensils, this solution may be used on glass bottles and other glass containers intended for holding milk.

* * * * *

(c) * * *

(5) Solutions identified in paragraph (b)(7) of this section will provide not more than 400 parts per million dodecylbenzenesulfonic acid and not more than 80 parts per million of polyoxyethylene-polyoxypropylene block polymers (having a minimum average molecular weight of 2,800) or not more than 40 parts per million of isopropyl alcohol.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before May 15, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 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 shall become effective April 15, 1980.

(Sec. 409(c)(1), 72 Stat. 1786 (21 U.S.C. 348(c)(1)))

Dated: April 8, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11288 Filed 4-14-80; 8:45 am]

BILLING CODE 4110-03-M

NAVAJO AND HOPI INDIAN RELOCATION COMMISSION

25 CFR Part 700

Commission Operations and Relocation Procedures; Revision of Regulations Regarding Commission Hearings

AGENCY: Navajo and Hopi Indian Relocation Commission.

ACTION: Final rule.

SUMMARY: This notice amends the grievance procedure regulation by which aggrieved relocation applicants may have their grievance heard and a determination made. The reason for this amendment is that the current regulation is constitutionally inadequate. The intended effect of the amendment is to provide relocation applicants with a constitutionally adequate and fair procedure for determinations of eligibility, hearings, and administrative review.

EFFECTIVE DATE: April 15, 1980.

FOR FURTHER INFORMATION CONTACT: Paul M. Tessler, CFR Liaison Officer, Navajo and Hopi Indian Relocation Commission, 2717 N. Steves Boulevard, Building A, Flagstaff, AZ 86001, telephone No., (602) 779–3311, ext. 1376, FTS: 261–1376

SUPPLEMENTARY INFORMATION: On September 17, 1978, there was published in the **Federal Register** (44 FR 53761) a notice of proposed revision of regulations regarding grievance procedures. The comment period ended October 17, 1979.

Discussion of Comments

1. Comment was received concerning adding a time limit on identification of the applicant's representive. Even if the lawyer-representative made no appearance before the hearing date, the hearing could proceed. The applicant will have been informed of his right to representation when notified of the determination. In the rare instances when representation is not sought until the last moment, provisions can be made for rescheduling the hearing to permit preparation. Section 700.8 (A) was reworded to say "Communication of determinations to the applicant shall include an explanation of the availability of grievance procedures, including hearings and representation of counsel." This more clearly informs the applicant of these rights.

2. Subparagraph K was added to provide retroactive rights to those who have already moved.

3. Comment was received concerning the Hearing Officer provision. The Administrative Procedure Act limits the choice of persons eligible to preside at hearings, and is applicable to the Commission, 5 U.S.C. §§ 554(a). 25 CFR § 700.8 (D) as proposed in its final form, comports with the Administrative Procedures Act and due process standards and is adopted as proposed.

4. Comment was received concerning notification of appeal rights. This comment related to (1) interpretation of communications, and (2) the time limit within which the hearing request must be made. Provision was made in the final rule for communication of appeal rights in person by Commission field staff. Insofar as this method is relied on, the Commission may thereby further assure that the applicant received notice and understood it.

5. Comment was received concerning interpreters at hearings. The course and conduct of the hearing is the Hearing Officer's domain; used of interpreters is reposed in his or her discretion.

6. Comment was received concerning possible ambiguity in the term "benefits." Definition of this term will be incorporated in 25 CFR 700.5 by future publication in the **Federal Register.**

7. Comment was received concerning provisions for the Certifying Officer to reconsider the initial determination. This concept is incorporated into the final rule.

8. Comment was received concerning imposing a thirty-day time limit on final agency action and this was done.

9. Comment was received recommending that the Commission pay successful applicant's attorney expenses and all applicants' per diem, mileage,

and related expenses. This suggestion was not incorporated into the final rule because of the cost involved and because it would reduce assets available for the fulfillment of the Commission's mandate under Pub. L. 93–531.

The principal author is William G. Lavell, Field Solicitor, Valley Bank Center, Suite 2080, 201 N. Central Avenue, Phoenix, AZ 85073.

Accordingly, 25 CFR 700.8 is amended in its final form to read as follows:

PART 700—COMMISSION OPERATIONS AND RELOCATION PROCEDURES

§ 700.8 Determinations of Eligibility, Hearings, and Administrative Review.

(a) *Initial Commission Determinations.*

(1) Initial Commission determinations concerning individual eligibility or benefits for any person who has filed a claim for benefits shall be made by the Certifying Officer pursuant to published Commission policy. The determination shall include the amount, if any, to which the individual is entitled, and shall state the reasons therefor. Such determinations shall be communicated to the Applicant by certified letter or in person by Commission staff. A record of such personal notice shall be maintained by the Commission.

(2) An explanatory conference shall be scheduled by and with the Certifying Officer if requested by the Applicant within fourteen days of the communication of the determination; the right to a hearing is not dependent on the holding of such a conference. The Certifying Officer may reverse, amend, or leave standing the initial determination as a result of such conference *provided that* his decision shall be communicated to the Applicant by certified letter or in person by Commission staff within five days after such conference.

(3) Communications of determinations to the Applicant as provided for in (a)(1) of this subsection shall include an explanation of the availability of grievance procedures, including hearings and representation of counsel.

(4) No decision which at the time of its rendition is subject to appeal to the Commission shall be considered final agency action subject to judicial review under 5 U.S.C. sec. 704 *provided that* in the event of a whole or partial denial, no benefits shall be paid unless and until said determination is reversed or modified as provided for herein.

(b) *Availability of Hearings.* All persons aggrieved by initial Commission determinations concerning eligibility or benefits may have a Hearing to present evidence and argument concerning the Determination. Parties seeking such relief from the Commission's initial determination shall be known as "Applicants." When multiple Applicants claim interest in one benefit, determination, or question of eligibility, their hearings may be consolidated at the Presiding Officer's discretion.

(c) *Request for Hearings.* Hearing requests may be made in person or by letter and must be received by the Commission within thirty days after the notice letter was received, the personal notice was given, or if an explanatory conference is held, after the decision of the Certifying Officer.

(d) *Presiding Officers.* The hearing shall be presided over and conducted by one of the Commissioners appointed pursuant to 25 U.S.C. § 640d–11(b) or by an Administrative Law Judge appointed under 5 U.S.C. § 3105 who may be procured from another agency as defined by 5 U.S.C. § 551(1).

(e) *Hearing Scheduling and Documents.*

(1) Hearings shall be held as scheduled by the Presiding Officer.

(2) Notice of the hearing shall be communicated in writing to the applicant at least fourteen days prior to the hearing and shall include:

(i) the time, date, and nature of the hearing;

(ii) the legal authority and jurisdiction under which the hearing is to be held; and

(iii) matters of law and fact asserted or at issue.

(3) Written notice of the Applicant's objections, if any, to the time, date, or place fixed for the Hearing shall be filed with the Presiding Officer at least five days before the date set for the Hearing. Such notice of objections shall state the reasons therefor and suggested alternatives. Discretion as to any changes in the date, time, or place of the hearing lies entirely with the Presiding Officer, *provided that* the fourteen-day notice period as provided in paragraph 2 above shall be observed unless waived in writing by the applicant or his representative.

(4) All hearings shall be held within thirty days after Commission receipt of the Applicant's request therefor unless this time limit is extended by the Presiding Officer.

(5) All hearings shall be conducted at the Commission offices in Flagstaff, Arizona, unless otherwise designated by the Presiding Officer.

(6) All time periods in this regulation include Saturdays, Sundays, and holidays. If any time period would end on a Saturday, Sunday, or holiday, it will be extended to the next consecutive day which is not a Saturday, Sunday, or holiday.

(7) A copy of each document filed in a proceeding under this section must be served by the filing party or any other party or parties in the case. In all cases where a party is represented by an attorney or representative, such attorney or representative will be recognized as fully controlling the case on behalf of his client, and service of any document relating to the proceeding shall be made upon such attorney or representative, which service shall suffice as if made upon the Applicant. Where a party is represented by more than one attorney or representative, service upon one of the attorneys or representatives shall be sufficient.

(8) Hearings will be recorded verbatim and transcripts thereof shall be made when requested by any parties; costs of transcripts shall be borne by the requesting parties unless waived according to § 700.8(F)(1)(e).

(9) Applicants may be represented by an attorney licensed by the highest court of the state in which the Hearing is conducted or by an advocate licensed to practice in any tribal court.

(f) *Evidence and Procedure.*

(1) At the Hearing and taking of evidence, the Applicant shall have an opportunity to:

(i) submit and have considered facts, witnesses, arguments, offers of settlement, or proposals of adjustment;

(ii) be represented by a lawyer or other representatives as provided herein;

(iii) have produced Commission evidence relative to the determination *provided that* that scope of pre-hearing discovery of evidence shall be limited to relevant matters and to methods as determined by the Presiding Officer;

(iv) examine and cross-examine witnesses;

(v) receive a transcript of the Hearing on request and upon payment of appropriate Commission fees which may be waived in cases of indigency.

(2) The Presiding Officer is empowered to:

(i) administer oaths and affirmations;

(ii) rule on offers of proof;

(iii) receive relevant evidence;

(iv) take depositions or have depositions taken when the ends of justice would be served and to permit other pre-hearing discovery within his discretion;

(v) regulate the course and conduct of the hearings, including prehearing procedures;

(vi) hold conferences for the settlement or simplification of the issues by consent of the parties;

(vii) dispose of procedural requests or similar matters;

(viii) make a record of the proceedings;

(ix) hold the record open for submission of evidence no longer than fourteen days after completion of the Hearing;

(x) make or recommend a decision in the case based upon evidence, testimony, and argument presented;

(xi) enforce the provisions of 5 USCA § 557(d) in the event of a violation thereof; and

(xii) issue subpoenas authorized by law.

(g) *Post-Hearing Briefs.* Applicants may submit post-hearing briefs or written comments to the Presiding Officer within fourteen days after conclusion of the Hearing. In the event of multiple applicants or parties to a Hearing, such briefs shall be served on all such applicants by the applicant submitting the brief.

(h) *Presiding Officer Decisions.*

(1) The Presiding Officer shall submit to the Commission written findings of fact, conclusions of law, and decision based upon the evidence and argument presented, within sixty days, not including any period the record is held open, if any, after conclusion of the Hearing.

(2) Copies of the Presiding Officer's findings of fact, conclusions of law, and decision shall be mailed to the Applicant. The Applicant may submit briefs or other written argument to the Commission within fourteen days of the date of the Presiding Officer's determination was mailed to them.

(i) *Final Agency Action.* Within 30 days after receipt of the Presiding Officer's decision, the Commission shall affirm or reverse the decision and issue its final agency action upon the application in writing; *provided that* in the event one Commissioner sits as the Presiding Officer, the final agency action shall be determined by the remaining Commissioners who did not so preside over the hearing.

(j) *Direct Appeal to Commissioners.* Commission determinations concerning issues other than individual eligibility or benefits which do not require a Hearing may be appealed directly to the Commission in writing. The Commission decision will constitute final agency action on such issues.

(k) *Completed Relocations.* These procedures shall apply to all relocatees who have completed moves on or before the effective date of this regulation. Such individuals shall have 180 days after the effective date of this regulation within which to request a Hearing under this regulation. Notice of this right shall be mailed to all such individuals within 30 days after the effective date of this regulation.

(Pub. L. 93–531, 85 Stat. 1712, 25 U.S.C. 640–d—640–d–24)

Sandra Massetto,

Chairperson, Navajo and Hopi Indian Relocation Commission.

[FR Doc. 80–11292 Filed 4–14–80; 8:45 am]

BILLING CODE 4310–HB–M

VETERANS ADMINISTRATION

38 CFR Part 3

Definition of Child

AGENCY: Veterans Administration.

ACTION: Final regulation.

SUMMARY: The Veterans Administration has amended its regulation defining the term "child". This action implements one of the provisions of a law called the Veterans' Health Care Amendments of 1979 which sets forth rules for recognition of a person adopted under foreign law as a child of a veteran.

EFFECTIVE DATE: This regulation amendment is effective June 13, 1979, the date of enactment of the law designated as Pub. L. 96–22.

FOR FURTHER INFORMATION CONTACT: T. H. Spindle (202–389–3005).

SUPPLEMENTARY INFORMATION: On pages 61210–11 of the **Federal Register** of October 24, 1979, there was published a proposed amendment to 38 CFR 3.57 to implement section 401 of Pub. L. 96–22 which provides rules for recognition of children adopted under foreign law.

Interested persons were given until December 3, 1979, to submit comments, suggestions or objections to the proposed amendment of § 3.57. We received no comment, suggestions, or objections.

Our own review, however, found that the proposed paragraph (e)(3)(i) did not specify that a veteran had to be receiving a dependent's allowance (or similar monetary benefit payable under title 38, United States Code) for the person that is the subject of the adoption. This has been corrected in the final regulation by the addition of the words "for the person" after the word "receiving" in the proposed regulation.

Approved: April 8, 1980.

By direction of the Administrator.

Rufus H. Wilson,

Deputy Administrator.

PART 3—ADJUDICATION

1. In § 3.57, the introductory portion of paragraph (c) preceding subparagraph (1) is revised and paragraph (e) is added so that the added and revised material reads as follows:

§ 3.57 Child.

* * * * *

(c) *Adopted child.* Except as provided in paragraph (e) of this section, the term means a child adopted pursuant to a final decree of adoption, a child adopted pursuant to an unrescinded interlocutory decree of adoption while remaining in the custody of the adopting parent (or parents) during the interlocutory period, and a child who has been placed for adoption under an agreement entered into by the adopting parent (or parents) with any agency authorized under law to so act, unless and until such agreement is terminated, while the child remains in the custody of the adopting parent (or parents) during the period of placement for adoption under such agreement. The term includes, as of the date of death of a veteran, such a child who

* * * * *

(e) *Child adopted under foreign law—*

(1) *General.* The provisions of this paragraph are applicable to a person adopted under the laws of any jurisdiction other than a State. The term "State" is defined in 38 U.S.C. 101(20) and also includes the Commonwealth of the Northern Mariana Islands. The term "veteran" includes, for the purposes of this paragraph, a Commonwealth Army veteran or new Philippine Scout as defined in 38 U.S.C. 1766.

(2) *Adopted child of living veteran.* A person residing outside any of the States shall not be considered to be a legally adopted child of a veteran during the lifetime of the veteran unless all of the following conditions are met.

(i) The person was less than 18 years of age at the time of adoption.

(ii) The person is receiving one-half or more of the person's support from the veteran.

(iii) The person is not in the custody of the person's natural parent unless the natural parent is the veteran's spouse.

(iv) The person is residing with the veteran (or in the case of divorce following adoption, with the divorced spouse who is also a natural or adoptive parent) except for periods during which the person is residing apart from the veteran for purposes of full-time attendance at an educational institution or during which the person or the veteran is confined in a hospital, nursing home, other health-care facility, or other institution.

(3) *Adopted child of deceased veteran.* A person shall not be considered to have been a legally adopted child of a veteran as of the date of the veteran's

death and thereafter unless one of the following conditions is met.

(i) The veteran was entitled to and was receiving for the person a dependent's allowance or similar monetary benefit payable under title 38, United States Code at any time within the 1-year period immediately preceding the veteran's death; or

(ii) The person met the requirements of paragraph (e)(2) of this section for a period of at least 1 year prior to the veteran's death.

(4) *Verification.* In the case of an adopted child of a living veteran, the requirements of paragraph (e)(2) (ii), (iii) and (iv) of this section are for prospective application. That is, in addition to meeting all of the requirements of paragraph (e)(2) of this section at the time of initial adjudication, benefits are not payable thereafter for or to a child adopted under the laws of any jurisdiction other than a State unless the requirements of paragraph (e)(2) (ii), (iii) and (iv) of this section continue to be met. Consequently, whenever Veterans Administration benefits are payable to or for a child adopted under the laws of any jurisdiction other than a State, and the veteran who adopted the child is living, the beneficiary shall submit, upon Veterans Administration request, a report, or other evidence, to determine if the requirements of paragraph (e)(2) (ii), (iii), and (iv) of this section were met for any period for which payment was made for or to the child and whether such requirements will continue to be met for future entitlement periods. Failure to submit the requested report or evidence within a reasonable time from date of request may result in termination of benefits payable for or to the child.

(38 U.S.C. 101(4), 210(c))

[FR Doc. 80-11271 Filed 4-14-80; 8:45 am]
BILLING CODE 8320-01-M

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38 CFR Part 3

Increased Compensation

AGENCY: Veterans Administration.

ACTION: Final regulations.

SUMMARY: The Veterans Administration has amended its regulations to implement the Veterans' Disability Compensation and Survivors' Benefits Amendments of 1979 enacted November 28, 1979. This law increases the rates of disability compensation and dependency and indemnity compensation payable to surviving spouses and children by 9.9 percent.

EFFECTIVE DATE: The change is effective October 1, 1979, the effective date specified by the Veterans' Disability Compensation and Survivors' Benefits Amendments of 1979 (Pub. L. 96-128).

FOR FURTHER INFORMATION CONTACT: T. H. Spindle, Jr., (202) 389-3005.

SUPPLEMENTARY INFORMATION: On pages 6416-17 of the Federal Register of January 28, 1980, the Veterans Administration published proposed amendments to §§ 3.350 and 3.552 of title 38, Code of Federal Regulations. In addition to the increase in the rates of disability compensation and dependency and indemnity compensation, the law provides that a veteran in receipt of disability compensation at the intermediate rate between 38 U.S.C. 314 (n) and (o) plus compensation under 38 U.S.C. 314(k) who is in need of aid and attendance, is entitled to the additional compensation authorized by 38 U.S.C. 314(r) (1) or (2). The law also provides that the intermediate rate shall be fixed at the arithmetic mean between the two rates concerned.

We gave the public until February 28, 1980 to submit comments, suggestions or objections to our proposed amendment of §§ 3.350 and 3.552. We received two letters from the same person.

Neither letter dealt with the specific changes that were proposed. The commentator discussed his own disability and offered a number of suggestions about Veterans Administration programs in general that would require legislation to implement. Consequently the proposed amendments of §§ 3.350 and 3.552 are adopted as proposed.

Approved: April 8, 1980.

By direction of the Administration.

Rufus H. Wilson,

Deputy Administrator.

1. In § 3.350, paragraphs (a) (introductory portion preceding subparagraph (1)), (f)(1) (i) and (iii), (2) (i) and (iii) and (5), and (h) are revised so that the added and revised material reads as follows:

§ 3.350 Special monthly compensation ratings.

The rates of special monthly compensation stated in this section are those provided under 38 U.S.C. 314.

(a) *Ratings under 38 U.S.C. 314(k).* Special monthly compensation under 38 U.S.C. 314(k) is payable for each anatomical loss or loss of use of one hand, one foot, both buttocks, one or more creative organs, blindness of one eye having only light perception, deafness of both ears, having absence of air and bone conduction, or complete organic aphonia with constant inability to communicate by speech. This special compensation is payable in addition to the basic rate of compensation otherwise payable on the basis of degree of disability, provided that the combined rate of compensation does not exceed $1,104 monthly when authorized in conjunction with any of the provisions of 38 U.S.C. 314 (a) through (j) or (s). When there is entitlement under 38 U.S.C. 314 (l) through (n) or an intermediate rate under (p) such additional allowance is payable for each such anatomical loss or loss of use existing in addition to the requirements for the basic rates, provided the total does not exceed $1,547 per month. The limitations on the maximum compensation payable under this paragraph are independent of and do not preclude payment of additional compensation for dependents under 38 U.S.C. 315, or the special allowance for aid and attendance provided by 38 U.S.C. 314(r).

* * * * *

(f) *Intermediate or next higher rate.* An intermediate rate authorized by this paragraph shall be established at the arithmetic mean, rounded to the nearest dollar, between the two rates concerned. (38 U.S.C. 314(p))

(1) *Extremities.* (i) Anatomical loss or loss of use of one extremity with the anatomical loss or loss of use of another extremity at a level or with complications preventing natural elbow or knee action with prosthesis in place will entitle to the rate intermediate between 38 U.S.C. 314 (l) and (m).

* * * * *

(iii) Anatomical loss or loss of use of extremity at a level preventing natural elbow or knee action with prosthesis in place with anatomical loss of another extremity so near the shoulder or hip as to prevent the use of a prosthetic appliance will entitle to the rate intermediate between 38 U.S.C. 314 (m) and (n).

(2) *Eyes, bilateral, and blindness in connection with deafness.* (i) Blindnss of one eye with 5/200 visual acuity or less and blindness of the other eye having only light perception will entitle to the rate intermediate between 38 U.S.C. 314 (l) and (m).

* * * * *

(iii) Blindness of one eye having only light perception and anatomical loss, or blindness having no light perception accompanied by phthisis bulbi, evisceration or other obvious deformity or disfigurement of the eye, will entitle to a rate intermediate between 38 U.S.C. 314 (m) and (n).

* * * * *

(5) *Three extremities.* Anatomical loss or loss of use, or a combination of anatomical loss and loss of use, of three extremities shall entitle a veteran to the next higher rate without regard to whether that rate is a statutory rate or an intermediate rate. The maximum monthly payment under this provision may not exceed the amount stated in 38 U.S.C. 314(p).

* * * * *

(h) *Special aid and attendance benefit; 38 U.S.C. 314(r)—(1) Maximum compensation cases.* A veteran receiving the maximum rate under 38 U.S.C. 314 (o) or (p) who is in need of regular aid and attendance or a higher level of care is entitled to an additional allowance during periods he or she is not hospitalized at United States Government expense. (See § 3.552(b)(2) as to continuance following admission for hospitalization.) Determination of this need is subject to the criteria of § 3.352. The regular or higher level aid and attendance allowance is payable whether or not the need for regular aid and attendance or a higher level of care was a partial basis for entitlement to the maximum rate under 38 U.S.C. 314 (o) or (p), or was based on an independent factual determination.

(2) *Entitlement to compensation at the intermediate rate between 38 U.S.C. 314 (n) and (o) plus special monthly compensation under 38 U.S.C. 314(k).* A veteran receiving compensation at the intermediate rate between 38 U.S.C. 314 (n) and (o) plus special monthly compensation under 38 U.S.C. 314(k) who establishes a factual need for regular aid and attendance or a higher level of care, is also entitled to an additional allowance during periods he or she is not hospitalized at United States Government expense. (See § 3.552(b)(2) as to continuance following admission for hospitalization.) Determination of the factual need for aid and attendance is subject to the criteria of § 3.352:

(3) *Amount of the allowance.* The amount of the additional allowance payable to a veteran in need of regular aid and attendance is specified in 38 U.S.C. 314(r)(1). The amount of the additional allowance payable to a veteran in need of a higher level of care is specified in 38 U.S.C. 314(r)(2). The higher level aid and attendance allowance authorized by 38 U.S.C. 314(r)(2) is payable in lieu of the regular aid and attendance allowance authorized by 38 U.S.C. 314(r)(1).

2. In § 3.552, paragraph (g) is revised to read as follows:

§ 3.552 Adjustment of allowance for aid and attendance.

* * * * *

(g) Where a veteran entitled to one of the rates under 38 U.S.C. 314 (l), (m), or (n) by reason of anatomical losses or losses of use of extremities, blindness (visual acuity 5/200 or less or light perception only), or anatomical loss of both eyes is being paid compensation of $1,547 because of entitlement to another rate under section 314(l) on account of need for aid and attendance the compensation will be reduced while hospitalized to the following:

(1) If entitlement is under section 314(l) and in addition there is need for regular aid and attendance for another disability, the award during hospitalization will be $1,217 since the disability requiring aid and attendance is 100 percent disabling. (38 U.S.C. 314(p))

(2) If entitlement is under section 314(m), $1,383.

(3) If entitlement is under section 314(n), $1,547 would be continued, since the disability previously causing the need for regular aid and attendance would then be totally disabling entitling the veteran to the maximum rate under 38 U.S.C. 314(p).

* * * * *

(38 U.S.C. 210(c))

[FR Doc. 80-11272 Filed 4-14-80; 8:45 am]

BILLING CODE 8320-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of the Secretary

41 CFR Parts 3-1, 3-2, and 3-3

Miscellaneous Amendments

AGENCY: Department of Health, Education, and Welfare.

ACTION: Final rule.

SUMMARY: The Office of the Secretary, Department and Health, Education, and Welfare is amending the departmental procurement regulations, 41 CFR Chapter 3, to make miscellaneous changes and deletions.

Subpart 3-1.53, Considerations in Selecting Award Instrument—Contract or Grant, is being deleted because it is outdated. The Department is preparing a new subpart addressing this subject which will be published at a later date.

Under Subpart 3-2.4, Opening of Bids and Award of Contract, changes are being made to clarify a portion of the regulation, redesignate subparagraphs to correspond to the recently issued FPR Amendment 204, and update organizational designations.

Under Subpart 3-3.2, Circumstances Permitting Negotiation, it was found that numerous changes were required to update and clarify the regulation so the entire subpart is being deleted and replaced by a new subpart.

EFFECTIVE DATE: April 15, 1980.

FOR FURTHER INFORMATION CONTACT: E. S. Lanham, Office of Procurement Policy, Office of Grants and Procurement, OASMB-OS, HEW, Washington, D.C. 20201 (202-245-0481).

SUPPLEMENTARY INFORMATION: It is the general policy of the Department to allow interested parties to participate in the rulemaking process. However, since these amendments are administrative in nature and concern the clarification of regulations, the public rulemaking process was deemed unnecessary in this instance. The provisions of these amendments are issued under 5 U.S.C. 301; 40 U.S.C. 486(c).

Therefore, 41 CFR Chapter 3 is amended as set forth below.

Dated: April 8, 1980.

Matthias Lasker

Acting Deputy Assistant Secretary for Grants and Procurement.

1. Under Part 3-1, General, Subpart 3-1.53, Considerations in Selecting Award Instrument—Contract or Grant, is deleted in its entirety, and the table of contents for Part 3-1 is amended to delete reference to that subpart.

2. Under Subpart 3-2.4, Opening of Bids and Award of Contract, of Part 3-2, Procurement by Formal Advertising, the following amendments are made:

§ 3-2.406-4 [Amended]

a. In § 3-2.406-4, Disclosure of mistakes after award, paragraph (a) is to remain reserved, paragraph (d) is redesignated paragraph (b), paragraph (c) is to remain reserved, and paragraph (e) is redesignated paragraph (d). In addition, the following is to be added as the last sentence in newly designated paragraph (b): "Contracting officers are not authorized to make these determinations."

§ 3-2.407-8(c) [Amended]

b. In § 3-2.407-8(c), *Protest after award,* subparagraph (2) is amended by deleting the opening phrase "Protests submitted to the Secretary" and substituting the phrase "Protests which have been lodged with the Secretary or the Comptroller General." In addition, the following is added as subparagraph (3):

* * * * *

(3) Protests lodged with the contracting officer shall be handled in the manner described in § 3-2.407-8(b)(2)(iii).

c. Throughout Subpart 3-2.4, change the organizational designation "Division of Procurement Policy and Regulations

Development" to read "Office of Procurement Policy."

3. Under Part 3–3, Procurement by Negotiation, Subpart 3–3.2, Circumstances Permitting Negotiation, is cancelled in its entirety, and a new Subpart 3–3.2 is established. In addition, the table of contents for Part 3–3 is amended to add the following:

Subpart 3–3.2—Circumstances Permitting Negotiation

Sec.
3–3.200 Scope of subpart.
3–3.201 National emergency.
3–3.205 Services of educational institutions.
3–3.206 Purchases outside the United States.
3–3.210 Impracticable to secure competition by formal advertising.
3–3.211 Experimental, developmental, or research work.
3–3.212 Purchases not to be publicly disclosed.
3–3.215 Otherwise authorized by law.

Subpart 3–3.2—Circumstances Permitting Negotiation

§ 3–3.200 Scope of subpart.

The citation of authority under which a contract is negotiated shall be referenced to the statutory provisions, e.g., the proper citation for use of the exception contained in § 1–3.211 is 41 U.S.C. 252(c)(11). The citation of authority to negotiate under other law (§ 1–3.215) shall be as prescribed in § 3–3.215.

§ 3–3.201 National emergency.

(a) [Reserved]

(b) [Reserved]

(c) [Reserved]

(d) *Limitations.* This authority shall not be used for other than assistance to labor surplus areas or small business concerns and administration of the Balance of Payments Program, without the prior written approval of the principal official responsible for procurement (not delegable).

§ 3–3.205 Services of educational institutions.

(a) [Reserved]

(b) *Limitations.* (1) This authority shall be used only for the procurement of specialized noncommercial services which are customarily performed by educational institutions. Use of this authority for any service other than those listed in § 1–3.205(a) shall require a written determination with supporting facts by the principal official responsible for procurement (not delegable) that the particular type of service is available only from educational institutions.

(2) Proposals shall be solicited from as many educational institutions as are known to possess the required capability. This shall be consistent with § 1–3.101(c). Solicitation of a single educational institution shall require a written "Justification for Noncompetitive Procurement" in accordance with the requirements of Subpart 3–3.53.

(3) Where the circumstances of both (1) and (2) above pertain in the same case, the required determinations shall be combined and made by the official designated in § 3–3.5306.

§ 3–3.206 Purchases outside the United States.

This authority shall be used in preference to any other authority under the circumstances set forth in § 1–3.206.

§ 3–3.210 Impracticable to secure competition by formal advertising.

(a) *Application.* (1) Negotiation under § 1–3.210 shall be conducted on a competitive basis to the maximum practicable extent, except when negotiation is justified under the circumstances specified in § 1–3.210(a)(1).

(2) The example specified in § 1–3.210(a)(3) shall apply only if the negotiation is for the identical requirements specified in the unresponsive bid. If specification deviations are authorized, or if delivery, quantity, or other requirements are changed, the revised requirements shall be readvertised or, if appropriate, negotiated under one of the other authorities prescribed in Subpart 1–3.2.

(3) Cases of doubt in applying the example specified in § 1–3.210(a)(13) shall be resolved in favor of formal advertising.

(b) *Limitations.* This authority shall not be used when negotiation is authorized by any other authority set forth in § 1–3.201 through § 1–3.215.

§ 3–3.211 Experimental, developmental, or research work.

(a) [Reserved]

(b) *Limitations.* Whenever more than single unit quantities of equipment or supplies are to be procured under this authority, the quantity shall be justified as reasonable and essential by the program authority submitting the procurement request.

§ 3–3.212 Purchases not to be publicly disclosed.

(a) [Reserved]

(b) *Limitations.* This authority shall be used in preference to any other authority when competition is to be limited because of the need for nondisclosure (also see § 1–1.1003–2(a)(1)).

§ 3–3.215 Otherwise authorized by law.

(a) [Reserved]

(b) When other statutory authority is the basis for negotiation, the proper citation for the contract is 41 U.S.C. 252(c)(15) plus the Section number, Title of the Act, and the Public Law number (or U.S. Code citation) of the statute which permits negotiation.

[FR Doc. 80–11383 Filed 4–14–80; 8:45 am]
BILLING CODE 4110–12–M

41 CFR Parts 3–1 and 3–7

Disabled Persons; Accessibility to Meetings, Conferences, and Seminars

AGENCY: Department of Health, Education, and Welfare.

ACTION: Final rule.

SUMMARY: The Office of the Secretary, Department of Health, Education, and Welfare is amending its procurement regulations by adding § 3–1.356, Accessibility of meetings, conferences, and seminars to persons with disabilities. The purpose of this amendment is to assure that meetings, conferences, and seminars sponsored by the Department will meet minimum accessibility standards so that persons with disabilities may fully participate.

In conjunction with this regulation, Subpart 3–7.50, Special Contract Clauses, is amended by adding a contract clause to assure contractor compliance with the regulation.

EFFECTIVE DATE: These amendments are effective April 15, 1980.

FOR FURTHER INFORMATION CONTACT: Hal G. Hubachek, Office of Procurement Policy, OGP–OASMB–OS, Room 538–H, Hubert H. Humphrey Building, Department of Health, Education, and Welfare, Washington, D.C. 20201 (202–245–8791).

SUPPLEMENTARY INFORMATION: On November 2, 1979, the proposed rule regarding the accessibility of meetings, conferences, and seminars was published in the Federal Register (44 FR 63115). Public comments were invited and sixteen comments were received. The Department received comments from three State governments, five groups representing disabled people, seven departmental activities, and one individual. All except one respondent supported the proposed regulation.

The respondent opposing the regulation expressed the opinion that the requirements would be "to[o]

stringent to be enforceable or gain any general acceptance by those persons responsible for planning public meetings for training, seminars, etc." The Department does not agree with the respondent's opinion, and, considering the comment in light of the preponderance of supporting comments, the Department is inclined to accept the majority view and is adopting the regulation. Furthermore, the Department does not agree that the requirements imposed by the regulation will put an onerous burden upon contractors who conduct meetings, conferences, and seminars for the Department. In addition, the Department is committed to making its programs accessible to all individuals, including the disabled.

Several respondents suggested a standard provision be added to the regulation that would recognize the variable additional costs of providing special services and facilities, (i.e., the costs of interpreters, recorders, tapes, readers, but not permanent fixtures or real property). The Department does not agree that such a standard provision is necessary because the majority of the contracts awarded by the Department are cost-reimbursement type contracts, so the contractor would be able to recover the variable costs generated by compliance with the regulation and contract clause. In addition, these costs, in comparison to the total cost of the contract, would vary according to the individual contract requirements. In some contracts, the costs of conducting a meeting or meetings may be an incidental part of the contract and hence a minute cost consideration, while in other contracts, these costs may represent the principal portion of the contract. The Department believes a standard provision is not appropriate and the situation must be dealt with on a contract-by-contract basis. Therefore, the recommendation is not adopted.

A number of respondents addressed the specific needs of hearing impaired attendees. Some respondents felt qualified interpreters are required to assure full participation of hearing impaired attendees, and the substitution of notetakers would not assure an adequate level of participation. The Department agrees with this recommendation, and has incorporated it in the final rule.

A further concern expressed by these respondents was the availability of teletype equipment to hearing impaired attendees. One respondent indicated that portable teletype equipment using regular phone lines is readily available for lease or purchase, and suggested on-site teletype capabilities be required.

The Department agrees that the use of on-site teletype equipment is the preferable method of providing this service. However, the Department also believes that providing transportation to a local teletype facility is an acceptable alternate means of supplying this service. Therefore, the Department has added the stipulation that the provision of on-site teletype equipment will be required only if local teletype facilities are unavailable.

One respondent recommended that an exception from the facilities requirements in the contract clause be allowed if the contractor knows that no physically disabled individual will be in attendance at the meeting, seminar, or conference. The Department does not agree with the recommendation because the policy is applicable to conferences, meetings, or seminars that are open to the public or involve HEW personnel, and it would be extremely difficult, if not impossible, to determine whether disabled individuals would be in attendance under those circumstances.

Some respondents noted minor differences between the technical terminology contained in the proposed rule and that in the accessibility standards established by the American National Standards Institute. Therefore, changes have been made to the regulation to make it consistent with established Federal Standards. For example, the term "jamb to jamb" does not clearly indicate the accepted technical usage, and the term "clear width" has been substituted for it.

A number of comments were received from departmental organizations suggesting changes to clarify minor ambiguities in the proposed rule, and those comments furthering the intent of the regulation have been incorporated.

Therefore, 41 CFR Chapter 3 is amended in the manner set forth below.

Dated: April 8, 1980.

Matthias Lasker,

Acting Deputy Assistant Secretary for Grants and Procurement.

1. Under Subpart 3–1.3, General Policies, of Part 3–1, General, the following section is added, and the table of contents for Part 3–1 is amended to add the following:

* * * * *

Subpart 3–1.3—General Policies

* * * * *

§ 3–1.356 Accessibility of meetings, conferences, and seminars to persons with disabilities.

Subpart 3–1.3—General Policies

* * * * *

§ 3–1.356 Accessibility of meetings, conferences, and seminars to persons with disabilities.

(a) It is the policy of HEW that all meetings, seminars, and conferences be accessible to individuals with disabilities. For the purposes of this policy, accessibility is defined as both physical access to meeting, conference, and seminar sites, and aids and services to enable individuals with sensory disabilities to fully participate in meetings, conferences, and seminars.

(b) In regard to procurement, the policy is applicable to all contracts where the statement of work requires the contractor to conduct conferences, meetings, or seminars that are open to the public or involve HEW personnel, but not to ad hoc meetings that may be necessary or incidental to contract performance.

(c) The contracting officer shall be responsible for including the clause described in § 3–7.5026 in every solicitation and resulting contract when the statement of work requires the contractor to conduct meetings, conferences, or seminars in accordance with paragraph (b), above.

(d) The project officer shall be responsible for obtaining, reviewing, and approving the contractor's plan, which is to be submitted in response to paragraph (a) of the contract clause described in § 3–7.5026. A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars will be acceptable. The project officer, prior to approving the plan, shall consult with the Office of Facilities Engineering, or the Office of Regional Operations for Facilities Engineering and Construction in the region where the meeting, conference, or seminar is to be held, to assure that the contractor's plan meets the accessibility requirements of the contract clause. The Office of Facilities Engineering or the Office of Regional Operations for Facilities Engineering and Construction shall make a determination on the adequacy of the contractor's plan, and notify the project officer, in writing, within ten (10) working days of receiving the request from the project officer.

2. Under Subpart 3–7.50, Special

Contract Clauses, of Part 3–7, Contract Clauses, the following section is added, and the table of contents for Part 3–7 is amended to add the following:

* * * * *

Subpart 3–7.50—Special Contract Clauses

* * * * *

Sec.

3–7.5026 Accessibility of meetings, conferences, and seminars to persons with disabilities.

Subpart 3–7.50—Special Contract Clauses

* * * * *

§ 3–7.5026 Accessibility of meetings, conferences, and seminars to persons with disabilities.

The following clause is to be used in accordance with § 3–1.356

Accessibility of Meetings, Conferences, and Seminars to Persons with Disabilities

The Contractor agrees as follows:

(a) *Planning.* The Contractor will develop a plan to assure that any meeting, conference, or seminar held pursuant to this contract will meet or exceed the minimum accessibility standards set forth below. This plan shall include a provision for ascertaining the number and types of disabled individuals planning to attend the meeting, conference, or seminar. This plan shall be submitted to the project officer for approval prior to initiating action. (A consolidated or master plan for contracts requiring numerous meetings, conferences, or seminars may be submitted in lieu of separate plans.)

(b) *Facilities.* Any facility to be utilized for meetings, conferences, or seminars in performance of this contract shall be accessible to persons with disabilities. The Contractor shall determine, by an on-site inspection if necessary, that the following minimum accessibility requirements are met, or suitable modifications are made to meet these requirements, before the meeting:

(1) *Parking.* (i) Where parking is available on or adjacent to the site, one 12' wide space must be set aside for the car of each mobility impaired attendee. The space need not be permanently striped but may be temporarily marked by signs, ropes, or other means satisfactory to carry out this provision.

(ii) Where parking is not available on or adjacent to the site, valet parking or other alternative means to assist a person who has a mobility impairment may be used. Alternative means must be satisfactory in the judgment of the Government project officer.

(2) *Entrances.* (i) "Entrances" shall include at least one accessible entrance from street/sidewalk level, and at least one accessible entrance from any available parking facility.

(ii) The entrance shall be level or accessible by ramp with an incline that allows independent negotiation by a person in a wheelchair. In general, the slope of the incline shall be no more than 1" rise per foot of ramp length (1:12).

(iii) Entrance doorways shall be at least 30" in clear width and capable of operation by persons with disabilities. Revolving doors, regardless of foldback capability, will not meet this requirement.

(3) *Meeting Rooms.* (i) Meeting room access from the main entrance area must be level or at an independently negotiable incline (approximately 1:12) and/or served by elevators from the main entrance level. All elevators shall be capable of accommodating a wheelchair 29" wide by 45" long.

(ii) Meeting rooms shall be on one level or, if on different levels, capable of being reached by elevators or by ramps that can be independently negotiated by a person in a wheelchair. Doorways to all meeting rooms shall be at least 30" in clear width.

(iii) The interior of the meeting room shall be on one level or ramped so as to be independently negotiable for a person in a wheelchair.

(iv) Stages, speaker platforms, etc. which are to be used by persons in wheelchairs must be accessible by ramps or lifts. When used, the ramps may not necessarily be independently negotiable if space does not permit. However, any slope over 1:12 must be approved by the project officer. Each case is to be judged on its own merits.

(v) If a meeting room with fixed seating is utilized, seating arrangements for persons in wheelchairs shall be made so that these persons are incorporated into the group rather than isolated on the perimeter of the group.

(4) *Restrooms.* (i) Restrooms shall have level access, signs indicating accessibility, and doorways shall be at least 30" clear width.

(ii) Sufficient turning space within restrooms shall be provided for independent use by a person in a wheelchair 29" wide by 45"long. A space 60" by 60" or 63" by 56" of unobstructed floor space as measured 12" above the floor is acceptable by standard; other layouts will be accepted if it can be demonstrated that they are usable as indicated.

(iii) There will be a restroom for each sex or a unisex restroom with at least one toilet stall capable of accommodating a wheelchair 29" wide by 45" long, (by standard, the minimum is 3' 0" by 4' 8") with outswinging doors or privacy curtains. Wall mounted grab bars are required.

(iv) When separate restrooms have been set up for mobility impaired persons, they shall be located adjacent to the regular restrooms and shall be fully accessible.

(5) *Eating Facilities.* (i) Eating facilities in the meeting facility must be accessible under the same general guidelines as are applied to meeting rooms.

(ii) If the eating facility is a cafeteria, the food service area (cafeteria line) must allow sufficient room for independent wheelchair movement and accessibility to food for persons in wheelchairs, and cafeteria staff shall be available to assist disabled persons.

(6) *Overnight Facilities.* If overnight accommodations are required:

(i) Sufficient accessible guest rooms to accommodate each attendee who is disabled shall be located in the facility where the meeting, conference, or seminar is held, or in a facility housing the other attendees which is conveniently located nearby, whichever is satisfactory to the project officer.

(ii) Overnight facilities shall provide for the same minimum accessibility requirements as the facility utilized for the meeting, conference, or seminar. In addition, guest room access from the main entrance area shall be level, ramped at an independently negotiable incline (1:12), and/or served by elevators capable of accommodating a wheelchair 29" wide by 45" long.

(iii) Doorways to guest rooms, including the doorway to the bathroom, shall be at least 30" in clear width.

(iv) Bathrooms shall have wall mounted grab bars at the tub and water closet.

(v) Guest rooms for persons with a disability shall be provided at the same rate as a guest room for other attendees.

(7) *Water Fountains.* Water fountains shall be accessible to disabled persons, or have cup dispensers for use by persons in wheelchairs.

(c) *Provisions of Services for Sensory Impaired Attendees.* (1) The Contractor, in planning the meeting, conference, or seminar, shall include in all announcements and other materials pertaining to the meeting, conference, or seminar a notice indicating that services will be made available to sensory impaired persons attending the meeting, if requested within five (5) days of the date of the meeting, conference, or seminar. The announcement(s) and other material(s) shall indicate that sensory impaired persons may contact a

specific person(s), at a specific address and phone number(s) to make their service requirements known. Phone number(s) shall include a teletype number for the hearing impaired.

(2) The Contractor shall provide, at no costs to the individual, those services required by persons with sensory impairments to insure their complete participation in the meeting, conference, or seminar.

(3) As a minimum, when requested in advance, the Contractor shall provide the following services:

(i) For hearing impaired persons, qualified interpreters. Provisions will also be made for volume controlled phone lines and, if necessary, transportation to local teletype equipment to enable hearing impaired individuals to receive and send meeting related calls. If local teletype equipment is not available, the Contractor shall provide on-site teletype equipment. Also, the meeting rooms will be adequately illuminated so signing by interpreters can be easily seen.

(ii) For vision impaired persons, readers and/or cassette materials, as necessary, to enable full participation. Also, meeting rooms will be adequately illuminated.

(iii) Agenda and other conference material(s) shall be translated into a usuable form for the visually and hearing impaired. Readers, braille translations, and/or tape recordings are all acceptable. These materials shall be available to sensory impaired individuals upon upon their arrival.

(4) The Contractor is responsible for making every effort to ascertain the number of sensory impaired individuals who plan to attend the meeting, conference, or seminar. However, if it can be determined that there will be no sensory impaired person (deaf and/or blind) in attendance, the provision of these services under paragraph (c) for the nonrepresented group, or groups, is not required.

[FR Doc. 80-11382 Filed 4-14-80; 8:45 am]

BILLING CODE 4110-12-M

Social Security Administration

45 CFR Parts 205 and 235

General Administration; Public Assistance Programs; Administration of Financial Assistance Programs; State Plan for Methods of Personnel Administration

AGENCY: Social Security Administration, HEW.

ACTION: Final rules.

SUMMARY: These final regulations simplify procedures for State plans in accordance with the revised Standards for a Merit System of Personnel Administration published by the Office of Personnel Management, February 16, 1979. The revised Standards provide for a simplified, more uniform approach to personnel requirements established as a condition for Federal grants-in-aid to State and local governments. The Standards, 5 CFR § 900.610–1, require certification of agreement by the chief executive of the jurisdiction to maintain a system of personnel administration in conformance with the Standards. The regulations will require the State plan to establish and maintain a personnel system that conforms with the Standards.

EFFECTIVE DATE: The regulations will be effective April 15, 1980.

FOR FURTHER INFORMATION CONTACT: Ms. Evelyn Greene, Program Specialist, Office of Family Assistance, Social Security Administration, 330 C Street, S.W., Washington, D.C. 20201; telephone (202) 245–1594.

SUPPLEMENTARY INFORMATION:

Background

Before March 9, 1977, the personnel administration regulations for the medical assistance, social service, and AFDC programs were administered by the Social and Rehabilitation Service (SRS). SRS was abolished by HEW's reorganization of March 9, 1977 (42 FR 13262). Former SRS functions are now performed by three agencies within HEW: the Office of Human Development Services (OHDS); the Health Care Financing Administration (HCFA); and the Social Security Administration (SSA).

HCFA administers the medical assistance programs; HCFA personnel management regulations are contained in 42 CFR 446.160. OHDS personnel management regulations for the social services programs under title XX of the Social Security Act are contained in 45 CFR 228.9

SSA administers the AFDC program; AFDC personnel administration regulations are contained in 45 CFR 205.200. We are amending § 205.200 to make it inapplicable to the financial assistance programs administered under title I, IV–A, X, XIV, or XVI (AABD) of the Social Security Act. We are adding new § 235.50 to apply to the financial assistance programs under title I, IV–A, X, XIV, or XVI (AABD) administered by the Social Security Administration. The remaining rules in § 205.200 which apply to the social services programs administered under title I, IV–A, X, XIV, or XVI (AABD) for Guam, Puerto Rico, and the Virgin Islands will be recodified and revised in Title 45, Chapter XIII by the Office of Human Development Services.

The Final Rules

These are final regulations. They update prior rules that apply to the financial assistance programs in all jurisdictions. They also provide administrative changes required by the revised Standards for a Merit System of Personnel Administration, 5 CFR 900.610–1. These revised Standards were published on February 16, 1979 in the Federal Register (44 FR 10237). These changes will prevent duplication in administering the Standards and they do not affect applicants or recipients under the programs. Consequently, the Secretary finds that it is unnecessary to publish a Notice of Proposed Rule Making.

Differences Between Current Rules and Final Rules

1. Amending § 205.200 removes from this section rules for standards of personnel administration for financial assistance programs. Previously, the rules on this subject for other programs were relocated. The HCFA rules for the Medicaid program are now contained in 42 CFR 446.160. The OHDS rules for the social services programs under title XX of the Social Security Act are contained in 45 CFR 228.9. OHDS will recodify and revise in title 45 CFR, Chapter XIII, the rules for the social services programs under title I, IV–A, X, XIV, or XVI (AABD) in Guam, Puerto Rico, and the Virgin Islands, which remain in 45 CFR 205.200. The SSA rules for the financial assistance programs will be contained in the new 45 CFR 235.50.

2. Section 205.200 has required States to submit statements of acceptance of State standards of personnel administration from all local jurisdictions, and to establish methods to assure compliance by local jurisdictions. Under the revised Standards, the chief executive of local jurisdictions is responsible for certifying conformance with the Standards. It would be a duplication for the State agency to require statements of acceptance and to assure compliance by local jurisdictions. Section 235.50 requires that the State agency establish and maintain a personnel system that conforms with the Standards.

3. Section 205.200 has required U.S. Civil Service Commission (CSC) review of a list of documents attached to the State plan; this is an unnecessary review because the basic documents listed have been reviewed by the CSC and now will be reviewed by the Office of Personnel Management. The new

§ 235.50 eliminates the requirement for submission of the list.

(Secs. 2, 402, 1002, 1102, 1402, and 1602 of the Social Security Act, as amended; 74 Stat. 987 as amended, 45 Stat. 627 as amended, 49 Stat. 645 as amended, 49 Stat. 647 as amended, 64 Stat. 555 as amended, 76 Stat. 198 as amended; 42 U.S.C. 302, 602, 1202, 1302, 1352, and 1382 Note.)

(Catalog of Federal Domestic Assistance Program No. 13.761, Public Assistance-Maintenance Assistance (State Aid).)

Dated: January 18, 1980.

William J. Driver,

Commissioner of Social Security.

Approved: April 8, 1980.

Patricia Roberts Harris,

Secretary of Health, Education, and Welfare.

45 CFR Chapter II is amended as set forth below:

PART 205—GENERAL ADMINISTRATION—PUBLIC ASSISTANCE PROGRAMS

1. Part 205, § 205.200(a) is amended to read as follows:

§ 205.200 Standards of personnel administration.

These rules apply only to the social services or programs in Guam, Puerto Rico, and the Virgin Islands. Rules for the financial assistance programs under title I, IV–A, X, XIV, or XVI (AABD) in all jurisdictions are found in Part 235, § 235.50 of this title.

(a) A State plan for social services programs in Guam, Puerto Rico, or the Virgin Islands, funded under title I, IV–A, X, XIV, or XVI of the Social Security Act shall provide that methods of personnel administration will be established and maintained in the State agency administering or supervising the State plan and in local agencies administering the State plan in conformity with the standards for a Merit System of Personnel Administration, 45 CFR Part 70 and any standards prescribed by the (former) U.S. Civil Service Commission, now the Office of Personnel Management, pursuant to section 208 of the Intergovernmental Personnel Act of 1970 modifying or superseding such standards. Under this requirement, State laws, rules, regulations, and policy statements effectuating such methods of personnel administration are a part of the State plan. Statements of acceptance of these standards by all official local agencies included in the State plan must be obtained and methods must be established by the State to assure compliance by local jurisdictions. These statements and citations of applicable State laws, rules, regulations, and policies which provide assurance of conformity to the standards in 45 CFR Part 70 or to modifying or superseding standards issued by the Commission must be submitted to the (former) U.S. Civil Service Commission, now the Office of Personnel Management, in accordance with 5 CFR Part 900 for determination as to adequacy. Copies of the materials cited and of similar local materials maintained by a State official responsible for compliance by local jurisdictions must be furnished to the Department of Health, Education, and Welfare on request.

PART 235—ADMINISTRATION OF FINANCIAL ASSISTANCE PROGRAMS

2. Part 235 is amended by adding § 235.50 to read as follows:

§ 235.50 State plan requirements for methods of personnel administration.

(a) A State plan for financial assistance programs under title I, IV–A, X, XIV, or XVI (AABD) of the Social Security Act must provide that methods of personnel administration will be established and maintained in public agencies administering or supervising the administration of the program in conformity with the Standards for a Merit System of Personnel Administration, 5 CFR Part 900, Subpart F, which incorporates the Intergovernmental Personnel Act Merit Principles (Pub. L. 91–648, Sec. 2, 84 Stat. 1909), prescribed by the Office of Personnel Management pursuant to Section 208 of the Intergovernmental Personnel Act of 1970 as amended.

[FR Doc. 80–11386 Filed 4–14–80; 8:45 am]

BILLING CODE 4110–07–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0

Amending Rules Reflecting a Reorganization of the Common Carrier Bureau; Correction

AGENCY: Federal Communications Commission.

ACTION: Final rule; correction.

SUMMARY: Paragraphs (a) through (j) were inadvertently left out of Section 0.91, Functions of the Bureau in Order FCC 79–882, amending the Commission's Rules and Regulations to reflect a reorganization of the Common Carrier Bureau published at 45 FR 16191, March 13, 1980.

EFFECTIVE DATE: March 17, 1980.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Joe Hall, Office of the Executive Director, (202) 632–7513.

SUPPLEMENTARY INFORMATION: In the Matter of Amendment of Part 0 of the Commission's Rules to reflect a reorganization of the Common Carrier Bureau, Errata.

Released: April 3, 1980.

In an order (FCC 79–882) issued March 7, 1980, the Commission announced amendments to Section 0.91 and 0.92 of the Commission's Rules and Regulations and deletion of Sections 0.93 through 0.102 to reflect a reorganization of the Common Carrier Bureau. The introductory paragraph of Section 0.91, Functions of the Bureau, was amended; however, the following paragraphs (a) through (j) were inadvertently left out of the Order although there were no changes or deletions to these paragraphs. Accordingly, paragraphs (a) through (j) are retained under the introductory paragraph in Section 0.91 of the Commission's Rules and Regulations.

Federal Communications Commission.

William J. Tricarico,

Secretary.

Accordingly, FR Doc 80–7747 published at 45 FR 16191, March 13, 1980 is corrected on page 16192 in the first column under "Appendix" as follows:

§ 0.91 [Amended]

1. Amendatory item 1 is revised to read:

"1. The introductory paragraph in § 0.91 is amended to read:"

2. Under the paragraph in § 0.91 and before amendatory item 2 insert five asterisks.

[FR Doc. 80–11363 Filed 4–14–80; 8:45 am]

BILLING CODE 6712–01–M

47 CFR Part 0

[FCC 80–179]

Transferring Authority for Common Carrier Matters Involving Public Coast Stations to the Private Radio Bureau

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The FCC amends its rules to transfer authority for common carrier matters involving public coast stations from joint delegation to the Chiefs of the Private Radio and Common Carrier Bureaus to sole delegation to the Chief of the Private Radio Bureau. This action will affect public coast station licensees. The consolidation of authority is expected to result in savings of time and

resources expended on common carrier matters in the maritime mobile service.

EFFECTIVE DATE: April 18, 1980.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Penny Wells, Private Radio Bureau (202–632–7175).

SUPPLEMENTARY INFORMATION:

Order

Adopted: March 31, 1980.
Released: April 7, 1980.

In the matter of Amendment of Part 0 to transfer authority for common carrier matters involving public coast stations to the Private Radio Bureau.

1. The purpose of this order is to amend our rules to transfer authority for all matters involving public coast stations in the maritime mobile service to the Private Radio Bureau. Until now, the Common Carrier Bureau and the Private Radio Bureau have been authorized to act jointly on common carrier aspects of our regulation of public coast stations. The consolidation of authority is expected to result in savings of time and resources expended on common carrier matters in the maritime mobile service. The licensees affected by this change are licensees of public coast stations.

2. Because these amendments relate solely to agency management, the public notice, procedure and effective date provisions of 5 U.S.C. 553 do not apply. Authority for the amendments is set out in Sections 4(i) and 5(d) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i) and 155(d).

3. Accordingly, it is ordered, effective April 18, 1980, that the rule amendments set forth in the attached Appendix are adopted.

(Secs. 4, 5, 303, 48 Stat., as amended, 1066, 1068, 1082; (47 U.S.C. 154, 155, 303))

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix

Part 0 of Chapter I of Title 47 of the Code of Federal Regulations is amended to read as follows:

PART 0—COMMISSION ORGANIZATION

1. Section 0.91 is amended to read as follows:

§ 0.91 Functions of the Bureau.

The Common Carrier Bureau develops, recommends and administers policies and programs for the regulation of the services, facilities, rates and practices of entities (excluding public coast stations in the maritime mobile service) which furnish interstate or foreign communications services for hire—whether by wire, radio, cable or satellite facilities—and of ancillary operations related to the provision or use of such services. The Bureau also licenses all radio facilities used for such services, including those dedicated entirely to intrastate use. The Bureau performs the following specific functions:

* * * * *

2. Section 0.131 is amended to read as follows:

§ 0.131 Functions of the Bureau.

The Private Radio Bureau develops, recommends, and administers policies and programs for the development and regulations of the Private Radio Services. These services include nationwide and international uses of radio by persons, businesses, state and local governments, and other organizations licensed to operate their own communications systems for their own use as an adjunct of their primary business or other activity. This program includes, among others (a) the compulsory use of radio for safety at sea purposes, and (b) the regulation of public coast station. The Bureau performs the following functions:

* * * * *

3. Paragraph (a) of § 0.291 is amended to read as follows:

§ 0.291 Authority delegated.

The Chief, Common Carrier Bureau, is hereby delegated authority to perform all functions of the Bureau, described in § 0.91, subject to the following exceptions and limitations.

(a) *Authority concerning applications.* (1) The Chief, Common Carrier Bureau shall not have authority to act on any formal or informal radio applications of Section 214 applications for common carrier services which are in hearing status or where the estimated cost of construction (or value of radio facilities where an assignment or transfer of facilities is involved) is in excess of $10 million or the annual rental is in excess of $2 million. (The only exception to these monetary limitations will be special temporary authorizations in the event of extraordinary circumstances requiring the immediate restoration or institution of public service.)

(2) * * *

* * * * *

4. Section 0.301 is amended to read as follows:

§ 0.301 Authority delegated jointly to Chiefs of Common Carrier and Private Radio Bureaus.

Authority is delegated jointly to the Chief of the Common Carrier Bureau and the Chief of the Private Radio Bureau to act upon applications involving common carrier matters in the aeronautical mobile service, and in the fixed service in Alaska. (For record of actions taken under this section, see Section 0.337.)

5. Section 0.333 is amended to read as follows:

§ 0.333 Authority delegated jointly to the Chief of the Common Carrier and Private Radio Bureaus.

Authority is delegated jointly to the Chief of the Common Carrier Bureau and the Chief of the Private Radio Bureau to act upon applications involving common carrier matters in the aeronautical mobile service, and in the fixed service in Alaska.

6. Section 0.335 is added to read as follows:

§ 0.335 Authority for common carrier matters delegated to Chief, Private Radio Bureau.

The Chief of the Private Radio Bureau is delegated authority for all common carrier matters involving public coast stations in the maritime mobile service.

[FR Doc. 80–11307 Filed 4–14–80; 8:45 am]

BILLING CODE 6712–01–M

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47 CFR Part 0

Change in the Office of Plans and Policy

AGENCY: Federal Communications Commission.

ACTION: Amendment of Rules.

SUMMARY: The Commission has centralized responsibility for coordinating its international functions in the Office of Science and Technology. This amendment changes the Commission's rules to incorporate the transfer of the Office of Plans and Policy's portion of that function.

EFFECTIVE DATE: April 18, 1980.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Charles Marietta, Jr., Office of Executive Director (202) 632–7513.

SUPPLEMENTARY INFORMATION:

Order

Adopted: April 3, 1980.
Released: April 7, 1980.

In the matter of Editorial Amendment of Part 0 of the Commission's rules to

reflect a change in the Office of Plans and Policy.

1. The Commission has voted to centralize responsibility for coordination of its international functions. This responsibility is transferred from the Office of Plans and Policy to the Office of Science and Technology. While all Bureaus and Offices will continue to participate as appropriate, this move will permit concentration of expert personnel.

2. The new assignment to the Office of Science and Technology was part of a larger action and will be published separately. Part 0 of the rules and regulations is being amended to reflect the change in the Office of Plans and Policy.

3. The amendment adopted herein pertains to agency organization. The prior notice procedure and effective date provisions of Section 4 of the Administrative Procedure Act, 5 U.S.C. 533, are therefore inapplicable. Authority for the amendment adopted herein is contained in sections 4(i) and 5(d) of the Communications Act of 1934, as amended.

4. In view of the foregoing, it is ordered, effective April 18, 1980, that Part 0 of the rules and regulations is amended as set forth in the Appendix below.

(Secs. 4, 5, 303, 48 Stat., as amended, 1066, 1068, 1082; (47 U.S.C. 154, 155, 303))

R. D. Lichtwardt,
Executive Director.

Appendix

Part 0 of Chapter I of Title 47 of the Code of Federal Regulations is hereby amended as indicated below.

1. In § 0.21, paragraph (h) is amended and paragraph (i) is redesignated as (j) and new paragraph (i) is added to read as follows:

§ 0.21 Functions of the Office.

* * * * *

(h) To coordinate the formation and presentation of Commission positions in domestic communications policy; represent the Commission at appropriate interagency discussions and conferences.

(i) To participate in the development of international communications policy with the Office of Science and Technology, as appropriate; provide representation at international meetings when appropriate.

(j) Develop and recommend procedures and plans for the effective handling of policy issues within the Commission.

[FR Doc. 80-11309 Filed 4-14-80; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[Docket BC 79-130; RM-3132; RM-3167]

Radio Broadcast Services; FM Broadcast Assignment to Nederland, Tex.

AGENCY: Federal Communications Commission.

ACTION: Final rule (Report and Order).

SUMMARY: Action taken herein assigns FM Channel 221A as a first FM channel to Nederland, Texas, in response to a petition filed by Ralph H. McBride. The channel could provide for a first aural broadcast service in the community.

EFFECTIVE DATE: May 23, 1980.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mark N. Lipp, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

Report and Order—Proceeding Terminated

Adopted: April 2, 1980.
Released: April 8, 1980.

In the matter of amendment of § 73.202(b), *Table of Assignments*, FM Broadcast Stations, (Port Neches and Bridge City, Texas), BC Docket No. 79-130, RM-3132, RM-3167.

1. The Commission has before it the *Notice of Proposed Rule Making*, released May 31, 1979, 44 FR 33120, in response to a petition from Ralph H. McBride ("McBride") of Port Neches, Texas, and Harold D. and Linda Richardson ("Richardson") of Bridge City, Texas. Both petitioners requested the assignment of FM Channel 221A to their respective community. Since these cities are only 11 kilometers (7 miles) apart and the required spacing is 104 kilometers (65 miles), the channel cannot be assigned to both communities. The *Notice* proposed the assignment of Channel 221A to either community, in the alternative, and requested petitioners to indicate what, if any, channels are available to the three precluded communities of: Newton, Texas; Merryville, Louisiana; and DeQuincy, Louisiana. Comments were filed by both petitioners.

2. Port Neches (pop. 10,894)[1] in Jefferson County (pop. 246,402), is located adjacent to Port Arthur, Texas, approximately 138 kilometers (85 miles) east of Houston. Port Neches is served locally by daytime-only AM Station KSUZ. Bridge City (pop. 8,164) in Orange County (pop. 71,170) is located 11 kilometers (7 miles) east of Port Neches. Bridge City has no local aural service.

3. McBride submits that no regular Class A channels are available for the precluded communities. However, he claims that adoption of the "Bergen" rule making proceeding (Dkt. 80-90)[2] would result in the availability of Class A channels for the precluded communities in addition to a different Class A channel for Bridge City, Texas. Richardson submits that the precluded communities will probably not be able to financially support a radio station.

4. Richardson contends that, since Port Neches is being served by a daytime AM station, the public interest would be best served by assigning Channel 221A to Bridge City and providing it with a first local aural service.

5. McBride states that upon further examination of the area, it was discovered that there is a greater existing need for a first FM service in another community, Nederland, Texas. Nederland is located approximately 3 miles southwest of Port Neches and is nearly twice as large. In view of this McBride has amended his petition by requesting that Channel 221A be assigned to Nederland, Texas, while further stating that he would accept a Port Neches assignment.

6. The Commission has concluded that, on the facts of this case, the 10-mile rule, § 73.203(b) of the Commission's rules can be utilized to permit the use of Channel 221A at any of the three communities. This means that, although the channel will be assigned to Nederland, any person can apply for it to serve either Nederland, Port Neches or Bridge City. Thus, no matter which of the three communities were to receive the allocation, neither of the other two would be foreclosed from specification as the community of license in an application citing the 10-mile rule. The ultimate city chosen will have to be decided by application processing.

7. Accordingly, it is ordered, that effective May 23, 1980, the FM Table of Assignments, § 73.202(b) of the Commission's rules and regulations is amended as follows:

City, Nederland, Texas; Channel No. 221A.

8. It is further ordered, That this proceeding is terminated.

9. For further information concerning this proceeding, contact Mark N. Lipp, Broadcast Bureau, (202) 632-7792.

(Secs. 4, 303, 307, 48 Stat., as amended, 1066, 1082, 1083; (47 U.S.C. 154, 303, 307))

[1] Population figures are taken from the 1970 U.S. Census.

[2] This rule making proceeding (Dkt. 80-90). *Notice* released March 14, 1980, as it pertains here, proposes to permit the use of Class A FM stations on channels reserved for Class B or C operation.

Federal Communications Commission.

Henry L. Baumann,

Chief, Policy and Rules Division, Broadcast Bureau.

[FR Doc. 11302 Filed 4-14-80; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[BC Docket No. 79-290; RM-3438]

Radio Broadcast Services; FM Assignment to Vandalia, Mo.

AGENCY: Federal Communications Commission.

ACTION: Final rule (Report and Order).

SUMMARY: Action taken herein assigns FM Channel 261A to Vandalia, Missouri, as that community's first FM assignment, in response to a petition filed by Roger C. Elliott. The proposed channel can provide for a first local aural broadcast service to Vandalia.

EFFECTIVE DATE: May 23, 1980.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION: In the matter of amendment of § 73.202(B), *Table of Assignments,* FM Broadcast Stations. (Vandalia, Missouri), BC Docket No. 79-290, RM-3438.

Report and Order—Proceeding Terminated

Adopted: April 2, 1980.

Released: April 8, 1980.

1. The Commission has before it the *Notice of Proposed Rule Making,* adopted October 26, 1979, 44 FR 64441, proposing the assignment of FM Channel 261A to Vandalia, Missouri, at the request of Roger C. Elliott ("petitioner"). Supporting comments were filed by petitioner in which he stated his readiness to apply for the channel, if assigned. An opposition to the proposal was filed by Pike County Broadcasting Co. ("Pike"), licensee of Stations KPCR (AM) and KPCR-FM, Bowling Green, Missouri, to which petitioner replied.

2. Vandalia (pop. 3,160)[1], in Audrain County (pop. 25,362), is located approximately 129 kilometers (80 miles) northwest of St. Louis, Missouri. There is no local aural broadcast service in Vandalia.

3. In opposition, Pike claims that its stations provide primary coverage to Vandalia. It asserts that if a station were to be operated in Vandalia, Pike would suffer loss of revenues as would some of the other stations in the area which serve Vandalia. Pike also notes that receivers would be skipping back and forth between two frequencies, especially in autos, so that instead of providing these people with a second primary FM service they would be deprived of one good primary FM service which they already have.

4. In response, petitioner states he does not deny that Pike is making an effort to serve Vandalia. However, petitioner contends that Vandalia deserves a station of its own so that more extensive coverage of local board meetings, special events and regular broadcasts of local events can be presented. As for receivers having to skip back and forth between two frequencies, petitioner notes that there are numerous FCC cases wherein stations substantially more powerful, with the same amount of separation between them, experience no difficulties.

5. We believe it is in the public interest to assign Channel 261A to Vandalia, Missouri. The argument made by Pike that a new station in Vandalia would take away revenues from other stations in the area is a matter we generally defer for resolution at the application stage rather than in a rule making context. It should be noted that in establishing the FM Table of Assignments we gave high priority to providing each community with at least one FM broadcast station, especially if the community lacked local aural service. Even if nearby stations do provide coverage of Vandalia and even if they offer some programming directed to Vandalia, this is not a basis for refusing to provide a community with a first broadcast outlet for local expression. An FM channel assignment here would provide a choice of programming and local programs directed to meeting the special needs, interests and problems of Vandalia. No station, owing its primary obligation to another locality, could be expected to provide the equivalent of such local service. As for the alleged technical difficulties described as skipping we have, in the past, authorized numerous situations in which the frequencies are only four channels removed, often in the same city, without such difficulties having been reported. We have not been offered a showing adequate to indicate special problems here. See also *Muncie, Indiana* (Notice), Dkt. 20834, 41 FR 24186 (1976). Further, we have undertaken a search of alternate channels but could find none available for assignment on a "drop-in" basis. We do not believe that Pike's allegation of expected technical difficulties should foreclose the opportunity of a first local aural service at Vandalia. Rather, Pike may seek for itself a change in frequency at a later date if unsatisfied with the reception of its station.

6. Authority for the action taken herein is contained in Sections 4(i), 5(d)(1), 303 (g) and (r) and 307(b) of the Communications Act of 1934, as amended, and § 0.281 of the Commission's rules.

7. In view of the foregoing, it is ordered, That effective May 23, 1980, § 73.202(b) of the Commission's rules, the FM Table of Assignments, is amended to read as follows:

City	Channel No.
Vandalia, Missouri	261A

8. It is further ordered, that this proceeding is terminated.

9. For further information concerning this proceeding, contact Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

(Secs. 4, 303, 307, 48 Stat., as amended, 1066, 1082, 1083; (47 U.S.C. 154, 303, 307))

Federal Communications Commission.

Henry L. Baumann,

Chief, Policy and Rules Division, Broadcast Bureau.

[FR Doc. 80-11303 Filed 4-14-80; 8:45 am]

BILLING CODE 6712-01-M

[1] Population figures are taken from the 1970 U.S. Census.

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1033

[Rev. S.O. No.1451]

St. Louis-San Francisco Railway Co. Authorized To Operate Over Tracks of Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

AGENCY: Interstate Commerce Commission.

ACTION: Revised Service Order No. 1451.

SUMMARY: This order authorizes the St. Louis-San Francisco Railway Company (SLSF) to operate over tracks of Chicago, Rock Island and Pacific Railroad Company (RI) at the folowing locations for the purpose of serving industries located adjacent to such tracks, and provides for the continuation of service to shippers which would otherwise be deprived of essential railroad service.

1. Stations between Wichita, Kansas, and Enid, Oklahoma.

2. Stations between Dallas, Texas, and Fort Worth, Texas.
3. Chickasha, Oklahoma.
4. Hobart, Oklahoma.
5. Okeene, Oklahoma.
6. Lawton, Oklahoma.
7. Oklahoma City, Oklahoma.

EFFECTIVE DATE: 12:01 a.m., March 24, 1980, and continuing in effect until 11:59 p.m., May 31, 1980.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Carter (202) 275–7840.

Decided: March 19, 1980.

The embargo of the lines of Chicago, Rock Island and Pacific Railroad Company (RI) is depriving shippers located adjacent to those tracks of essential railroad service. The St. Louis-San Francisco Railway Company (SLSF) connects with the RI and has consented to operate over these tracks in order to serve the industries.

It is the opinion on the Commission that an emergency exists requiring the operation by SLSF over tracks formerly operated by RI in the interest of the public; that notice and public procedure are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered,

§ 1033.145 Revised Service Order No. 1451.

(a) *St. Louis-San Francisco Railway Company authorized to operate over tracks of Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee).* St. Louis-San Francisco Railway Company (SLSF) is authorized to operate over tracks of the Chicago, Rock Island and Pacific Railroad Company (RI) at the following locations for the purpose of serving industries located adjacent to such tracks.

(1) Stations between Wichita, Kansas, and Enid, Oklahoma.
(2) Stations between Dallas, Texas, and Fort Worth, Texas.
(3) Chickasha, Oklahoma.
(4) Hobart, Oklahoma.
(5) Okeene, Oklahoma.
(6) Lawton, Oklahoma.
(7) Oklahoma City, Oklahoma.*

(b) *Application.* The provisions of this order shall apply to intrastate, interstate and foreign traffic.

(c) Similar applications have been received from Missouri-Kansas-Texas Railroad Company and Fort Worth and Denver Railway Company to operate portions of RI tracks herein indicated. The Railroad Service Board has reviewed these applications and considered the recommendations of the Department of Transportation, and has approved the application of the SLSF to conduct these temporary operations in the public interest as listed in paragraph (a). Nothing herein shall be considered as a prejudgment of any application seeking permanent authority to operate over these tracks.

(d) Compensation will be on terms established between the Trustee and the affected carrier(s); or upon failure of the parties to agree as hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by Section 11123(b)(2) of the Interstate Commerce Act.

(e) *Rate applicable.* Inasmuch as this operation by the SLSF over tracks previously operated by the RI is deemed to be due to carrier's disability, the rates applicable to traffic moved over these lines shall be the rates applicable to traffic routed to, from, or via these lines which were formerly in effect on such traffic when routed via RI, until tariffs naming rates and routes specifically applicable via SLSF become effective.

The operator under this temporary authority will not be required to protect transit rate obligations incurred by the RI or the directed carrier, Kansas City Terminal Railway Company, on transit balances currently held in storage.

(f) In transporting traffic over these lines, SLSF and all other common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to that traffic. Divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between the carriers; or upon failure of the carriers to so agree, the divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(g) *Employees.* On March 4, 1980, a number of rail carriers and labor unions reached an agreement regarding the proper level of employee protection entitled "*Labor Protective Agreement Between Railroads Parties Hereto Involved in Midwest Rail Restructuring and Employees of Such Railroads Represented by the Rail Labor Organizations operating through the Railway Labor Executives' Association*" (Negotiated Labor Protection Agreement). We have reviewed the negotiated labor protection agreement and find that it adequately safeguards the interests of affected employees.

Accordingly, if SLSF chooses to exercise the authority granted by this decision, it shall afford affected employees the protection contemplated by the negotiated labor protection agreement and any subsequent amendments to it.

(h) *Effective date.* This order shall become effective at 12:01 a.m., March 24, 1980.

(i) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., May 31, 1980, unless otherwise modified, amended, or vacated by order of this Commission.

This action is taken under the authority of 49 U.S.C. 10304–10305 and 11121–11126.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

James H. Bayne,

Acting Secretary.

[FR Doc. 80-11343 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

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49 CFR Part 1033

[S.O. No. 1466]

Atchison, Topeka & Santa Fe Railway Co., Authorized To Substitute 60-Foot Boxcars for 50-Foot Boxcars for Loading Tires

AGENCY: Interstate Commerce Commission.

ACTION: Service Order No. 1466.

SUMMARY: This order authorizes The Atchison, Topeka and Santa Fe Railway Company to substitute 60-foot boxcars for 50-foot boxcars for loading tires from Ardmore, Oklahoma, in order to improve freight car utilization.

EFFECTIVE DATE: 12:01 a.m., April 11, 1980, and continuing in effect until 11:59 p.m., June 30, 1980.

FOR FURTHER INFORMATION CONTACT: J. Kenneth Carter (202) 275–7840.

Decided: April 10, 1980.

The Atchison, Topeka and Santa Fe Railway Company (ATSF) is authorized to transport tires under Southwestern Freight Bureau Tariff (SWFB) tariffs 2005–J and 2006–K in boxcars not over 52 feet 6 inches in length. The ATSF has 60-foot boxcars which are available for

*Addition.

this loading but which cannot be used because of the tariff restrictions. The ATSF requests authority to substitute 60-foot boxcars for 50-foot boxcars for loading tires at Ardmore, Oklahoma, in order to improve car utilization.

It is the opinion of the Commission that an emergency exists requiring immediate action to promote car service in the interest of the public and the commerce of the people. Accordingly, the Commission finds that notice and public procedure are impracticable and contrary to the public interest, and that good cause exists for making this order effective upon less than thirty days' notice.

It is ordered,

§ 1033.1466 Service Order No. 1466.

(a) *The Atchison, Topeka and Santa Fe Railway Company authorized to substitute 60-foot boxcars for 50-foot boxcars for loading tires.* The Atchison, Topeka and Santa Fe Railway Company is authorized to substitute 60-foot boxcars for 50-foot boxcars for loading tires at Ardmore, Oklahoma, subject to the rates as provided in Item 19800 in ICC–SWFB 2005–J Tariff and in Item 19800 in ICC–SWFB 2006–K Tariff.

(b) *Concurrence of shipper required.* The concurrence of the shipper must be obtained before 60-foot boxcars are substituted for 50-foot boxcars as authorized in paragraph (a) of this order.

(c) *Application.* The provisions of this order shall apply to intrastate, interstate and foreign commerce.

(d) Bills of lading covering movements authorized by this order shall contain a notation that shipment is moving under authority of Service Order No. 1466.

(e) *Rules and regulations suspended.* The operation of tariffs or other rules and regulations, insofar as they conflict with the provisions of this order, is hereby suspended.

(f) *Effective date.* This order shall become effective at 12:01 a.m., April 11, 1980.

(g) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., June 30, 1980, unless otherwise modified, changed or suspended by order of this Commission.

(49 U.S.C. (10304–10305 and 11121–11126))

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-11341 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 651

Atlantic Groundfish Fisheries; Fishery Closure

AGENCY: National Oceanic and Atmospheric Administration (NOAA)/ Commerce.

ACTION: Notice of closure of the yellowtail flounder fishery west of 69° West Longitude.

SUMMARY: This notice closes the yellowtail flounder fishery west of 69° West Longitude to all vessel classes effective April 13, 1980. The closure is based on requirements of the Fishery Management Plan for Atlantic Groundfish that the annual quotas for cod, haddock, and yellowtail flounder be enforced through fishery closures. The annual quota for yellowtail flounder in the management area west of 69° West Longitude has been attained.

EFFECTIVE DATE: The closure is effective as of 0001 hours EST, April 13, 1980.

FOR FURTHER INFORMATION CONTACT: Mr. Allen E. Peterson, Jr., Regional Director, Northeast Region, National Marine Fisheries Service, 14 Elm Street, Gloucester, Massachusetts 01930, telephone: (617) 281–3600.

SUPPLEMENTARY INFORMATION: Final regulations governing domestic fishing for Atlantic groundfish (cod, haddock, and yellowtail flounder) were promulgated on January 3 and 11, 1979 (44 FR 885 and 44 FR 2397). These regulations implement the Fishery Management Plan for Atlantic Groundfish (FMP), as amended, which was prepared by the New England Fishery Management Council (Council) in consultation with the Mid-Atlantic Fishery Management Council. These regulations establish annual and quarterly quotas for each fishery by species, area, and vessel class. The regulations also establish catch limitations on per week or per trip basis and provide for adjustment of these limitations as a means of spreading fishing effort over the fishing year and avoiding fishery closures. Finally, the regulations implement the intent of the FMP that a fishery must be closed to prevent annual quotas from being exceeded.

The FMP was extended for the 1979–1980 fishing year beginning on October 1, 1979, and ending September 30, 1980 (44 FR 55885). The annual quota for yellowtail flounder west of 69° W. (commercial and recreational) is 3,700 mt. The annual quota for the area east of 69° W. is 4,400 mt.

The Regional Director, Northeast Region, National Marine Fisheries Service, has monitored catches and landings of yellowtail flounder in the current fishing year. Based on the fishery statistics for the first and second quarters, the Regional Director has determined that the annual quota of yellowtail flounder west of 69° W. has been attained. In accordance with § 651.24(b) of the final regulations (44 FR 890), the Regional Director has recommended that the yellowtail flounder fishery west of 69° W. be closed on April 13, 1980. The Assistant Administrator for Fisheries has reviewed the findings and recommendation of the Regional Director and confirms that they set forth the appropriate evidence and date for a fishery closure. Therefore, the Assistant Administrator, under § 651.24(c) of the final regulations (44 FR 890), has determined that the yellowtail flounder fishery west of 69° W. will be closed April 13, 1980, for all vessel classes.

The yellowtail flounder fishery closure west of 69° W. will continue until the end of the fishing year (September 30, 1980). During this closure period, all vessel classes will be limited to an incidental catch of yellowtail flounder west of 69° W. specified by the emergency amendment to § 651.24(d)(2) of the regulations made effective on April 6, 1980 (45 FR 22949). This incidental catch allowance for all vessels is 1,000 pounds per trip from the area west of 69° W.

Appendix B of the regulations, which contains the catch limitations by vessel class, species, and area, has been revised to include this closure and is set out below.

Signed at Washington, D.C., this 9th day of April, 1980.

Winfred H. Meibohm,

Executive Director, National Marine Fisheries Service.

(16 U.S.C. 1801, *et seq.*)

Appendix B.—*Catch Limitations*

[Revised Effective April 13, 1980]

Cod (pounds/week)[1]

Vessel class	Gulf of Maine	Georges Bank and South
0–60 GRT	2,500	7,000
61–125 GRT	5,000	14,000
126+ GRT	7,000	20,000
Fixed Gear	5,000	16,000

Haddock (pounds/week)[1]

Vessel class	Gulf of Maine	Georges Bank and South
0–60 GRT	5,000	7,000
61–125 GRT	7,000	14,000
126+ GRT	10,000	20,000
Fixed Gear	16,000	16,000

Yellowtail Flounder (pounds/week or trip)[2]

Vessel class	West of 69° W.	East of 69° W.
0–60 GRT	Closed April 13	5,000
61–125 GRT	Closed April 13	5,000
Over 125 GRT	Closed April 13	5,000

[1] No overruns are allowed.

[2] Pounds per week or per trip, whichever is the longer time period. No overruns are allowed.

[FR Doc. 80–11385 Filed 4–11–80; 8:45 am]

BILLING CODE 3510–22–M

DEPARTMENT OF LABOR

Pension and Welfare Benefit Programs

29 CFR Part 2520

Regulation Relating to Reporting and Disclosure Under Title I of the Employee Retirement Income Security Act of 1974

AGENCY: U.S. Department of Labor.

ACTION: Notice of interim rulemaking with request for comments.

SUMMARY: This document contains a notice of adoption on an interim basis and requests comments for permanent adoption of a regulation that describes an alternative method of compliance with the reporting and disclosure requirements of Part 1 of Title I of the Employee Retirement Income Security Act of 1974 (the Act) for certain simplified employee pensions (SEPs) other than those created by the use of Internal Revenue Service (IRS) Form 5305–SEP.

DATES: The interim regulation is effective April 14, 1980. Written comments must be received by the Department of Labor (the Department) on or before June 15, 1980.

ADDRESS: Interested persons are invited to submit written data, views or arguments (preferably at least three copies) concerning any part or all of the interim regulation to "Section § 2520.104–49, Office of Reporting and Plan Standards, Pension and Welfare Benefit Programs, N–4508, U.S. Department of Labor, Washington, D.C. 20216." All written submissions will be open for public inspection at the Public Documents Room, Pension and Welfare Benefit Programs, N–4677, 200 Constitution Avenue, NW., Washington, D.C. 20216.

FOR FURTHER INFORMATION CONTACT: Timothy S. Smith, Plan Benefits Security Division, Office of the Solicitor, U.S. Department of Labor, Washington, D.C. 20216, (202) 523–6855 or Robert Doyle, Office of Reporting and Plan Standards, Pension and Welfare Benefit Programs, Department of Labor, Washington, D.C. 20216, (202) 523–7901. (These are not toll free numbers.)

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Department has adopted interim regulation § 2520.104–49, effective April 14, 1980. The interim regulation sets forth an alternative method for satisfying the reporting and disclosure requirements of Part 1 of Title I of the Act (Part 1) for certain SEPs other than those that are created by use of IRS Form 5305–SEP.

A. Background

On September 25, 1979, the Department published in the Federal Register a notice of proposed rulemaking which described a proposed alternative method of compliance with the reporting and disclosure requirements of Part 1 of Title I of the Act (Part 1) for SEPs established by use of IRS Form 5305–SEP (Model SEPs) (44 FR 55205). Many of the commentators on that proposed regulation indicated that Model SEPs were of limited utility to employers and requested that the Department provide an alternative method of compliance for SEPs other than Model SEPs. In the discussion of those comments in the preamble to the final regulation concerning Model SEPs (§ 2520.104–48 (45 FR 24866, April 11, 1980)), the Department noted that it believed that an alternative method of compliance might be appropriate for SEPs other than Model SEPs.[1]

In creating SEPs, Congress provided that individual retirement accounts and individual retirement annuities (collectively IRAs) might be incorporated into employer funded retirement arrangements. By doing so, Congress intended to provide a type of pension arrangement that would be easier to establish and administer and would entail less reporting and disclosure than existing employer maintained retirement plans.[2] However, if SEPs must comply with the reporting and disclosure requirements of Part 1, this intention would be largely thwarted.

The Department, therefore, issued regulation § 2520.104–48, and is publishing the alternative method of compliance for SEPs other than Model SEPs that is described below. This alternative was developed in coordination with the IRS, and it is the Department's intention that the reporting and disclosure requirements set forth in the alternative method of compliance will, in most cases, be satisfied by compliance with IRS reporting and disclosure requirements regarding SEPs. In this regard, it is anticipated that the IRS will issue a form that will provide information concerning SEPs and IRAs which, if furnished to employees, will satisfy the requirements of section (a)(2) of the alternative.

B. Discussion of Regulation § 2520.104–49

The interim regulation set forth below prescribes an alternative method of compliance with the reporting and disclosure requirements of Part 1 for all non-Model SEPs, except in those cases where the employer who establishes or maintains the SEP selects, recommends or substantially influences its employees to choose the IRAs into which employer contributions will be made, and those IRAs are subject to internal provisions which prohibit withdrawals of funds by participants for any period of time.[3] The Department notes that, if IRAs are selected by an employer who establishes a SEP and are subject to provisions that allow withdrawals but reduce earnings or impose other

[1] Under section 110 of the Act, the Department may prescribe an alternative method for satisfying any requirement of Part 1 with respect to a pension plan or class of pension plans subject to that requirement if it determines:

(1) That the use of the alternative method is consistent with the purposes of Title I and that it provides adequate disclosure to participants and beneficiaries of the plan, and adequate reporting to the Department.

(2) That the application of that requirement would—

(A) increase the costs to the plan, or

(B) impose unreasonable administrative burdens with respect to the operation of the plan, having regard to the particular characteristics of the plan or type of plan involved; and

(3) That the application of Part 1 would be adverse to the interests of plan participants in the aggregate.

[2] See section 19 of H.R. Report No. 95–1800, 95 Cong., 2nd Sess. 212 (1978) and section IV G.2 of Senate Report No. 95–1263, 95 Cong., 2nd Sess. 91 (1978).

[3] Non-Model SEPs which are subject to such prohibitions would, therefore, be subject to the reporting and disclosure requirements of Part 1.

penalties, the SEP would be covered by this alternative method of compliance.[4]

The alternative method of compliance requires the administrator of a non-Model SEP, generally the employer who establishes or maintains the SEP, to furnish certain written information to participants in the SEP. The bulk of this information must be furnished to an employee at the time he or she becomes eligible to participate in the SEP. At that time the administrator must furnish specific information about the particular SEP arrangement adopted and general information concerning SEPs and IRAs. Those administrators whose SEPs provide for integration with Social Security or involve certain particular types of IRAs must furnish certain additional information. All administrators must also furnish each participant information concerning any amendment to the terms of the SEP and any employer contributions made under the SEP to the participant's IRA.

The specific information items concerning the SEP that must be furnished to an employee at the time he or she becomes eligible to participate in the SEP are: The requirements for employee participation in the SEP; The formula under which employer contributions to the SEP will be allocated among participants' IRAs; The name or title of the individual who is designated by the employer to provide additional information to participants concerning the SEP and employer contributions thereunder; and, If the employer selects or recommends, or substantially influences employees to choose the IRAs into which employer contributions will be made,[5] the terms of those IRAs.

The general information that must be furnished to an employee at the time he or she becomes eligible to participate in the SEP includes a statement concerning the various types of IRAs into which employer or participant contributions may be made and a clear explanation of, among other things: The operation of a SEP; The statutory provisions concerning SEPs and contributions thereunder; and How a participant treats SEP contributions for tax purposes.

In the case of a SEP that provides for integration with Social Security,[6] the information furnished to an employee when the employee becomes eligible to participate in the SEP must make it clear that Social Security taxes paid by the employer on account of a participant will, in whole or in part, be counted as employer contributions under the SEP allocation formula.[7] The information must also contain examples of the effect that integration will have on actual employer contributions under the SEP.

In addition to the information that must be furnished by the administrator of a SEP to employees at the time they become eligible to participate in the SEP, the administrator must also furnish each participant a copy of any amendment to the terms of the SEP and a written explanation of its effect within 30 days of the effective date of the amendment. Following the end of each calendar year, the administrator of a SEP also must notify each participant in writing of any employer contribution made under the SEP to the participant's IRA(s) for that year. Such notification must be made no later than the later of January 31 of the year following the year for which the contribution is made, 30 days after the contribution is made, or 30 days after the effective date of this regulation.

It should be noted that, under the alternative method of compliance, a plan administrator would not be required to file a summary plan description or an annual report. It appears to the Department that the filing of a summary plan description is not necessary because, among other things, all SEPs that meet the requirements of section 408(k) of the Code will be substantially similar. It also appears that the filing of annual reports with the Department is not necessary because of the type of control that a participant in a covered SEP will have over the IRA(s) in which the assets of the SEP are held and because the sponsors of those IRA(s) are regulated by various federal and state agencies or are specifically approved by the IRS.

C. Temporary Regulation

The Department recognizes that employers who either cannot use or wish not to use a Model SEP may desire to establish a non-Model SEP, and that many such employers may be discouraged from doing so unless an alternative method of compliance for non-Model SEPs is available. In order to be useful for those employers who wish to establish a non-Model SEP and make contributions for 1979, an alternative method of compliance should be effective before April 15, 1980, the deadline for making SEP contributions for calendar year 1979, so that employers will know the reporting and disclosure obligations applicable to such SEPs. For the foregoing reason, and because the regulation provides an exemption from the otherwise applicable requirements of Part 1, the Department finds that good cause exists for making this regulation temporarily effective without advance publication as specified in the Administrative Procedure Act (5 U.S.C. 553(d)).

Pursuant to the requirements of section 110 of the Act, the Secretary makes the following determination:

(1) That the use of the alternative method of compliance is consistent with the purposes of Title I of the Act and that it provides adequate disclosure to participants and beneficiaries in the covered SEPs, and adequate reporting to the Secretary,

(2) That the application of the requirements of Part 1 would—

(A) Increase the costs to the covered SEPs, or

(B) Impose unreasonable administrative burdens with respect to the operation of such plans, having regard to the particular characteristics of those plans; and

(3) That the application of Part 1 would be adverse to the interests of participants in the covered SEPs in the aggregate.

D. Drafting Information

The principal author of this interim regulation is Timothy S. Smith of the Plan Benefits Security Division, Office of the Solicitor, Department of Labor. However, other persons in the Department of Labor participated in developing the interim regulation both on matters of substance and style.

E. Statutory Authority

The interim regulation set forth below is adopted on a temporary basis pursuant to sections 110 and 505 of the

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[4] A SEP is a SEP described in section 408(k) only if "(A) employer contributions thereto are not conditioned on the retention in such pension of any portion of the amount contributed, and (B) there is no prohibition imposed by the employer on withdrawals from the simplified employee pension."

Nothing in this notice or in the interim and proposed regulation is intended to express an opinion by the Department as to whether that section prohibits an employer from selecting as the IRAs into which employer contributions will be made IRAs that contain or are subject to restrictions on a participant's ability to withdraw funds.

[5] The Department notes that, if the assets of a SEP are used for the benefit of a party in interest or disqualified person with respect to that SEP (as defined in sections 3(14) of the Act and 4975(e)(2) of the Code) violations of sections 406 of the Act and 4975(c)(1) of the Code may occur. For example, if, in connection with the establishment and maintenance of a SEP, an employer directs its employees to open IRAs with a particular financial institution and in return for making SEP contributions to those IRAs the employer receives from that institution a loan or other benefit, such conduct would involve violations of sections 406(a)(1)(D) and 406(b) of the Act and 4975(c)(1) (D), (E) and (F) of the Code.

[6] A SEP under which employer contributions are integrated with or offset by part or all of employer contributions made under the Federal Insurance Contributions Act (26 U.S.C. 3111(a)).

[7] This requirement would be satisfied if the allocation formula itself is sufficiently clear concerning integration.

Act (Pub. L. 93–406, 88 Stat. 829, 851, 894, 29 U.S.C. 1030, 1135).

F. Interim Regulation

Accordingly, Part 2520 of Chapter XXV of Title 29 of the Code of Federal Regulations is amended by adding in the appropriate place § 2520.104–49 to read as follows:

Subpart D—Provisions Applicable to Both Reporting and Disclosure Requirements

§ 2520.104–49 Alternative method of compliance for certain simplified employee pensions.

Under the authority of section 110 of the Act, the provisions of this section are prescribed as an alternative method of compliance with the reporting and disclosure requirements set forth in Part 1 of Title I of the Act for a simplified employee pension (SEP) described in section 408(k) of the Internal Revenue Code of 1954 as amended, except for (1) a SEP that is created by use of Internal Revenue Service Form *5305–SEP,* and (2) a SEP in connection with which the employer who establishes or maintains the SEP selects, recommends or influences its employees to choose the IRAs into which employer contributions will be made and those IRAs are subject to provisions that prohibit withdrawal of funds by participants for any period of time.

(a) At the time an employee becomes eligible to participate in the SEP (whether at the creation of the SEP or thereafter) or up to 90 days after the effective date of this regulation, whichever is later, the administrator of the SEP (generally the employer establishing or maintaining the SEP) shall furnish the employee in writing with:

(1) Specific information concerning the SEP, including:

(i) The requirements for employee participation in the SEP,

(ii) The formula to be used to allocate employer contributions made under the SEP to each participant's individual retirement account or annuity (IRA),

(iii) The name or title of the individual who is designated by the employer to provide additional information to participants concerning the SEP, and

(iv) If the employer who establishes or maintains the SEP selects, recommends or substantially influences its employees to choose the IRAs into which employer contributions under the SEP will be made, a clear explanation of the terms of those IRAs, such as the rate(s) of return and any restrictions on a participant's ability to roll over or withdraw funds from the IRAs, including restrictions that allow rollovers or withdrawals but reduce earnings of the IRAs or impose other penalties.

(2) General information concerning SEPs and IRAs, including a clear explanation of:

(i) What a SEP is and how it operates,

(ii) The statutory provisions prohibiting discrimination in favor of highly compensated employees,

(iii) A participant's right to receive contributions under a SEP and the allowable sources of contributions to a SEP related IRA (SEP–IRA),

(iv) The statutory limits on contributions to SEP–IRAs,

(v) The consequences of excess contributions to a SEP–IRA and how to avoid excess contributions,

(vi) A participant's rights with respect to contributions made under a SEP to his or her IRA(s),

(vii) How a participant must treat contributions to a SEP–IRA for tax purposes,

(viii) The statutory provisions concerning withdrawal of funds from a SEP–IRA and the consequences of a premature withdrawal, and

(ix) A participant's ability to roll over or transfer funds from a SEP–IRA to another IRA, SEP–IRA, or retirement bond, and how such a rollover or transfer may be effected without causing adverse tax consequences.

(3) A statement to the effect that:

(i) IRAs other than the IRA(s) into which employer contributions will be made under the SEP may provide different rates of return and may have different terms concerning, among other things, transfers and withdrawals of funds from the IRA(s),

(ii) In the event a participant is entitled to make a contribution or rollover to an IRA, such contribution or rollover can be made to an IRA other than the one into which employer contributions under the SEP are to be made, and

(iii) Depending on the terms of the IRA into which employer contributions are made, a participant may be able to make rollovers or transfers of funds from that IRA to another IRA.

(4) A description of the disclosure required by the Internal Revenue Service to be made to individuals for whose benefit an IRA is established by the financial institution or other person who sponsors the IRA(s) into which contributions will be made under the SEP.

(5) A statement that, in addition to the information provided to an employee at the time he or she becomes eligible to participate in a SEP, the administrator of the SEP must furnish each participant:

(i) Within 30 days of the effective date of any amendment to the terms of the SEP, a copy of the amendment and a clear written explanation of its effect, and

(ii) No later than the later of:

(A) January 31 of the year following the year for which a contribution is made,

(B) 30 days after a contribution is made, or

(C) 30 days after the effective date of this regulation

written notification of any employer contributions made under the SEP to that participant's IRA(s).

(6) In the case of a SEP that provides for integration with Social Security

(i) A statement that Social Security taxes paid by the employer on account of a participant will be considered as an employer contribution under the SEP to a participant's SEP–IRA for purposes of determining the amount contributed to the SEP–IRA(s) of a participant by the employer pursuant to the allocation formula, and

(ii) Several examples of the effect that integration with Social Security would have on actual employer contributions under a SEP.

(b) No later than the later of:

(1) January 31 of the year following the year for which a contribution is made,

(2) 30 days after a contribution is made, or

(3) 30 days after the effective date of this regulation

the administrator of the SEP shall notify a participant in the SEP in writing of any employer contributions made under the SEP to the participant's IRA(s).

(c) Within 30 days of the effective date of any amendment to the terms of the SEP, the administrator shall furnish each participant a copy of the amendment and a clear explanation in writing of its effect.

Signed at Washington, D.C. this 14th day of April 1980.

Ian D. Lanoff,

Administrator, Pension and Welfare Benefit Programs, Labor-Management Services Administration, U.S. Department of Labor.

[FR Doc. 80–11627 Filed 4–14–80; 11:50 am]

BILLING CODE 4510–29–M

Proposed Rules

Federal Register
Vol. 45, No. 74
Tuesday, April 15, 1980

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

DEPARTMENT OF AGRICULTURE

Agriculture Marketing Service

7 CFR Part 1124

[Docket No. AO-368-A10]

Milk in the Oregon-Washington Marketing Area; Notice of Hearing on Proposed Amendments to Tentative Marketing Agreement and Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Public hearing on proposed rules.

SUMMARY: The hearing is being held to consider three dairy farmer cooperatives' proposal to temporarily amend certain provisions of the order. The provisions proposed to be amended relate to how much milk not needed for fluid (bottling) use may be moved directly from farms to manufacturing plants and still be priced under the order. The cooperative associations contend that these temporary changes are needed to help them keep their member milk associated with the order during the next several months. The proposed changes would apply to April–August 1980.

DATE: April 22, 1980.

ADDRESS: Holiday Inn, Portland South, 25425 SW. Boones Ferry Road, Wilsonville, Oregon 97070.

FOR FURTHER INFORMATION CONTACT: Maurice M. Martin, Marketing Specialist, Dairy Division, Agricultural Marketing Service, United States Department of Agriculture, Washington, D.C. 20250, (202) 447–7183.

SUPPLEMENTARY INFORMATION: Notice is hereby given of a public hearing to be held at the Holiday Inn, Portland South, 25425 S.W. Boones Ferry Road, Wilsonville, Oregon 97070 (at Stafford Road Exit on Interstate 5), beginning at 9:30 a.m., local time, on April 22, 1980, with respect to proposed amendments to the tentative marketing agreement, and to the order, regulating the handling of milk in the Oregon-Washington marketing area.

The hearing is called pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900).

The purpose of the hearing is to receive evidence with respect to the economic and marketing conditions which relate to the proposed amendments, hereinafter set forth, and any appropriate modifications thereof, to the tentative marketing agreement and to the order.

The hearing is being convened in less than April 30, 1980, as the only means of providing due consideration at a public hearing to emergency marketing conditions relating to the proposed amendments contained herein.

Evidence will be taken to determine whether emergency marketing onditions exist that would warrant omission of a recommended decision under the rules of practice and procedure (7 CFR Part 900.12(d)) with respect to the proposals being considered. Evidence also will be taken to determine whether the temporary suspension procedure should be used to implement any action found to be necessary on the basis of the tesimony and evidence presented.

The proposed amendments, set forth below, have not received the approval of the Secretary of Agriculture.

Proposed by Farmers Cooperative Creamery, Corvallis Milk Producers Association, and Eugene Farmers' Creamery:

Proposal No. 1

In the third sentence of paragraphs (a) and (b) of § 1124.11, delete the work "not" for the months of April–August 1980.

Proposed by the Dairy Division, Agricultural Marketing Service:

Proposal No. 2

Make such changes as may be necessary to make the entire marketing agreement and the order conform with any amendments thereto that may result from this hearing.

Copies of this notice of hearing and the order may be procured from the Market Administrator, James A. Burger, P.O. Box 23606, Portland, Oregon 97223; or from the Hearing Clerk, Room 1077, South Building, United States Department of Agriculture, Washington, D.C. 20250, or may be there inspected.

From the time that a hearing notice is issued and until the proceeding is completed, Department employees involved in the decisional process are prohibited from discussing the merits of the hearing issues on an ex parte basis with any person having an interest in the proceeding. For this particular proceeding, the prohibition applies to employees in the following organizational units:

Office of the Secretary of Agriculture.
Office of the Administrator, Agricultural Marketing Service.
Office of General Counsel.
Dairy Division, Agricultural Marketing Service (Washington office only).
Office of the Market Administrator, Oregon-Washington marketing area.

Signed at Washington, D.C., on April 9, 1980.

Irving W. Thomas,
Acting Deputy Administrator, Marketing Program Operations, Agricultural Marketing Service.

[FR Doc. 80-11301 Filed 4-14-80; 8:45 am]
BILLING CODE 3410-02-M

7 CFR Part 1124

Milk in the Oregon-Washington Marketing Area; Termination of Proceeding on Proposed Suspension of Certain Provisions of the Order

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Termination of proceeding on proposed suspension of rules.

SUMMARY: This action terminates a proceeding on a proposal to suspend certain provisions of the order relating to how much milk not needed for fluid (bottling) use may be moved directly from farms to manufacturing plants and still be priced under the order. The suspension was requested by three cooperative associations to assure the efficient disposition of milk not needed for fluid use and to maintain producer status under the order for their dairy farmer members regularly associated with the market.

A cooperative association representing a substantial number of producers on the market submitted comments opposing the proposed suspension. Because of the conflicting

viewpoints among interested parties, no action is being taken at this time to temporarily suspend the provisions in question. The Department, however, has scheduled a public hearing to further explore the matter in depth.

FOR FURTHER INFORMATION CONTACT: Maurice M. Martin, Marketing Specialist, Dairy Division, Agricultural Marketing Service, United States Department of Agriculture, Washington, D.C. 20250, (202) 447–7183.

SUPPLEMENTARY INFORMATION: Prior document in this proceeding: Notice of proposed suspension, issued March 26, 1980; published March 28, 1980 (45 FR 20490).

This termination of proceeding is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601 *et seq.*). The proceeding was initiated by a notice of proposed suspension of certain provisions of the order issued March 26, 1980 (45 FR 20490). In the notice of proposed suspension, the public was invited to submit comments not later than April 4, 1980.

The provisions that were proposed to be suspended for the months of March–August 1980 are as follows:

In the third sentence of paragraphs (d) and (b) of § 1124.11, the word "not."

Statement of Consideration

The proposed suspension would have removed the limit on the amount of producer milk that a cooperative association or other handlers may divert from pool plants to nonpool plants during the months of March–August 1980. The order now provides that during any month a cooperative association may divert a total quantity of producer milk not in excess of the total quanitity received during the month from all member producers at pool plants. Similarly the operator of a pool plant may divert a total quanitity of producer milk not in excess of the total quantity received from producers (for which the operator of such plant is the handler during the month) at such pool plant.

The suspension was requested by three coopertive associations representing a substantial number of producers on the market. It was supported by three additional cooperative associations.

The basis of the request for suspension was that current marketing conditions require the three associations to handle an increasing quantity of reserve milk supplies because of substantial increases in milk deliveries by their member producers. They indicated this situation is aggravated by the fact that sales to one of their principal fluid outlets have declined substantially since the first of the year because the outlet lost a large wholesale account. Also, the cooperatives state that sales to another outlet can no longer count as a credit in determining their diversion allowances since the outlet is no longer a pool plant.

The cooperatives indicate that their reserve milk supplies are normally moved directly from member farms to nonpool manufacturing plants. However, because of current marketing conditions, they expect their reserve milk supplies during the months of March–August 1980 to exceed substantially the order's present allowable diversions. They contend that without the suspension a substantial part of their member producers who have regularly supplied the fluid market would have to be moved uneconomically, first to pool plants and then to nonpool manufacturing plants, in order to still maintain producer status for such milk during the March–August 1980 period.

Another cooperative association which represents a substantial number of producers on the market submitted written views opposing the proposed suspension. The cooperative's principal objection to the proposed suspension was the concern that additional unneeded Grade A milk supplies would be pooled that would further depress returns to producers that regularly serve the fluid market. In the cooperative's view, the proposed suspension would disrupt the normal supply arrangements of the market. The cooperative concluded that the petitioners' request would provide for disorderly marketing conditions.

In view of the conflicting viewpoints among interested parties concerning the request, it is concluded that the requested suspension should not be implemented on the basis of this proceeding. Instead, the matter should be considered at a public hearing where the issue may be explored in depth. Accordingly, the proceeding begun in this matter on March 26, 1980, is hereby terminated.

A notice of hearing is being issued concurrently with this termination of proceeding.

Signed at Washington, D.C., on April 9, 1980.

Irving W. Thomas,

Acting Deputy Administrator, Marketing Program Operations, Agricultural Marketing Service.

[FR Doc. 80-11340 Filed 4-14-80; 8:45 am]

BILLING CODE 3410-02-M

Office of the Secretary

7 CFR Part 2900

[Docket No. 80-1]

Proposed Amendment Regarding Certification of Essential Agricultural Uses and Requirements; Natural Gas Policy Act

AGENCY: Office of the Secretary, USDA.

ACTION: Proposed rule.

SUMMARY: The Department of Agriculture proposes to amend its regulations certifying essential agricultural uses and requirements under the Natural Gas Policy Act. This amendment would add SIC 3412—Metal shipping barrels, drums, kegs and pails (food related only) to the list of essential agricultural uses certified by the Secretary of Agriculture. The proposed amendment is in response to a petition submitted by the Steel Shipping Container Institute.

DATES: Written comments are due by 4:30 p.m., June 12, 1980.

ADDRESS: All written comments should be sent to Weldon V. Barton, Director, Office of Energy, Room 226–E, Administration Building, U.S. Department of Agriculture, 14th and Independence Avenue, SW., Washington, D.C. 20250.

FOR FURTHER INFORMATION CONTACT: Weldon V. Barton, Director, Office of Energy, Room 226–E, Administration Building, U.S. Department of Agriculture, 14th and Independence Avenue, SW., Washington, D.C. 20250; Telephone Number: (202) 447–2455.

The proposed action does not alter the impacts described or conclusions drawn in the combined Environmental Impact Statement and Final Impact Statement developed May 14, 1979, in connection with the Essential Agricultural Uses Requirements certification rule (7 CFR Part 2900). Thus, the combined statement describing the options considered in developing this proposed rule and the impact of implementing each option is available on request from Earle Gavett, Office of Energy, Room 5173, South Building, 12th and Independence Avenue, SW., U.S. Department of Agriculture, Washington, D.C. 20250.

SUPPLEMENTARY INFORMATION:

I. Background

Under Section 401 of the Natural Gas Policy Act of 1978 (NGPA), the Secretary of Agriculture is required to certify to the Secretary of Energy and the Federal

Energy Regulatory Commission (FERC) essential agricultural uses of natural gas and the amounts of natural gas for such essential agricultural uses necessary for full food and fiber production. A final rule containing such certification was issued by the Secretary of Agriculture on May 17, 1979 (44 FR 28782).

The Secretary of Energy and the FERC have incorporated the USDA certification in their rules promulgating and implementing agricultural priority in curtailment plans of interstate pipelines, in accordance with the NGPA.

This proposed action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been classified as "not significant." Also, the proposal has been reviewed pursuant to USDA's responsibilities under the National Environmental Policy Act of 1969 (42 U.S.C. 4321) and USDA has determined that the proposed action alters the impacts disclosed by less than one-tenth of 1 percent and does not affect the conclusions drawn in the combined Environmental Impact Statement and Final Impact Analysis prepared May 14, 1979, in connection with the Essential Agricultural Uses and Requirements certification rule. Therefore, this action is proposed under the same analysis.

II. Description of Proposal

7 CFR 2900.3 includes sanitary food packaging necessary for "food quality maintenance." This category contains a list of SIC codes for safe packaging of foods including those for paper coating and glazing, bags, paperboard boxes, sanitary food containers, metal cans, glass containers, and other food packaging materials.

The Steel Shipping Container Institute has petitioned the USDA to amend 7 CFR 2900.3 to include under Sanitary Food Packaging, SIC 3412—Metal shipping barrels, drums, kegs and pails (food related only). The metal containers identified range in size from 3.5 to 65 gallons. Certain foods, including highly perishable items such as bananas, tomatoes, and vegetable oils or delicate flavorings such as vanillas, clove oils and cola concentrates are stored in large coated steel shipping containers, which when properly sealed, create an environment where the foods may be safely stored without special temperatures for long periods of time. Some cheeses are actually processed and aged in metal drums. Many food products such as fruits and vegetables are first processed into large containers to rapidly place in safe storage large quantities of highly perishable commodities during extremely short harvest periods. Food processors later reprocess the product into consumer products. For example, much of the production of tomatoes grown for processing is initially processed into a tomato paste or puree and stored in large metal drums. Later, as needed, the drums are shipped to points near consumption and the product reprocessed into pizza sauces, catsup, and other tomato-food products and repackaged in various consumer size containers.

Since the development of the interior coated steel shipping container in the 1920–1930 period, a great number of foods and flavorings have been packaged only in steel containers either for economical advantages or because delicate flavorings cannot be maintained in other packages because of permeation, subtle migration or chemical reaction.

Natural gas is essential to the metal food container industry as a process gas to apply the protective coatings to these large food shipping containers. A high quality, high-temperature flame is essential so that the products of combustion do not contaminate the coatings.

These large food containers are not easily stored and most food processors have limited storage capability for empty food containers. Generally, the processors keep only small inventories of large containers, and when the size of the crop or livestock production is known they will order sufficient containers to be manufactured to meet their needs. This often times requires container manufacturers to be fabricating and coating food containers only days before they are used by food processors, with container manufacturing occurring concurrently with harvesting and processing.

The natural gas use for manufacturing food related metal containers is about 250,000 mcf annually. This is less than one-hundredth of 1 percent of the interstate gas component identified as essential agricultural use in the May 14, 1979 combined Environmental Impact Statement and Final Impact Statement.

The USDA considered the option of denial of the petition, but after due consideration of the points raised by the petitioner the USDA believes that sufficient justification exists to institute rulemaking procedures to modify the existing Essential Agricultural Use certification.

III. Public Comment

The public is invited to participate in any aspect of this proposed amendment by submitting data, views, or arguments with respect to the proposals herein set forth.

Written comments must be submitted by 4:30 p.m., June 12, 1980, to the address indicated in the "Address" section of this preamble, and should be identified on the outside envelope and on the document with the designation: "Part 2900—Metal Food Containers." Five copies should be submitted. All comments received will be available for public inspection in Room 5173 South Building, 12th and Independence Avenue, SW., Washington, D.C. 20250 between the hours of 9 a.m. and 4 p.m., Monday through Friday. All comments received by 4:30 p.m., June 12, 1980, and other relevant information will be considered by the Director, Office of Energy before final action is taken on this proposed amendment.

Any information or data submitted which is considered by the party who submitted it to be confidential must be so identified and submitting in writing, one copy only. The Director reserves the right to determine the confidential status of the information or data and to treat it accordingly.

§ 2900.3 [Amended]

In consideration of the foregoing, it is proposed to amend Chapter XXIX of Title 7 § 2900.3 Code of Federal Regulations by adding under "Food Quality Maintenance—Food Packaging," immediately after 3411 Metal Cans (food related only): 3412 Metal Shipping Barrels, Drums, Kegs and Pails (food related only).

(Pub. L. 95–621, 15 U.S.C. Section 3301 *et seq.*, November 8, 1978.)

Dated: April 9, 1980.

Weldon V. Barton,

Director, Office of Energy.

[FR Doc. 80-11300 Filed 4-14-80; 8:45 am]

BILLING CODE 3410-01-M

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1307

Consumer Products Containing Benzene; Extension of Time for Rulemaking

AGENCY: Consumer Product Safety Commission.

ACTION: Extension of time for promulgation of rule.

SUMMARY: The Commission extends for 180 days, from April 16, 1980 to October 13, 1980, the time in which it must issue a consumer product safety rule to delcare that certain benzene-containing consumer products are banned

hazardous products under section 8 of the Consumer Product Safety Act (CPSA) or withdraw the rule proposed on May 19, 1978. This extension is necessary to enable the Commission to obtain and evaluate data from several ongoing projects, which data will provide a firmer basis for considering final action on the proposal. In taking this action, the Commission recognizes that the need for immediate action on the use of benzene in consumer products may have or has diminished because of the declining use of benzene in such products.

DATE: The Commission extends the time for issuance of a final rule or withdrawal of the proposal from April 16, 1980 to October 13, 1980.

ADDRESS: All the information that the Commission has that is relevant to this proceeding may be examined in the Office of the Secretary, Consumer Product Safety Commission (CPSC), 1111 18th St., N.W., Third floor, Washington, D.C. 20207.

FOR FURTHER INFORMATION CONTACT: Rory Sean Fausett, Health Sciences, Consumer Product Safety Commission (CPSC), Washington, D.C. 20207, 301–492–6481.

SUPPLEMENTARY INFORMATION: On May 19, 1978, the Commission proposed a ban under section 8 of the Consumer Product Safety Act (CPSA) of all consumer products, except gasoline and solvents or reagents for laboratory use, containing benzene as an intentional ingredient or as a contaminant at a level of 0.1 percent or greater by volume. (See 43 FR 21838.) Based on the information discussed in the proposal, the Commission preliminarily concluded that benzene-containing consumer products present an unreasonable risk of injury to the public because benzene inhalation can cause blood disorderrs, chromosomal abnormalities, and leukemia. The Commission also preliminarily concluded that no feasible safety standard could adequately protect the public from these risks.

The Commission received a total of 44 written comments as well as 6 oral presentations concerning the proposed ban. Many of the comments criticized the proposal and raised complex scientific and technical issues, including the claim that there is no evidence that low levels of exposure to benzene constitute a health hazard, the assertion that the Commission's risk assessment is inadequate, and the claim that the proposed contamination level is neither justified nor commercially feasible. In order to adequately address these comments, the Commission on October 10, 1978 (43 FR 47197) and again on April 16, 1979 (44 FR 22499) extended the time in which it must publish a final rule or withdraw the proposal. This time currently expires on April 16, 1980.

During the present extension period, the Commission staff conducted a limited market survey of selected consumer products to determine their benzene content. (The final report of this survey is under preparation.) The data gathered indicate that benzene is no longer being intentionally added to consumer products. These data also indicate that approximately 10 percent of the products surveyed contained over 0.1 percent benzene; however, none of the products contained over 0.25 percent benzene. The staff believes, furthermore, that the survey shows that solvents are available which permit formulation of products whose final benzene content is below the proposed 0.1 percent limit. (The findings of the survey are consistent with a report provided to the Commission in December, 1978 by Battelle Columbus Laboratories, entitled "Analysis of Technical and Economic Feasibility of a Ban on Consumer Products Containing 0.1 Percent or More Benzene.")

In addition to the staff market survey, a study of benzene air levels resulting from typical use of various consumer products is currently being conducted for the Commission at Edgewood Arsenal. The Commission believes it is appropriate to await the results from this study, exptected in several months, before proceeding on benzene. The study will provide data necessary to determine consumer exposure.

Another factors supporting an extension of time is that the Commission plans to issue a general order requiring any firms which have manufactured, imported, or privately labeled any consumer products, except gasoline, containing benzene as an intentional ingredient since January 1, 1979 to provide the Commission with specified information concerning such products. The order privides 45 days for firms to report the required information; in addition, firms are required to update the information or report new uses of benzene as an intentional ingredient in consumer products for a one year period. The Commission believes information received in response to the order will be helpful in determining appropriate final action on the proposed benzene ban. The Commission notes that it will be several months before it receives initial responses under the order since the order must be cleared by the General Accounting Office (GAO) under the Federal Reports Act (44 U.S.C. 3512).

The Commission also points out that the U.S. Supreme Court heard oral argument this past fall in the case to review the decision of the Fifth Circuit setting aside the Occupational Safety and Health Administration (OSHA) benzene standard. (*American Petroleum Institute* v. *OSHA* 581 F.2d 493; *Industrial Union Department* v. *A.P.I.* and *Marshall* v. *API.*, S. Ct. Nos. 911 and 1036, 1978 Term.) It is expected that the Supreme Court will issue its opinion in the case, which may have a bearing on Commission regulation of benzene, before the end of June of this year.

Therefore, in view of the need to obtain and evaluate data from several ongoing benzene projects (i.e., the exposure study, the market survey, and the general order), the diminished need for immediate action because of the declining use of benzene in consumer products, and the soon expected ruling of the Supreme Court in the OSHA benzene case, the Commission in accordance with section 9(a)(1) of the Consumer Product Safety Act (15 U.S.C. 2058(a)), finds that good cause exists to extend for 180 days, until October 13, 1980, the period within which it must issue a consumer product safety rule or withdraw the proposal. This period may be further extended for good cause by notice published in the **Federal Register.**

Dated: April 9, 1980.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 80–11259 Filed 4–14–80; 8:45 am]

BILLING CODE 6355–01–M

DEPARTMENT OF LABOR

29 CFR Part 29

Labor Standards for the Registration of Apprenticeship Programs: List of Occupations Meeting the Criteria for Apprenticeability; Extension of Comment Period

AGENCY: Department of Labor.

ACTION: Extension of time for comments.

SUMMARY: This notice extends the time for filing comments on proposed rulemaking on Title 29 CFR § 29.4 (Criteria for Apprenticeable Occupations) that sets forth the characteristics that denote an apprenticeable occupation. Appendix A is an initial listing of those occupations that appear to possess all of the required characteristics. Additional occupations now approved by BAT and/one or more states or territorial apprenticeship agencies remain under review and will be published at a later date.

DATE: Comments are now due on or before July 11, 1980.

ADDRESSES: Send comments, communications to Paul H. Vandiver, Director, Office of National Industry Promotion, Employment and Training Administration, U.S. Department of Labor, Bureau of Apprenticeship and Training, Washington, D.C. 20213. Comments shall be in writing and submitted in duplicate.

FOR FURTHER INFORMATION CONTACT: Paul H. Vandiver (202) 376-6214.

SUPPLEMENTARY INFORMATION: On March 11, 1980, a document was published in the Federal Register (45 FR 15571) proposing to amend Title 29 CFR Part 29, by adding Appendix A—List of Occupations Meeting the Criteria for Apprenticeability. That proposal allowed a comment period of 60 days or until May 12, 1980.

Since the publication of that document, various requests for the extension of the period provided for the receipt of comments have been received. The importance of the issues addressed in that proposal requires that the Department proceed to final rulemaking as expeditiously as possible. However, the Department also wishes to provide sufficient time for all interested parties to prepare and submit comments. Therefore, an additional 60 day period is provided and comments will be received on this proposal until July 11, 1980.

Dated: April 9, 1980.

Ernest G. Green,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 80-11258 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-30-M

VETERANS ADMINISTRATION

38 CFR Part 36

Allowable Easements for Drainage and Irrigation Purposes—Guaranteed Home and Mobile Home Lot Loans

AGENCY: Veterans Administration.

ACTION: Proposed regulations.

SUMMARY: The VA (Veterans Administration) is proposing to amend its regulations to specify the conditions under which easements for drainage and irrigation purposes will be viewed as acceptable limitations on title. Adoption of these amendments should reduce the paperwork burdens of both lenders and the VA with regard to drainage and irrigation easements.

DATES: Comments must be received on or before May 15, 1980. It is proposed that these amendments become effective on the date of final approval.

ADDRESSES: Send written comments to: Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue, NW, Washington, DC 20420. Comments will be available for inspection at the address shown above during normal business hours until May 27, 1980.

FOR FURTHER INFORMATION CONTACT: Mr. Lyman T. Miller, Assistant Director for Construction and Valuation (262), Loan Guaranty Service, Veterans Administration, Washington, DC 20420, (202-389-2691).

SUPPLEMENTARY INFORMATION: Section 36.4350 sets forth the requirements concerning the estate in the realty which must be acquired by the veteran before the property will be deemed eligible for GI financing. Paragraph (c) of that section sets forth certain limitations on title which are acceptable and taken into account in the property appraisal and determined by the Administrator as not materially affecting the reasonable value of the property. As presently written, paragraph (c)(4)(i) includes only easements for public utilities as a generally acceptable limitation on the quantum or quality of the estate to be acquired by the veteran. It is proposed to amend paragraph (c)(4)(i) to provide that easements for irrigation and drainage purposes which do not interfere with the use of any buildings or improvements are else acceptable, having been taken into account in the appraisal of residential property and determined by the Administrator as not materially affecting the reasonable value of such property. This should result in a reduction in requests by lenders for case-by-case rulings on the acceptability of individual drainage and irrigation easements. The time and effort involved in submitting and processing these requests places unnecessary paperwork burdens on program participants and on VA personnel. The formalized position on acceptable easements in regulatory form will eliminate unnecessary paperwork and save time and effort for all parties. Inclusion of the requirement that the drainage and irrigation easements will not interfere with any of the buildings or improvements on the property is to assure that there will be no diminution of protection for the VA or the veteran.

An identical amendment is proposed for § 36.4253(c)(4)(i) which provides title requirements for mobile home lots.

These amendments are proposed under authority granted the Administrator by sections 210(c), 1803(c) and 1819(g) of title 38, United States Code.

Additional Comment Information

Interested persons are invited to submit written comments, suggestions or objections regarding the proposal to the Administrator of Veterans Affairs (271A), Veterans Administration, 810 Vermont Avenue, NW, Washington, DC 20420. All written comments received will be available for public inspection at the above address only between 8 am and 4:30 pm, Monday through Friday (except holidays) until May 27, 1980. Any person visiting Central Office for the purpose of inspecting any such comments will be received by the Central Office Veterans Services Unit in room 132. Such visitors to any VA field station will be informed that the records are available for inspection only in Central Office and furnished the address and the above room number.

Approved: April 8, 1980.

By direction of the Administrator.

Rufus H. Wilson,

Deputy Administrator.

1. Section 36.4253 is amended as follows:

(a) By deleting the words "his price" and inserting the words "the price" in paragraph (b)(5)(iii).

(b) By revising paragraph (c)(4)(i) as set forth below:

§ 36.4253 Title and lien requirements.

* * * * *

(c) The following limitations on the quantum or quality of the estate or property shall be deemed for the purposes of paragraph (b) of this section to have been taken into account in the appraisal of the mobile home lot and determined by the Administrator as not materially affecting the reasonable value of such property:

* * * * *

(4) *Easements.* (i) Easements for public utilities along one or more of the property lines and easements for drainage or irrigation ditches, provided the exercise of the rights thereof do not interfere with the use of the mobile home or improvements located on the subject property.

* * * * *

2. In § 36.4350, paragraph (c)(4)(i) is revised as follows:

§ 36.4350 Estate of veteran in real property.

* * * * *

(c) The following limitations on the quantum or quality of the estate or property shall be deemed for the purposes of paragraph (b) of this section to have been taken into account in the appraisal of residential property and determined by the Administrator as not

materially affecting the reasonable value of such property:

* * * * *

(4) *Easements.* (i) Easements for public utilities along one or more of the property lines and easements for drainage or irrigation ditches, provided the exercise of the rights thereof do not interfere with the use of any of the buildings or improvements located on the subject property.

* * * * *

(38 U.S.C. 210(c), 1803(c), 1819(g).)

[FR Doc. 80-11273 Filed 4-14-80; 8:45 am]

BILLING CODE 8320-01-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

42 CFR Part 74 and 405

Clinical Laboratories—Quality Control

AGENCY: Center for Disease Control, Public Health Service, HEW.

ACTION: Notice of decision to develop regulations.

SUMMARY: The Public Health Service proposes to amend the quality control regulations applicable to clinical laboratories by including additional quality control and testing requirements for procedures which measure Alpha-fetoprotein levels in mid-pregnancy maternal sera and amniotic fluids. Laboratories licensed under the Clinical Laboratories Improvement Act of 1967 are subject to Part 74 of Title 42, Code of Federal Regulations; and laboratories certified for reimbursement under the Medicare program, Title XVIII of the Social Security Act, are subject to Part 405. We plan to publish a Notice of Proposed Rulemaking (NPRM) containing the amendments concurrently with an NPRM by the Food and Drug Administration which will establish restrictions on the sale, distribution, and use as a condition of approval of any application for Premarket Approval of Alpha-fetoprotein test kits.

FOR FURTHER INFORMATION CONTACT: Joseph H. Boutwell, M.D., Deputy Director, Bureau of Laboratories, Center for Disease Control, Atlanta, GA 30333, Phone: (404) 329-3263 or FTS: 236-3263.

Dated: April 1, 1980.

Julius B. Richmond,

Assistant Secretary for Health.

[FR Doc. 80-11387 Filed 4-14-80; 8:45 am]

BILLING CODE 4110-86-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 2 and 90

[Gen. Docket No. 80-135; RM-3378; FCC 80-178]

Permitting the Continued Assignment of Frequencies in the 420-450 MHz Band for Non-Government Radiolocation

AGENCY: Federal Communications Commission.

ACTION: Notice of Proposed Rule Making.

SUMMARY: The Federal Communication Commission proposes to amend its regulations relating to frequency allocations and private land mobile radio services by deleting the January 1, 1981 cut-off date to permit the continued assignment of frequencies in the 420–450 MHz band for non-Government radiolocation usage. This action is taken in response to a petition filed by Del Norte Technology, Inc.

DATES: Comments must be received on or before May 16, 1980 and Reply Comments must be received on or before June 2, 1980.

ADDRESSES: Federal Communications Commission, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Mr. Sam Tropéa/Mr. George Sarver, Office of Science & Technology (202) 632-6350

In the matter of Revision of Parts 2 and 90 of the Commission's Rules and Regulations to permit the continued assignment of frequencies in the 420–450 MHz band for non-Government radiolocation; Gen. Docket No. 80-135; RM-3378; Proposed rule making.

Adopted: March 31, 1980;

Released: April 8, 1980.

I. Introduction

1. The Commission has under consideration a petition in the above-entitled matter filed by Del Norte Technology, Inc. (hereinafter "Del Norte"). Petitioner requests that footnote US 217 of Part 2 and Section 90.103(c)(21) of the rules be amended to delete the January 1, 1981, cut-off date for assignment of frequencies in the 420–450 MHz band for non-Government radiolocation. Petitioner further proposes that expanded operation be allowed inland [1] using spred spectrum techniques and that technical standards be developed to govern the continued operation of non-Government radiolocation equipment in the 420–450 MHz band.

2. Timely comments were filed by Crown Zellerback; Geophysical Service, Inc.; Hardcastle Ag-Air, Inc.; The Helicopter Association of America; The National Agricultural Aviation Association; Sercal, Inc.; The U.S. Department of Agriculture; and Weyerhauser Company. All comments filed were supportive of the petition.

3. The Del Norte petition will be handled as a two-part request with one part requiring summary action before January 1, 1981, and the other part requiring in depth analysis and consideration to determine expanded usage and operative technical standards. The first issue, to delete the cut-off date from the rules, needs consideration as soon as possible so that the status of current non-Government shoreline radiolocation users in the band can be determined. In accordance with the current rules, these radiolocation users must cease operation by January 1, 1981. The second issue, to develop technical standards for continuing radiolocation usage and the possible expanded usage to include inland operation and spread spectrum techniques, is complex in nature and will require extensive and careful consideration. This consideration will include coordination with the Interdepartmental Radio advisory Committee (IRAC) as well as other users of the band to invite their comments on the expanded usage. Since the Commission has no established policy or rules pertaining to the use of spread spectrum techniques, technical evaluation which could possible include field testing during an experimental/developmental phase to determine the electromagnetic compatibility of Del Norte's systems, especially with the primary users of the band, could be required. It is estimated that this evaluation along with consideration of the comments of other users will require considerably longer than the Januray 1, 1981 deadline. Accordingly, the scope of this proceeding will be limited only to consideration of the issue to delete the January 1, 1981 cut-off date. The remaining issues will be considered in a subsequent rule making action.

II. Background

4. On August 21, 1974, the Commission adopted a Notice of Proposed Rule Making in Docket 20147 [2] to amend Parts 2 and 91 (now Part 90) of the Commission's Rules to permit the assignment of frequencies in the 420–450

[1] Current use of the band by non-Government radiolocation is restricted to the shorelines of Alaska and the contiguous 48 states.

[2] See Notice of Proposed Rule Making, FCC 74-882.

MHz band for non-Government radiolocation. The amendment was necessary to accommodate old SHORAN-type radiolocation systems that were required to vacate frequencies in the 220–310 MHz band. The NPRM considered the 420–450 MHz and the 2900–3700 MHz bands as possibilities for allocation. Use of the 2900–3700 MHz band was considered least desirable by users since operational systems were not available at the time. On the other hand, equipemnt in the 420–450 MHz band was available for immediate use and, in fact, equipment designed for operation int he 220–310 MHz band could be converted and continue to be used with a relatively simple modification.

5. On March 10, 1976, the Commission adopted a Report and Order in Docket 20147 [3] to permit the assignment of the 420–450 MHz band for non-Government radiolocation. The Commission did qualify the assignment, however, by requiring the operation to cease on January 1, 1981. In the Report and Order the Commission stated that the enactment of the January 1, 1981 cut-off date would be subject to further review at that time. Accordingly, such review now appears necessary in view of the instant petition by Del Norte requesting deletion of the cut-off date to provide continued use of the 420–450 MHz band for non-Government radiolocation.

III. Why Continued Usage of the 450 MHz Band?

6. Del Norte is a manufacturer of radiolocation equipment operating in the 9 GHz range. These radiolocation devices are used in a variety of applications such as the mapping of offshore areas for oil exploration, the precise determination of possible drilling locations, and for other hydrography purposes. Moreover, with the increased reliance on agricultural chemicals in food production and forestry, accurate positioning has become essential to ensure that these substances are applied in a manner that is environmentally safe and productively efficient. Because of widespread demands from users of radiolocation equipment for greater ranges than available from 9 GHz gear, Del Norte undertook a program of research and development involving use of the 420–450 MHz band. Equipment tests conducted by the petitioner demonstrated that the path loss of a signal at 9.4 GHz was considerably greater than at a 435 MHz test frequency. For example a radiolocation system operating at 435 MHz could achieve a range of up to 50 miles over water whereas a comparable system operating at 9.4 GHz could only achieve a 15 mile range. Moreover, the propagation findings at 9 GHz correspond with comments filed by Offshore Navigation, Inc. in the 1974 rulemaking action that alleged that 2900–3700 MHz band is not a practical substitute for the 420–450 MHz band because of propagation difficulties and the consequent lack of suitable equipment. Accordingly, since greater ranges than obtainable above 2900 MHz are considered necessary for offshore radiolocation operations, the continued use of the 420–450 MHz band is considered necessary. Del Norte also notes that the desirability of the 420–450 range is further demonstrated by the fact that foreign manufacturers are competing for the production of radiolocation equipment in this band.

IV. Compatibility With Primary Users.

7. Del Norte purports that the present non-Government radiolocation operation should be allowed to continue since it is compatible with that of other users in the band. With continued usage on a secondary basis as the current rules provide, operation would be on a non-interference basis with primary users. Thus, radiolocation users would therefore be responsible to protect the primary users of the band from interference. In this regard, when the petition for rule making in Docket 20147 was first received, it was referred to IRAC for consideration because the primary allocation of the band was for Government radiolocation. Following extensive discussions and actual system testing, results indicated the operations to be compatible and, thus, IRAC agreed to permit non-Government radiolocation in the 420–450 MHz band on a secondary basis.

8. The probability of interference to primary users is believed minimal because of the transient nature of the operations and the use of highly directional antennas which generally are pointed out to sea and tilted slightly downward. Furthermore, compatibility is enhanced by the physical separation that exists between the non-Government radiolocation systems and other users. The non-Government radiolocation users are generally confined to rural and offshore areas providing an isolation which insures that interference problems are unlikely to arise. To maintain maximum isolation, continued operation would only be authorized along the shorelines of Alaska and the contiguous 48 states as the Commission's Rules presently allow. Compatibility appears to be further supported by the absense of any known interference complaints on file with the Commission regarding the non-Government radiolocation users in almost four years since Docket 20147 was enacted. A further safeguard is available in that each application for operation will be closely reviewed by the Commission on a case-by-case basis before authorization to determine compatibility with the primary users.

V. Proposals

9. Accordingly, it is proposed to delete the January 1, 1981 cut-off date in § 2.106, Footnote US 217 and § 90.103(c)(21) to permit the continued operation of non-Government radiolocation stations in the 420–450 MHz band subject to the following conditions:

a. Operation is permitted on a secondary basis to the Government Radiolocation Service and the Amateur Radio Service.

b. Operation is limited to usage along the shorelines of Alaska and the contiguous 48 states.

c. Authorization will be granted on a case-by-case basis with particular attention given to the proposed power and antenna system requirements.

In formulating these proposals, the Commission took into account the modifications to the 420–540 MHz band adopted by the 1979 World Administrative Radio Conference as well as the operating agreements with Canada and Mexico. In this regard, the same interference protection that is provided for the Government Radiolocation and Amateur Radio Services shall be afforded any other user of the frequencies. Also, the usual coordination procedures with Canada and Mexico during licensing shall be employed when geographical considerations so require.

VI. Procedural Matters

10. For further information concerning procedures to follow with respect to this rulemaking proceeding, contact Sam Tropea (202) 632–6350. A summary of the Commission's procedures governing *ex parte* contacts in informal rulemaking [4] is available from the Commission's Consumer Assistance Office, FCC, Washington, D.C. 20554, (202) 632–7000.

11. The proposed amendments to Parts 2 and 90 of the rules, as set forth in the Appendix, are issued pursuant to the authority contained in Sections 4(i) and 303(c), (h) and (r) of the Communications Act of 1934, as amended.

[3] See *Report and Order*, FCC 76–228.

[4] See 68 F.C.C. 2d 804 (1978) where the Commission set forth its interim policy.

12. Pursuant to applicable procedures set forth in Section 1.415 of the Commission's Rules, interested persons may file comments on or before May 16, 1980, and reply comments on or before June 2, 1980. All relevant and timely comments will be considered by the Commission before final action is taken in this 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.

13. In accordance with the provisions of Section 1.419 of the Commission's Rules, an original and 5 copies of all statements, briefs or comments filed shall be furnished the Commission. Responses will be available for public inspection during business hours in the Commission's Public Reference Room in its headquarters in Washington, D.C.

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix

Parts 2 and 90 of Chapter I of Title 47 of the Code of Federal Regulations are amended as follows:

PART 2—FREQUENCY ALLOCATION AND RADIO TREATY MATTERS, GENERAL RULES AND REGULATIONS

1. In § 2.106, footnote US 217 is amended to read as follows:

§ 2.106 Table of frequency allocations.

* * * * *

US 217 Pulse-ranging radiolocation systems may be authorized for Government and non-Government use in the 420–450 MHz band along the shorelines of Alaska and the contiguous 48 states. Such authorizations will be granted on a case-by-case basis, and all stations operating in accordance with those authorizations will be secondary to stations operating in accordance with the allocation table. All power and antenna height specifications shall be made on a case-by-case basis.

* * * * *

PART 90—PRIVATE LAND MOBILE RADIO SERVICES

2. In § 90.103, paragraph (c)(21) is amended to read as follows:

§ 90.103 Radiolocation service.

(c) * * *

* * * * *

(21) Non-Government pulse-ranging radiolocation stations in this band are secondary to the Government Radiolocation Service, the Amateur Radio Service and the Amateur Satellite Service. All power and antenna height specifications shall be made on a case-by-case basis.

* * * * *

[FR Doc. 80-11388 Filed 4-14-80; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[BC Docket No. 80-50]

Extending Time for Filing Comments and Reply Comments to FM Assignment in Coeur D'Alene, Idaho

AGENCY: Federal Communications Commission.

ACTION: Proposed rule (order extending time for filing comments and reply comments).

SUMMARY: Action taken herein extends the time for filing comments and reply comments in a proceeding involving the assignment of FM channels at Coeur D'Alene, Idaho. Idaho Broadcasting, Inc., requested the additional time to enable it to file additional information in this proceeding.

DATES: Comments must be filed on or before June 9, 1980, and reply comments must be filed on or before June 30, 1980.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

Adopted: April 4, 1980.

Released: April 7, 1980.

In the matter of amendment of § 73.202(b), *Table of Assignments*, FM Broadcast Stations. (Coeur D'Alene, Idaho), BC Docket No. 80-50, RM-3183.

1. On February 6, 1980, the Commission adopted a *Notice of Proposed Rule Making*, 45 FR 12451, concerning the above-entitled proceeding. The dates for filing comments and reply comments are April 7, and April 28, 1980, respectively.

2. On March 26, 1980, Idaho Broadcasting, Inc. ("Idaho B/C"), filed a timely request seeking an extension of time for filing comments to and including July 15, 1980. Idaho B/C states it wishes to engage an engineer who can provide it with more information on the alternatives presented in the proceeding.

3. We are of the view that the public interest would be served by this extension so that Idaho B/C may file any information which might be helpful to the Commission in reaching a decision in this proceeding. We cannot agree that an additional 3 months is necessary for a thorough study of the issues in this case. However, we are willing to extend the time period to provide another 2 months. Also, as a result, it is necessary to extend the reply comment date.

4. Accordingly, it is ordered, That the dates for filing comments and reply comments in BC Docket No. 80-50 are extended to and including June 9, 1980, and June 30, 1980, respectively.

5. This action is taken pursuant to authority found in Sections 4(i), 5(d)(1) and 303(r) of the Communications Act of 1934, as amended, and § 0.281 of the Commission's rules.

Federal Communications Commission.

Henry L. Baumann,

Chief, Policy and Rules Division Broadcast Bureau.

[FR Doc. 80-11304 Filed 4-14-80; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[BC Docket No. 80-142; RM-3446]

Proposed FM Broadcast Assignment to Elkins, W. Va.

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rule making.

SUMMARY: Action taken herein proposes the assignment of FM Channel 237A to Elkins, West Virginia, as that community's first FM assignment, in response to a petition filed by Garry L. Bowers, Eleanor I. Freed and Richard H. McGraw, a Joint Venture. The proposed channel could provide a first local commercial FM broadcast service to Elkins.

DATES: Comments must be filed on or before June 2, 1980, and reply comments on or before June 24, 1980.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792.

SUPPLEMENTARY INFORMATION:

Adopted: April 1, 1980.

Released: April 9, 1980.

In the matter of amendment of § 73.202(b), *Table of Assignments*, FM Broadcast Stations. (Elkins, West Virginia), BC Docket No. 80-142, RM-3446.

1. *Petitioner, Proposal, Comments.* (a) A petition for rule making [1] was filed by Garry L. Bowers, Eleanor I. Freed and Richard H. McGraw, a Joint Venture ("petitioners"), proposing the assignment of Channel 237A to Elkins, West Virginia, as its first FM commercial assignment.

(b) The channel can be assigned in compliance with the minimum distance separation requirements.

(c) Petitioners state they will apply for the channel, if assigned.

2. *Community Data.*—(a) *Location.* Elkins, seat of Randolph County, is located approximately 161 kilometers (100 miles) northeast of Charleston, West Virginia.

(b) *Population.* Elkins—8,287;[2] Randolph County—24,596.

(c) *Local Aural Broadcast Service.* Elkins is served locally by fulltime AM Station WDNE and noncommercial educational FM Station WCDE(FM), Channel 212.

3. *Economic Considerations.* Petitioners state that, according to the Randolph County Development Authority, the 1975 population of Elkins was approximately 9,000. They note that the existing businesses in Elkins center around coal, lumber, health services and government. Petitioner has submitted demographic data with respect to Elkins in order to demonstrate its need for a first commercial FM assignment.

4. Petitioners note that Elkins is in the "Quite Zone" of the National Radio Astronomy Observatory ("NRAO") at Green Bank, West Virginia, and the Naval Installation at Sugar Grove, West Virginia. They attached a letter from NRAO which indicated that NRAO believed it could approve an Elkins FM site without a special antenna and would be willing to allow a maximum of 3 kW ERP toward Green Bank. Petitioners also attached a letter from the Naval Research Laboratory which stated that a quick survey was made of the sites suggested by petitioners' engineering consultant, and that several sites appear to be acceptable in the area proposed by petitioners. A more precise determination is to be made when a firm proposal is submitted.

5. We believe it would be in the public interest to propose the assignment of Channel 237A to Elkins, West Virginia. The proposed channel could provide Elkins with its first local commercial FM broadcast service.

6. Comments are invited on the proposal to amend the FM Table of Assignments § 73.202(b) of the Commission's rules) with regard to Elkins, West Virginia, as follows:

City	Channel No.	
	Present	Proposed
Elkins, West Virginia		237A

7. The Commission's authority to institute rule making proceedings, showings required, cut-off procedures, and filing requirements are contained in the attached Appendix and are incorporated by reference herein.

Note.—A showing of continuing interest is required by paragraph 2 of the Appendix before a channel will be assigned.

8. Interested parties may file comments on or before June 2, 1980, and reply comments on or before June 24, 1980.

9. For further information concerning this proceeding, contact Mildred B. Nesterak, Broadcast Bureau, (202) 632-7792. However, members of the public should note that from the time a notice of proposed rule making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel assignments. An *ex parte* contact is a message (spoken or written) concerning the merits of a pending rule making other than comments officially filed at the Commission or oral presentation required by the Commission.

Federal Communications Commission.

Henry L. Baumann,

Chief, Policy and Rules Division, Broadcast Bureau.

Appendix

[Docket No. 80-142 RM-3446]

1. Pursuant to authority found in Sections 4(i), 5(d)(1), 303(g) and (r), and 307(b) of the Communications Act of 1934, as amended, and § 0.281(b)(6) of the Commission's rules, it is proposed to amend the FM Table of Assignments, § 73.202(b) of the Commission's rules and regulations, as set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached.

2. *Showings required.* Comments are invited on the proposal(s) discussed in the Notice of Proposed Rule Making to which this Appendix is attached. Proponent(s) will be expected to answer whatever questions are presented in initial comments. The proponent of a proposed assignment is also expected to file comments even if it only resubmits or incorporates by reference its former pleadings. It should also restate its present intention to apply for the channel if it is assigned, and, if authorized, to build the station promptly. Failure to file may lead to denial of the request.

3. *Cut-off procedures.* The following procedures will govern the consideration of filings in this proceeding.

(a) Counterproposals advanced in this proceeding itself will be considered, if advanced in initial comments, so that parties may comment on them in reply comments. They will not be considered if advanced in reply comments. (See § 1.420(d) of Commission rules.)

(b) With respect to petitions for rule making which conflict with the proposal(s) in this Notice, they will be considered as comments in the proceeding, and Public Notice to this effect will be given as long as they are filed before the date for filing initial comments herein. If they are filed later than that, they will not be considered in connection with the decision in this docket.

4. *Comments and reply comments; service.* Pursuant to applicable procedures set out in §§ 1.415 and 1.420 of the Commission's rules and regulations, interested parties may file comments and reply comments on or before the dates set forth in the *Notice of Proposed Rule Making* to which this Appendix is attached. All submissions by parties to this proceeding or persons acting on behalf of such parties must be made in written comments, reply comments, or other appropriate pleadings. Comments shall be served on the petitioner by the person filing the comments. Reply comments shall be served on the person(s) who filed comments to which the reply is directed. Such comments and reply comments shall be accompanied by a certificate of service. (See § 1.420(a), (b) and (c) of the Commission rules.)

5. *Number of copies.* In accordance with the provisions of § 1.420 of the Commission's rules and regulations, an original and four copies of all comments, reply comments, pleadings, briefs, or other documents shall be furnished the Commission.

6. *Public inspection of filings.* All filings made in this proceeding will be available for examination by interested parties during regular business hours in the Commission's Public Reference Room at its headquarters, 1919 M Street, NW., Washington, D.C.

[FR Doc. 80-11308 Filed 4-14-80; 8:45 am]

BILLING CODE 6712-01-M

[1] Public Notice of the petition was given on August 17, 1979, Report No. 1188.

[2] Population figures are taken from the 1970 U.S. Census.

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47 CFR Part 87

[PR Docket No. 80-137; RM-3429; FCC 80-184]

Providing for Automatic Digital Communications in the Aeronautical En Route Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: The FCC proposes to amend the rules to provide for the operation of automatic digital communications systems in the aeronautical enroute service. This action was requested by Aeronautical Radio, Inc., which is a non-profit communications company owned

by the air transport industry. The intended effects are more efficient use of radio frequencies and improved airline operations.

DATES: Comments must be received on or before May 16, 1980, and reply comments must be received on or before June 2, 1980.

ADDRESSES: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: Robert H. McNamara, Private Radio Bureau, (202) 632–7175.

SUPPLEMENTARY INFORMATION:

Adopted: March 31, 1980.

Released: April 10, 1980.

In the matter of amendment of Part 87 of the rules to provide for automatic digital communications in the aeronautical enroute service, PR Docket No. 80–137, RM 3429.

1. In this Notice we are proposing to amend the Commission's rules to establish regulations for the operation of automatic digital communications systems in the aeronautical enroute service.

Background

(Aeronautical En Route Service)

2. The aeronautical enroute service provides for air-ground communications for the operational control (i.e., flight management) of aircraft by the owners or operating companies.[1] Communications relate to the safe and efficient operation of aircraft. Typical messages concern aircraft position reports, performance, fuel, weather, supplies, passenger needs and the like. Public correspondence, that is private or personal messages of passengers or crew, is not permitted on enroute frequencies.

3. Aeronautical enroute stations (ground stations) are the means by which companies satisfy FAA requirements to maintain reliable communications between each aircraft and the appropriate dispatch office in the case of large airlines, or maintain flight following systems in the case of small airlines and large commercial aircraft operations (14 CFR 121.99 and 121.125, respectively).

4. The Commission's rules governing enroute stations are set forth in Subpart E of Part 87 (Aviation Services). These stations are required to "* * * provide all necessary non-public service, HF and VHF, * * * without discrimination to any aircraft station licensee who makes cooperative arrangements for the operation and maintenance of the aeronautical enroute stations which are to furnish such service and for shared liability in the operation of such stations * * *" [2] Further, only one enroute station in the domestic service and one such station in the international service may be authorized at any one location.[3] (Location for the purposes of this rule is defined as an area which can be adequately served by the particular station.)

(Aeronautical Radio, Inc.)

5. Aeronautical Radio, Inc. (ARINC) Is the licensee of all but a half dozen of the more than 2500 VHF and HF enroute stations located throughout the United States. ARINC was incorporated in 1929, with the encouragement of the then Federal Radio Commission, as a private communications company serving the air transport industry on a non-profit, cost-sharing basis. Its principal customers as well as principal stockholders are the U.S. scheduled airlines. However, ARINC provides enroute service to all aircraft operators, including foreign airlines, business entities and private individuals, who make cooperative arrangements. ARINC has done an outstanding job in effectively and efficiently utilizing available spectrum and regularly introducing improvements in operational techniques.

Petition

6. ARINC has filed a petition for rulemaking requesting that we amend Part 87 of the rules to establish regulations for the operation of automatic digital communications systems in the aeronautical enroute service. ARINC indicates that in cooperation with the aviation industry it has developed an automatic digital communications system.[4] This system consists of digital message generating and decoding equipment located on board aircraft and at selected ground facilities together with the normal VHF transmitters and receivers.

7. ARINC points out that an automatic digital communications system in the enroute service will provide two important public benefits. First, spectrum will be conserved by reducing the time required to make routine reports. Digital communications take only a fraction of the time necessary to transmit the same information by voice. Second, airline operations will be improved and cockpit workloads reduced by automatically reporting routine information via nonvoice data. Examples of such routine information include aircraft arrival/departure times, estimated arrival times, fuel, and passenger capacity. Various events will initiate the messages, such as closure of a cabin door or engine oil pressure for departure time. By relieving the flight crew of the responsibility of making these reports via voice communications, the cockpit workload will be eased and the reliability of reported information increased.

8. At page 3 of its petition ARINC states that the airborne installations will employ conventional VHF aeronautical transceivers to send and receive messages. When a message has been received from an aircraft by an aeronautical enroute ground station, it will go the ARINC control computer. There it will be checked for transmission errors, and if it is correct, the computer will key the appropriate ground station to transmit an acknowledgment. Once received in appropriate form, the ARINC computer will automatically route the message to the airline operating agency over ARINC's Electronic Switching System. If no acknowledgment is received, the aircraft station will automatically retransmit the message, typically up to six times. If no acknowledgment is received after the sixth retransmission, a light will flash in the cockpit to alert the crew that the message has not been received. At this point, the crew may activate the system to retransmit the message digitally or contact an ARINC communications center for transmission of the message by voice.

9. ARINC indicates that its system will initially operate on a single frequency for both air-to-ground and ground-to-air. Expansion to a second frequency in the enroute band may be desirable in the future. It will utilize audio phase shift keying transmitting 2400 bits per second of ASCII encoded data. The use of audio phase and frequency shift keying in the band (117.975–136 MHz) is currently provided for in Section 87.67 of the rules. We feel that the existing emission designator (13A9) in conjunction with an authorized

[1] Operational control communications are defined in Volume II of Annex 10 to the Convention on International Civil Aviation as communications required for exercising authority over initiation, continuation, diversion or termination of a flight. In other words, such communications are used by an organization to directly manage its aircraft operations.

These operational control communications should not be confused with air traffic control communications which relate to the safe, and orderly flow of air traffic, i.e., provide safe separation of aircraft. In the United States, air traffic control services are provided by the Federal Aviation Administration (FAA).

[2] 47 CFR 87.291(a)

[3] 47 CFR 87.291(b)

[4] The system is known as the ARINC Communications Addressing and Reporting System (ACARS). ACARS is a registered trademark.

bandwidth of 25 kHz, adequately prescribes the emission limitations which the equipment must meet to be compatible with other emissions used in the band 117.975–136 MHz. Also maximum flexibility will be provided for equipment designers.

10. The system will employ two modes of operation. The demand mode will be used where traffic is light. The airborne terminal will first listen to avoid interference and then transmit data on its own initiative. The polled mode will be used when traffic management is advantageous. After switching the airborne terminals to the polled mode, the ground facility will poll the aircraft periodically. The terminal will alert the flight crew if it is not polled for more than 2.5 minutes.

11. After extensive operational tests ARINC indicates that a number of rule amendments and clarifications are needed to establish a basis for the regular operation of an automatic digital communications systems in the aeronautical enroute service. Essentially, the changes proposed by ARINC relate to the form of station identification, the requirement for a licensed radio operator at a control point, the maintenance of station logs, and transmitter control requirements. Although ARINC's proposed changes are based on its own system, other automatic digital communications are not precluded.

Discussion

12. We believe that the implementation of an automatic digital communications system in the aeronautical enroute service, as proposed by ARINC, would be in the public interest. The substitution of automatic data communications for routine voice reports would increase efficiency and conserve scarce spectrum. As the Commission's UHF Task Force previously noted, the present spectrum available for enroute communications will be saturated by 1985.[5] Further the so-called Golden Triangle, the area between Boston, Chicago and Washington, is apparently nearly saturated today. In addition to the conservation of scarce spectrum, such an automatic digital communications system would benefit air transport operations by increasing information reliability and decreasing cockpit workload.

13. The rule changes requested by ARINC are designed to accommodate the operation of a computer controlled digital communications system in what is presently a voice communications system. The first area to be clarified involves station identification. Section 87.115(b) currently provides, in part, for station identification " * * * either by call sign or other recognized means of identification * * * " which includes " * * * name of station, location of station, operating agency, official registration, flight identification number, characteristic signal, characteristic of emission or other clearly distinguishing features readily recognized." Further, § 87.115(i) exempts certain radio systems from transmission of identification where impracticable (e.g., weather radar, radio altimeter, air traffic control transponder). Although ARINC considers that § 87.115 is sufficiently broad to encompass its digital system, it suggests that a new subparagraph be added to clarify system identification requirements. In that there only will be approximately 200 such ground facilities utilizing the line-of-sight range of UHF communications and a characteristic emission in the band, we believe that station identification would be impracticable within the meaning of § 87.115(i). Therefore, the addition of such a digital system to to the examples listed in paragraph (i) is preferable to adding new paragraph to the rules. However, if in the future such systems proliferate in the Aviation or other Services, some form of station identification may be required.

14. Second, implementation of an automatic digital communications system will necessitate that the rules be changed to indicate that licensed radio operators are not required in the initiation of digital messages at enroute ground stations. Section 87.139(a) now provides that operator licenses are not required for flight personnel operating airborne radionavigation aids, for the operation of an emergency locator transmitter or survival craft station, and for the operation of stations which retransmit communications received by automatic means.[6] The ARINC system is computer controlled. It incorporates circuitry to prevent interference and excessively long transmissions. Alarm circuits are employed to notify personnel of system malfunctions and test circuits are available to test the operation of the entire ground system. Therefore, we consider such computer controlled digital communications systems similar to other automatically controlled systems and, likewise, the presence of a licensed operator at the "control point" unnecessary.

15. Third, since the ground terminals will automatically be controlled by computer, we concur with ARINC's view that it would not be practicable to maintain an operator's station log as required by § 87.99. The proposed system, however, will keep a record of the hours of operation, messages transmitted and operational status of the stations. Additionally, FAA's requirements[7] regarding the retention of records relating to any emergency, claim or complaint will be complied with.

16. Lastly, automatic digital enroute stations which are computer controlled (as all such systems must be) appear not to require a licensed radio operator at a "control point" as envisioned in § 87.75. Similarly, the additional requirements for a visual indication when the transmitter is radiating, and for equipment to permit aural monitoring would appear unnecessary.[8] ARINC proposes exempting such automatic digital enroute stations from these requirements. The system requirements suggested, although based on the ARINC system do not preclude other automatic digital system.

Proposal

17. In view of the above, we propose to amend §§ 87.75, 87.99, 87.115 and 87.139 of the rules to provide for the operation of automatic digital communications systems in the aeronautical enroute service. The proposed amendments to the Commission's rules as set forth in the attached Appendix below, are issued pursuant to the authority contained in Sections 4(i) and 303(r) of the Communications Act of 1934, as amended.

Comments

18. Pursuant to applicable procedures set forth in § 1.415 of the Commission's rules, interested persons may file comments on or before May 16, 1980, and reply comments on or before June 2, 1980. All relevant and timely comments

[5] UHF Task Force Working Paper, March 1978, at page 97. This projection did not take into consideration the increased efficiencies resulting from technological improvements as the substitution of data communication for voice communication.

[6] 47 CFR 87.139(a):

§ 83.139 Operator licenses not required for certain operations.

(a) Operator licenses are not required for the following:

(1) Flight personnel when concerned with the operation of airborne radar sets, radio altimeters, transponders and other airborne automatic radionavigation aids.

(2) Operation of an aircraft station using only an emergency locator transmitter, or a survival craft station while it is being used solely for survival purposes, or for testing of such stations.

(3) Operation of any radio station authorized under this part which retransmits by automatic means communications received by radio.

[7] 14 CFR 121.711.

[8] Typical digital transmissions will be less than one second.

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.

19. In accordance with the provisions of § 1.419 of the Commission's rules, an original and 5 copies of all statements, briefs or comments filed shall be furnished to the Commission. Responses will be available for public inspection during regular business hours in the Commission's Public Reference Room at its headquarters in Washington, D.C.

20. Regarding questions on matters covered in this document contact Robert McNamara (202) 632-7175.

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix

Part 87 of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

PART 87—AVIATION SERVICES

1. In § 87.75, the introductory sentence of paragraphs (c) and (d) are amended and new paragraph (f), added to read as follows:

§ 87.75 Transmitter control requirements.

* * * * *

(c) Except for stations governed by paragraph (f) of this section, a control point is a position which meets all of the following conditions: * * *

(d) Except for stations governed by paragraph (f) of this section, at each control point the following facilities shall be installed: * * *

* * * * *

(f) In the aeronautical enroute service, the control point for an automatically controlled enroute station shall be the computer facility which controls the transmitter. Each such computer facility shall be installed and protected so that it is not accessible to or capable of operation by persons other than those duly authorized by the licensee. Any transmitter controlled by such a computer facility shall be equipped with automatic controls to render the transmitter inoperative following a continuous transmission of more than 180 seconds.

2. In § 87.99, the first sentence of paragraph (a) is amended to read as follows:

§ 87.99 Information required in station logs.

(a) Except for radionavigation land test stations (MTF) and automatically controlled aeronautical enroute stations, all stations at fixed location shall maintain logs showing hours of operation, frequencies used and hours of duty and the signature of the operator(s) on duty. * * *

* * * * *

3. In § 87.115 paragraph (i) is amended by adding the words "automatically controlled aeronautical enroute station" at the end of the paragraph, to read as follows:

§ 87.115 Station identification.

* * * * *

(i) Radio systems, where the transmission of specific identification is considered to be impracticable, are exempted from the provisions of this section; e.g., airborne weather radar, radio altimeter, air traffic control transponder, distance measuring equipment, collision avoidance equipment, racon, radiosonde, radio relay, radionavigation land test station (MFT), and automatically controlled aeronautical enroute stations that transmit digital communications.

* * * * *

4. In § 87.139, new paragraph (a)(4) is added to read as follows:

§ 87.139 Operator licenses not required for certain operations.

(a) * * *

(4) Operation of any aeronautical enroute station which transmits by automatic means digital communications to aircraft stations.

* * * * *

[FR Doc. 80-11305 Filed 4-14-80; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 97

[Gen. Docket No. 80-136; RM-2910; RM-2939; RM-3281; RM-3302; FCC 80-183]

Amending Rules Concerning Station Identification Requirements

AGENCY: Federal Communications Commission.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: The FCC proposes to amend station identification requirements in the Amateur Radio Service. The present rule requires amateur radio stations to identify the station with which contact was made, at the end of the transmission. The proposal would eliminate this requirement for all communications except those involving international third party traffic. The adoption of this proposal would reduce channel usage, and would permit amateur radio operators to complete their transmissions in less time.

DATES: Comments must be received on or before July 16, 1980 and Reply Comments must be received on or before August 15, 1980.

ADDRESS: Federal Communications Commission, Washington, D.C. 20554.

FOR FURTHER INFORMATION CONTACT: John Jonston, Private Radio Bureau, (202) 254-6884.

Adopted: March 31, 1980.

Released: April 9, 1980.

In the matter of Amendment of Part 97.84(a) of the Amateur Radio Service Rules, PR Docket No. 80-136, RM-2910, RM-2939, RM-3281, RM-3302.

1. The Commission has before it four petitions for rulemaking separately filed by James R. Sebolt in 1977, John C. Kanode on behalf of the Potomac Valley Radio Club in 1977, Arlington R. Kaeding in 1978, and Stephen R. Mann in 1978. The petitioners request that the Commission consider simplifying the identification requirements for amateur radio stations. 47 CFR 97.84.

2. Section 97.84(a) of the Amateur Radio Service Rules and Regulations provides that:

(a) An amateur station shall be identified by the transmission of its call sign at the beginning and end of each single transmission or exchange of transmissions and at intervals not to exceed 10 minutes during any single transmission or exchange of transmission of more than 10 minutes of duration. Additionally, at the end of an exchange of telegraphy (other than teleprinter) or telephony transmissions between amateur stations, the call sign (or generally accepted network identifier) shall be given for the station, or for at least one of the group of stations with which communicatin was established.

Two petitioners request that the Commission eliminate completely the requirement that amateur radio operators identify the station with which they were in contact, at the end of the trasmission. The third petitioner also favors elimination of this requirement, except that he would retain the restriction for international third party communications. The fourth petitioner requests that this requirement be eliminated where the entire exchange of communication lasts less than one minute. In addition, one petitioner requests that the rules be amended to allow stations completing an exchange in less than one minute to identify themselves at any time during the

exchange, rather than at the beginning and end of each transmission.

3. FCC monitoring observers sample transmissions in progress, as well as the beginning or end of transmissions. For this reason, the proposal to allow identification at any time during a transmission lasting less than one minute rather than at the beginning and end of transmission, cannot be adopted. If adopted, this proposal would preclude FCC monitoring observers from identifying the transmitting station, if, for instance, the observer began monitoring the transmission after the identification was given.

4. The petitioners, and others who have filed comments pursuant to the Public Notices released by this Commission, advance the following arguments for amending § 97.84(a)'s requirement that amateur radio operators identify the station with which they were in contact, at the end of the transmission.

(1) Each station is required to identify its own transmission; therefore there is no need to require stations to also identify each other.

(2) The removal of this restriction would reduce channel usage, and therefore reduce channel congestion.

(3) This amendment would benefit United States amateur radio operators engaged in contest operations by increasing the number of communications that could be completed within a set period of time.

(4) The Amateur Radio Service is the only radio service where station operators are still required to identify the station with which contact has been made. A similar requirement was deleted from the Citizens Radio Service Rules in 1975. 54 F.C.C. 2d 841, 40 FR 33667 (1975).

Proposal

5. The Commission proposes to delete the requirement that amateur radio stations identify the station with which they were in contact for all transmission except those involving international third party communications.[1] International third party communications are excluded from the scope of the proposed amendment because of the Commission's obligation to enforce the International Radio Regulations. Article N30/41, No. 6355/1561 of the International Radio Regulations provides, in part, that "* * * [i]t is absolutely forbidden for amateur stations to be used for transmitting international communications on behalf of third parties." The United States does have bilateral agreements with 29 countries which permit third party traffic, but with regard to other countries, the prohibition is still applicable. Without the identification requirement presently imposed by our rules, enforcement of the prohibition would be very difficult.

6. We are also proposing to extend requirement that radio stations identify the station with which they were in contact where international third party communication is involved, to teleprinter communications. Heretofore, teleprinter had been excluded from this requirement, but there appears to be no reason not to require this type of identification, especially where the requirement would strengthen the enforcement mechanism available to the Commission, and only minimally impact the licensee.

7. Our proposal is not limited to only those transmissions which last less than one minute. The arguments advanced in favor of that proposition (i.e. that contest operations would be enhanced * * *) extend to the less restrictive proposal we have adopted as well.

8. In view of the above, the petitions proposing to simplify station identification requirements in the Amateur Radio Service are adopted to the extent that they are not inconsistent with this *Notice*. All proposals contained in the petitions which are inconsistent with this *Notice* are denied. The proposed amendment of the Commission's rules, as set forth in the attached appendix below, is issued pursuant to the authority contained in Section 4(i) and 303(r) of the Communications Act of 1934, as amended.

9. Pursuant to the applicable procedures set forth in § 1.415 of the Commission's rules, interested persons may file comments on or before July 16, 1980, and reply comments on or before August 15, 1980. All relevant and timely comments will be considered by the Commission before final action is taken in this 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.

10. In accordance with the provisions of § 1.419 of the Commission's rules, an original and 5 copies of all statements, briefs, or comments shall be furnished the Commission. All comments received in response to Notice of Proposed Rule Making will be available for public inspection in the Docket Reference Room in the Commission's Office in Washington, D.C.

11. Regarding questions on the matters covered in this document contact John B. Johnston, Rules Division, (202) 254–6884.

Federal Communications Commission.

William J. Tricarico,

Secretary.

Appendix

I. Part 97 of the Commission's Rules is amended as follows:

1. In § 97.84, paragraph (a) is amended and paragraph (h) is added to read as follows:

§ 97.84 Station identification.

(a) Each amateur radio station shall give its call sign—

(1) When it begins or ends each single transmission or exchange of transmissions, and

(2) At least every ten minutes during a transmission or exchange of transmissions.

* * * * *

(h) At the end of an exchange of third party communications with a station located in a foreign country, each amateur radio station shall also give the call sign of the station with which third party communications was exchanged.

[FR Doc. 80–11306 Filed 4–14–80; 8:45 am]
BILLING CODE 6712–01–M

[1] See the Appendix for the complete text of the proposed amendment.

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1041

[Ex Parte No. MC–139]

Removal of Mechanical Refrigeration Restrictions

AGENCY: Interstate Commerce Commission.

ACTION: Notice of Proposed Rules.

SUMMARY: The Interstate Commerce Commission is proposing to adopt a rule which would delete from all existing certificates and permits restrictions limiting transportation service to that which is provided in "vehicles equipped with mechanical refrigeration."

Carriers operating pursuant to authorities so restricted may be authorized to "dry freight" (commodities not requiring refrigeration while in transit) as well as commodities requiring refrigeration. However, the vehicle restriction may prevent them from achieving maximum efficiency, because a trailer equipped with mechanical refrigeration devices has a reduced load capacity and usually represents a larger capital investment than an ordinary trailer. Removal of the restriction could, therefore, enable affected carriers to provide shippers of dry freight with

improved service due to fuel savings and lower costs.

DATE: Comments should be filed May 30, 1980.

ADDRESSES: Send an original and 15 copies, if possible, of comments to: Ex Parte No. MC–139, Office of Proceedings, Room 5416, Interstate Commerce Commission, Washington, DC 20423.

FOR FURTHER INFORMATION CONTACT: Eliot C. Horowitz, (202) 275–7973; or Donald J. Shaw, Jr. (202) 275–7292.

SUPPLEMENTARY INFORMATION: This proceeding stems from a petition seeking institution of rulemaking filed by Refrigerated Transport Company, Inc., of Forest Park, GA. Petitioner is an irregular route motor common carrier primarily engaged in the transportation of foodstuffs.

Petitioner states that many shippers of dry foodstuffs look to specialized motor carriers in the "protective service field" to transport their traffic, because of these carriers' general expertise concerning marketing and distribution patterns germane to the food industry. It asserts that the removal of the vehicle restriction would enable these carriers better to serve shippers of dry freight, in their authorized origin territories, by using ordinary trailers with increased cargo space (perhaps yielding as much as 10 percent increased load capacity). Since many of these carriers also possess authorities to transport other kinds of dry commodities, petitioner urges that the removal of the restriction would result in more efficient service on backhauls.[1]

Petitioner claims that the restriction serves basically to protect the interests of general commodities carriers, which have only "peripheral and insubstantial interests" in the movement of foodstuffs. It believes that, in general, where individual carriers have filed applications for the purpose of having the restriction removed from their specific authorities, no substantial opposition has been encountered from existing carriers.

Discussion

"Protective service" is provided by motor carriers with respect to a broad range of commodities (including, for example, various chemicals and drugs). Some articles require heating, others refrigeration, while in transit.

Where a carrier has recevied authority to engage in a "temperature controlled service," the Commission has, from time to time, imposed the vehicle restriction at issue. The underlying rationale for the use of the term is discussed in *Refrigerated Transport Co., Inc., Extension—Foodstuffs,* 88 M.C.C. 71 (1961). Essentially, the vehicle restriction is used instead of a more limited commodity description such as "refrigerated commodities," in order to avoid interpretive problems.

The Commission has occasionally imposed the restriction on an applicant's authority based on the evidence in an adjudication. More often, the restriction resulted without any affirmative showing of necessity. In either event, its effect has been to shield carriers engaged in the transportation of dry freight from additional competition. As the Commission has stated, "the additional expense inherent in the operation of mechanically refrigerated vehicles should effectively prohibit the entry of applicants into the dry freight business." *Frozen Food Express, Ext.—Four States,* 103 M.C.C. 913 (1967).

Even so, as a practical matter, the vehicle restriction has not precluded many specialists from participating in the transportation of dry freight. Such participation stems from a variety of factors. For example, many shippers (e.g. those in the food industry), require the transportation of dry freight as well as commodities requring temperature-controlled service. Many tender truckloads of dry freight to carriers operating under the restriction because of these carriers general expertise regarding the handling and distribution of the involved commodities. Still others require dry freight service from these carriers because existing carriers cannot furnish sufficient units to handle their traffic volumes. In a number of adjudications, where the Commission has explicitly addressed the issue, it has removed the vehicle restriction from the certificates of carriers to enable them to provide shippers with a complete service. See, for example, *Clay Hyder Trucking Ext.—Removal of Restriction,* 89 M.C.C. 757 (1962). In so doing the Commission recognized that the enhanced efficiencies and economies of the applicants' operations overrode the interests of existing carriers in keeping applicants out of the dry freight market.

The time has come to examine the restriction closely. We believe that the vehicle restriction at issue may no longer serve the public interest. Restrictions are inherently undersirable and should not be imposed or retained except where it is shown conclusively that they are necessary in the public interest and consistent with practicable and effective transportation regulation. See *Fox-Smythe Transp. Co. Extension—Oklahoma,* 106 MC.C. 1, 9 (1967). Restrictions can prevent affected carriers from rendering shippers and their consignees a fully efficient and economical service. We have long recognized that the utilization of equipment to its fullest capacity is economically sound and that improved transportation methods must be recognized and encouraged. Cf. *Removal of Truckload Lot Restrictions,* 106 M.C.C. 455 (1968).

In the temperature-controlled service market, there is a particularly strong basis for questioning the retention of the restriction at issue. As noted by the Commission's task force (see footnote 1), "refrigerated carriers" are heavily dependent upon and transport substantial volumes of non-refrigerated commodities to achieve a balance in their operations. (For this reason alone, many specialists have acquired independent licenses to transport dry commodities as backhauls. Yet as noted by petitioner, even where dry freight is transported between service points in both directions, the restriction mandates that service must still be provided in special equipment). Accordingly, there appear to be compelling grounds for the wholesale removal of the vehicle restriction.

We must nonetheless consider whether the obvious benefits accruing to affected motor carriers and shippers outweigh the interests of existing carriers of dry freight. In essence, would the action contemplated result in destructive competition contrary to the public interest? We doubt it. Removal of the restriction, after all, would not result in any expansion of the actual commodities, or the service points authorized to be served, in the existing licenses of petitioner and similarly situated carriers. Plainly, however, it could have competitive implications, since carriers in the "protective service" field would be able to commit additional resources to the general carriage of dry freight, unencumbered by regulatory constraint. We view this as a salutary effect.

It is the Commission's policy to encourage competition in the transportation industry. The need to do so is widely recognized. In *Bowman Transportation* v. *Arkansas—Best Freight System,* 419 U.S. 281, 298 (1974), the Supreme Court stated that a policy in favor of competition embodied in the laws has application in a variety of economic affairs. Even where Congress has chosen Government regulation as the primary device for protecting the public interest, a policy of facilitating

[1] See also, *Initial Report of the Motor Carrier Task Force.* Interstate Commerce Commission (May, 1979), p. 59.

competitive market structure and performance is entitled to consideration. Other, more recent, Court decisions addressing the need to consider the effects of our actions on competition include *Sawyer Transport, Inc.* v. *Interstate Commerce Commission*, 565 F. 2d 474 (7th Cir. 1977), and *P. C. White Truck Line, Inc.* v. *Interstate Commerce Commission*, 551 F. 2d 1326 (D.C. Cir. 1977). Accordingly, respondents to this notice of proposed rules who disagree with this approach must demonstrate why we should not follow it here.

We are concerned with the effect which the proposed action could have on the current availability of refrigerated equipment to shippers of commodities requiring temperature controlled equipment. Insofar as refrigerated equipment is being used for the transportation of dry freight, it is counterproductive and inefficient. In fact, the Motor Carrier Task Force, (footnote 1, *supra*) in its initial report at p. 66, states that the use of refrigerated equipment for movements where it is unnecessary is one of the factors leading to present equipment shortages in areas where it is essential. We anticipate that removal of the equipment restrictions will make a larger pool of refrigerated equipment available for protective service—at least in the short run—because some dry commodities will shift to transporttion in non-refrigerated equipment. While carriers may not replace this equipment in the future as a result of this proposal, this could support petitioner's claim that unnecessarily sophisticated vehicles are being used. Respondents are urged to address this important issue.

Environmental and Energy Consequences

A preliminary review of the proposal by the Commission's Energy and Environment Branch suggests that the proposed regulation will not have a significant effect upon the quality of the human environment, nor does it constitute a major regulatory action under the Energy Policy and Conservation Act of 1975. The probable effect of the rule would be to enhance operating efficiencies, and to generate fuel savings over the course of time, although at the outset a possible excess of competition for dry freight could result in additional vehicle miles for certain commodities on certain routes. It is extremely difficult to quantify the potential long or short term energy effects at this time. Therefore, parties are urged to submit, where possible, statistical information regarding the extent to which dry freight is currently transported in vehicles equipped with temperature control devices. A more detailed energy analysis will be issued with the final decision.

Accordingly, we propose to revise Title 49 of the Code of Federal Regulations by the addition of a new § 1041.25 which would read substantially as follows:

§ 1041.25 "Vehicles equipped with mechanical refrigeration" restriction.

Restrictions embraced in individual motor carrier certificates and permits, which limit service to that provided "in vehicles equipped with mechanical refrigeration," shall be considered as of no further force and effect. These certificates and permits shall be considered as authorizing transportation services without regard to the restrictions.

This notice of proposed rulemaking is issued pursuant to 49 U.S.C. 10321, and 10922 and 5 U.S.C. 553 and 559.

Decided: March 24, 1980.

By the Commission, Chairman Gaskins, Vice Chairman Gresham, Commissioners Stafford, Clapp, Trantum, and Alexis. Commissioners Stafford and Clapp concurring with a separate expression.

Agatha L. Mergenovich,

Secretary.

Commissioner Stafford (Concurring)

I have no objection to putting out the proposed restriction elimination for public comment. I do, however, object to the statements in the notice which seem to indicate that a judgment on the issue has already been made.

Commissioner Clapp (Concurring)

While I am in favor of soliciting comments on the proposed removal of the equipment restriction, I am concerned about the language and tone of this Notice. A notice proposing a rule or policy change should encourage comments, not discourage them as I fear this Notice does. Because many rule changes have ramifications far beyond what six Commissioners may anticipate, public comments are extremely critical to our deliberative process.

The Notice includes several unnecessary statements and pronouncements with which I am not prepared to agree. First, I cannot agree that "restrictions are inherently undesirable." If that were true, there would be no need to proceed further. Second, I cannot conclude at this time that transportation of dry freight in refrigerated vehicles "is counterproductive and inefficient." This could be true or false depending on the circumstances. The relative quantities of dry vs. perishable commodities and the location of the service points would, I suspect, be significant factors. Third, I cannot say that there are "compelling" grounds for wholesale removal of the vehicle restriction or that removal of the restriction involves "obvious" benefits. I prefer to see the comments before making these judgments.

[FR Doc. 80-11344 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 611 and 671

Tanner Crab Off Alaska; Amendment to Fishery Management Plan and Proposed Regulations

AGENCY: National Oceanic and Atmospheric Administration (NOAA)/ Commerce.

ACTION: Amendment to fishery management plan and proposed regulations.

SUMMARY: Amendment No. 5 to the Fishery Management Plan for Tanner Crab off the Coast of Alaska (FMP) has been approved. The amendment is necessary because new information indicates that the quantity and distribution of Tanner crab stocks have changed. Participation in the fishery by U.S. vessels has increased dramatically in the last several years. The amendment will ensure protection of the Tanner crab stocks by establishing new harvest limits, and reducing the total allowable level of foreign fishing (TALFF). Regulations to implement this amendment are proposed for public comment.

DATE: Comments on the amendment and proposed regulations are invited until June 14, 1980.

ADDRESS: Please send comments to: Denton R. Moore, Permits and Regulation Division, National Marine Fisheries Service, 3300 Whitehaven Street, N.W., Washington, D.C. 20235. Please indicate "Tanner crab comments" on the envelope.

FOR FURTHER INFORMATION CONTACT: Harry L. Rietze, Regional Director, National Marine Fisheries Service, P.O. Box 1668, Juneau, Alaska 99802, Telephone: (907) 586–7221.

SUPPLEMENTARY INFORMATION:

A. Background

The FMP for Tanner crab off Alaska was prepared by the North Pacific Fishery Management Council (Council), approved by the Assistant Administrator for Fisheries on behalf of the Secretary of Commerce, and published in the **Federal Register** on May 16, 1978 (43 FR 21170) under authority of the Act (16 U.S.C. 1801 *et seq.*). Final regulations applicable to

vessels of the United States were published on December 6, 1978 (43 FR 57149). Final regulations applicable to vessels of foreign nations were published on December 19, 1978 (43 FR 59075; 43 FR 59292).

The FMP has been amended four times. The first amendment extended the implementing regulations through October 31, 1979 (44 FR 1115). The second amendment increased the optimum yield (OY) for the Kodiak district from 25 million pounds to 35 million pounds, and the third authorized vessels of foreign nations to take a portion of the TALFF in a specified area south of 58° N. latitude (44 FR 15503). Amendment No. 4 extended the FMP and implementing regulations, as amended, through October 31, 1980 (45 FR 785).

The Council considered new information on the Tanner crab fishery at its October 4–5, 1979 meeting. At that time, the Council reviewed the results of the 1979 National Marine Fisheries Service (NMFS) Tanner crab trawl survey in the Bering Sea, and received extensive testimony from U.S. and foreign interests participating in this fishery. On the basis of new information presented and analysis of fishery performance, the Council prepared Amendment No. 5, which has been reviewed and approved by the Assistant Administrator.

B. Substance of Amendment

Amendment No 5 and implementing proposed regulations would make changes in the management of the Bering Sea and Aleutian Islands area Tanner crab stocks as follows:

1. *Optimum Yields* (OY). (a) Reduce the OY for *C. bairdi* Tanner crab from the current level of 40,381 m.t. to a range of 10–15,000 m.t.; and

(b) Increase the OY for *C. opilio* Tanner crab from the current levels of 16,360–17,268 m.t. north of 58° N. latitude, and 10,000 m.t. south of 58° N. latitude to a total OY of 58,984 m.t.

2. *Domestic Annual Harvest* (DAH). (a) Increase the estimate of DAH for *C. opilio* from the current level of 12,268 m.t. to 51,484 m.t.; and

(b) Decrease the estimate of DAH for *C. bairdi* from the current level of 40,381 m.t. to a range of 10–15,000 m.t. which is the new OY.

3. *TALFF.* Reduce the TALFF for *C. opilio* from the current level of 15,000 m.t. to 7,500 m.t.

4. *Area Restrictions.* Restrict foreign fishing to the area north of 58° N. latitude and west of 164° west longitude.

5. Joint Venture Amendment. Implement provisions of the Joint Venture Amendment. For clarity, the amendment incorporates parts of the FMP which had previously been approved.

C. Discussion

The OY for *C. bairdi* has been reduced because a 1979 NMFS trawl survey and a review of 1979 fishery performance both indicate that the abundance of *C. bairdi* is declining, and will continue to decline over the next few years. Although this decline is attributed to natural stock fluctuations, the OY has been reduced to provide additional protection, and to assure continuing availability of crabs to the U.S. fishery.

It also appears that abundance of *C. opilio* stocks will be slightly lower in 1980. Nevertheless, it was possible to raise the OY for *C. opilio* because 1979 OY level has been set low for socio/economic reasons. Consequently, the Council is able to assure adequate protection of the resource while allowing an increase in harvest to accommodate the developing U.S. fishery.

One of the reasons the 1979 OY specification for *C. opilio* was set lower than necessary to protect the resource was the Council policy of encouraging growth in the U.S. *C. opilio* fishery. Partly as a result of this policy, the U.S. *C. opilio* fishery has grown rapidly in the past few years.

The estimate of DAH has been reassessed, based principally upon analysis of recent past performance, and testimony of U.S. harvesters and processors as to their capacity and intent to harvest and process the resource. The DAH is now increased from 12,268 m.t. to 51,484 m.t. of crab. The principal unknown in making this estimate is how the market will perform given a decrease in *C. bairdi* and an increase in *C. opilio;* and the extent to which any demand changes will affect amounts of crab harvested. The DAH estimate of 51,484 m.t. reflects the best judgment of the Council, taking these uncertainties into account, of the amount of *C. opilio* U.S. fishermen can reasonably be expected to harvest. A higher DAH and inseason adjustment of DAH and TALFF was considered impracticable because of the economics and logistics of the fishery.

The TALFF for *C. opilio* has been reduced to 7,500 m.t. which must be taken north of 58° N. latitude and west of 164° W. longitude. The purpose of this measure is to avoid gear conflicts and to minimize foreign incidental harvest of *C. bairdi. C. bairdi* stocks occur predominately south of 58° N. latitude, and are fully utilized by U.S. fishermen. Surveys indicate that *C. bairdi* stocks occur only in insignficant amounts north of this line. A directed fishery on *C. bairdi* in this area therefore would not be feasible, and retention of the few incidental *C. bairdi* caught is expected to have no impact on the resource. The regulations therefore authorize both foreign and U.S. vessels fishing for *C. opilio* north of 58° N. latitude to retain any incidental *C. bairdi* which may be taken.

In accordance with the requirements of P.L. 95–354, the Council has considered the possibility of "joint venture" participation in this fishery, and has concluded that no joint venture operations are likely during 1980. The amendment also authorizes, and the regulations provide for, an annual survey of processor capacity and intent to process Tanner crab.

The Assistant Administrator for Fisheries, NOAA, under delegation of authortiy from the Secretary of Commerce, has determined that the regulations as described above:

(1) Are necessary and appropriate to the conservation and management of Tanner crab resources off the coast of Alaska;

(2) Are consistent with the National Standards and other provisions of the Act and other applicable law;

(3) Does not constitute a major Federal action requiring the preparation of an environmental impact statement under the National Environmental Policy Act; and

(4) Are significant under the provisions of Executive Order 12044, "Improving Government Regulations." A Regulatory Analysis has been prepared and may be obtained from Harry L. Rietze, Director, Alaska Region, National Marine Fisheries Service, NOAA, P.O. Box 1668, Juneau, Alaska 99802.

(16 U.S.C. 1801 *et seq.*)

Signed at Washington, D.C. this 10th day of April 1980.

Winfred H. Meibohm,

Executive Director, National Marine Fisheries Service.

BILLING CODE 3510-22-M

A. The Fishery Management Plan for Tanner Crab off Alaska which was published on May 16, 1978 in the Federal Register (43 FR 21170) is amended as follows:

(All changes made in sequential order by Federal Register page and section numbers.)

Page 21176; Summary; Table A - insert new table

Page 21181; Section 2.2 (B) 2 delete and replace as follows:

"2. DAH (Domestic Annual Harvest) is the estimated portion of the U.S. Tanner crab harvest which will be utilized by domestic processors (DAP), and the estimated portion, if any, delivered to foreign processors which are permitted to receive U.S. harvested Tanner crab in the Fishery Conservation Zone. DAH = DAP + JVP

a. DAP (Domestic Annual Processing) is the estimated portion of DAH that is expected to be processed by U.S. processors.

TABLE A -- Alaska Tanner Crab Maximum Sustainable Yield (MSY), Acceptable Biological Catch (ABC), Optimum Yield (OY), Domestic Annual Harvest (DAH), Domestic Annual Processing (DAP), & Total Allowable Level of Foreign Fishing (TALFF) by Management Area for 1979/1980.

(lbs = millions) ( ) indicate point estimate

AREA	MSY lbs	MSY MT	ABC lbs	ABC MT	OY lbs	OY MT	DAH lbs	DAH MT	DAP lbs	DAP MT	TALFF lbs	TALFF MT
SOUTHEASTERN												
Southeast	2.5	1,134	1/		2/		3/		4/		5/	
Yakutat	3.0	1,361	1/		2/		3/		4/		5/	
PR. WM. SOUND	7.2	3,266	3-7	1,361-3,175	2/		3/		4/		5/	
COOK INLET	5.3	2,404	1/		2/		3/		4/		5/	
KODIAK	21.5	9,752	15-25	6,804-11,340	2/		3/		4/		5/	
S. PEN/ALEUTIAN												
S. Peninsula	20.0	9,072	20-30	9,072-13,608	2/		3/		4/		5/	
Aleutian	2.0	907	1/		2/		3/		4/		5/	
BERING SEA												
C. bairdi	22-33	9,980-14,970	1/		2/		3/		4/		5/	
C. opilio	103-153	46,720-69,400	103-153	46,720-69,400	130	58,984	113.47	51,484	4/		16.53	7,500*
	(126)	57,150	(126)	(57,150)	2/							

1/ ABC=MSY 2/ OY=ABC 3/ DAH equals or exceeds OY 4/ DAP=DAH 5/ N/A

* TALFF restricted to north of 58 degrees N. latitude

The Council will reassess and revise the DAP annually based on processor reports and any changes in factors which would alter the level of resource utilization. b. JVP (Joint Venture Processing) is the U.S. harvested portion of the OY in excess of the capacity and intent of U.S. processors to utilize or for which actual U.S. markets are not available that will be delivered to foreign processors which are authorized to receive such U.S. harvested Tanner crab in the Fishery Conservation Zone. The components of the DAH are dynamic and require annual assessment to insure that DAH remains realistic and based on the best available, current information. Accordingly, DAH values will be amended as required.	
Section 2.2. C	delete; insert as follows: C. TALFF (Total Allowable Level of Foreign Fishing) is determined by deducting DAH from OY (TALFF = OY - DAH).
Page 21183; Section 3.2.1	1st paragraph, delete 3rd sentence; insert new sentence as follows: "The 1977 harvest was 94 million pounds (42,800 mt), the 1978 harvest was 125 million pounds (56,770 mt) and the 1979 harvest was approximately 145 million pounds (65,090 mt).
Page 21185 Section 3.2.1.3	delete section; insert new section as follows: "From its beginning, the Alaska catch of Tanner crab has shown a steady, yearly increase from the 1961 harvest of 6,800 pounds (3.1 mt) to the 1974 harvest of 64 million pounds (29,000 mt). However, the 1975 catch decreased by 20 million pounds compared to 1974. A remarkable increase is shown since: 79 million pounds in 1976, 98 million pounds in 1977 and 125 million pounds in 1978. In 1979, the total catch was approximately 145 million pounds with a dramatic increase in C. opilio crabs, from 1.3 million to over 30 million pounds. C. bairdi catches were reduced because of lower resource abundance in the Bering Sea."

Page 21185; Section 3.2.2.2 & 3.2.2.3

1st paragraph, next to last sentence; delete and insert as follows:

"The Japanese quota for Tanner crab in 1977 was 12,500 mt; in 1978, 15,000 mt and 15,000 mt in 1979. The quota for 1980 was set at 7,500 mt. Due to the decline of the resource, and the increasing domestic fishery, the Council forecast no available surplus over DAH for assignment to TALFF beyond 1980."

Page 21187; Section 3.5.1.2

delete section; insert new section as follows:

"Tanner crab is processed into four primary forms: whole/dressed, section, meat and canned. As a by-product, fish meal is also produced. Table 2 shows the 1976 shellfish production and wholesale value. In 1976, the wholesale value of Tanner crab was about $37 million, of which $20.1 million was from whole/dressed, $9.3 million from meat, $5.8 million from canned, $1.5 million from section and $20,600 from meal. This was the peak production year to that time and the next highest year was 1973 ($33.7 million). Central Alaska was the dominant Tanner crab production area where, in terms of wholesale value, more than 70 percent of all Alaska Tanner crab production was realized.

Table 2 contains the 1976 shellfish production and wholesale values."

Page 21189; Section 3.5.1.3

delete section and replace as follows:

"In 1976, 32.6 million pounds of Tanner crab products were available for distribution from Alaska with a wholesale value of about $37 million. This comprised about 21 percent of the total wholesale value of shellfish in Alaska.

Tanner crab catches in 1976 and 1977 were 79 and 98 million pounds respectively. (Table 1.)

In 1976, the composition of total Tanner crab wholesale value in Alaska by product form shows that 54.6 percent is in whole/dressed (frozen) form, 25.3 percent in meat, 15.8 percent in canned, 4.2 percent in section form and 0.1 percent in meal."

Page 21191; Section 3.5.3.1

1st line, change "1975" to "1976".

3rd line, change figure to "$36,764,849".

Page 21193; Section 3.7

4th line, change year to "1970-1977";

3rd line, change year to "1977";

8th line, change figures to $486,160 and 1977.

Page 21198; Section 4.8

Estimate of Future Stock Conditions

delete all after "Bering Sea."

insert the following:

Eastern Bering Sea: Declining stock conditions associated with C. bairdi with lower catches forecast through 1981; C. opilio stock remains stable but pre-recruit abundance is down 29% from the 1978 survey.

Page 21199; Section 7.0

delete "FAC" from title; 2nd sentence from bottom, delete "for the 1978 fishing season.";

Add new paragraph after "...U.S. Fishery Conservation Zone." as follows.

"Some C. bairdi will be caught by the Japanese fishery North of 58° N. latitude in the Bering Sea. Historically, the proportions of that species in the crab catch of that area has ranged from 8-12%, the rest being C. opilio. Retention of C. bairdi by the Japanese fishery is permitted, since the amount taken is expected to be minimal. The impact on the resource of the removal of that number of mature males (immature males are not of marketable size), is not expected to have any deleterious effect on the scattered stocks of C. bairdi in this area which is the northern periphery of its range, C. bairdi is so sparsely distributed in this area that no directed fishery for them by the U.S. fishermen will be feasible."

Page 21200; Section 8.3.2

6th line, place period (.) after "latitude" and delete rest of sentence.

Page 21201; Section 8.7

5th line; delete all after "to"; insert: "Section 204 of the Fishery Conservation and Management Act of 1976."

Page 21210; Section A.7.0

delete title and replace as follows: "Total Allowable Level of Foreign Fishing (TALFF)"

Page 21215; Section B. 6. 1

Delete "The estimated ABC of 3-7 million pounds (1,360-3,175 mt) includes the estimated MSY." Add "The estimated ABC of 3-7 million pounds (1,360-3,175 mt) approaches the estimated MSY."

Page 21215; Section B.7.0

delete "FAC"; insert "TALFF" delete text, replace with: "No surplus stocks are available to foreign nations from this management area."

Page 21227; Section C.7.0

delete "FAC" and insert "TALFF" delete text, replace with: "No surplus stocks are available to foreign nations from this management area."

Page 21229; Section D.3.2

add to last paragraph as follows:

"The 1978 season (January-April) in the Kodiak area had a guideline harvest level of 15-25 million pounds (6,804-11,340 mt) and a harvest of 33.1 million pounds."

Page 21232; Section D.7.0

delete "FAC" and insert "TALFF" delete text, replace with: "No surplus stocks are available to foreign nations from this management area."

Page 21238; Section E.7.0

delete "FAC" and insert "TALFF" delete text, replace with: "No surplus stocks are available to foreign nations from this management area."

Page 21238; Section F.3.0

delete section; replace with new material as follows:

F.3.0 DESCRIPTION OF FISHERY

F.3.1 Species and location

The Bering Sea management area is defined as all Bering Sea waters north of 54°36' N. latitude.

The target species are C. bairdi and C. opilio. (C. bairdi is the larger of the two.) All but a fraction (estimated 2%) of the C. bairdi resource is located south of 58° N. latitude.

F.3.2 History of Exploitation

F.3.2.1 Domestic Fishery

United States fishermen entered the Bering Sea in 1947 to harvest red king crab (Paralithodes camtshatica). The first reported catches of Tanner crab were made in 1968 and were incidental to the king crab harvest. In 1974, a directed Tanner crab fishery was started with the target species being C. bairdi. The fishery has grown dramatically since that time. In three years (to 1977), over 34.5 million pounds (15,028 mt) were landed; the catch in 1978 totaled 70 million pounds (31,818 mt) and the 1979 catch was nearly 74 million pounds (33,636 mt).

The ocean areas fished by U.S. fishermen are predominantly International North Pacific Fisheries Commission (INPFC) areas [1/] 5564 and 5569, located north and northwest of Unimak

1/ 1 degree latitude/longitude rectangles.

Island and INPFC areas 5669 and 5670 near St. George Island in the Pribilof Islands.

F.3.2.1.1 Description of User Groups

Seattle-based fishermen, non-resident to the State of Alaska, are the primary exploiters of the Tanner crab resource in the Bering Sea. A growing number of Alaskan residents who own salmon or shrimp vessel fish the Bering Sea after first fishing their local area during competing fisheries.

F.3.2.1.2 General Description of Fishing Effort

Fishing effort in the Bering Sea continues to increase annually in numbers of vessels and vessel size. A large-scale effort is presently being conducted to harvest and process the allowable biological catch. Projections for 1980 are that the estimated fishing effort/processing capacity is capable of utilizing the entire optimum yield. The increase in the number of vessels participating in the Tanner crab fishery from the 1978 to the 1979 fishery was more than 40%, resulting in a fleet size of approximately 220 crabbers.

F.3.2.1.3 Catch Trends

U.S. fishermen caught 18,000 pounds (8.2 mt) of Tanner crab in 1968. In 1976, the catch was 22.3 million pounds (10,115 mt), in 1977 the catch was 51.5 million pounds (23,400 mt), 70 million pounds in 1978 (31,818 mt), and approximately 74 million pounds (33,636 mt) in 1979. The combined harvesting/processing projection for 1980 is based partly on the increase in catch and effort during 1979.

An additional perspective in the catch trend for the Bering Sea Tanner crab is shown in the comparisons of the 1978 C. opilio catch of 1.8 million pounds and the 1979 catch of over 34.1 million pounds. (See Table 1.)

F.3.2.1.4 Description of Vessels and Gear

Boats fishing Tanner crab are generally steel constructed "crabber" vessels that average 140 net tons and 93.4 feet in keel length. New vessel construction tends to the "combination boat", primarily a crab fishing vessel which can be converted to trawling for the emerging trawl fishery in the Gulf of Alaska and Bering Sea areas.

Gear fished from these boats are rebar stock crab pots, approximately seven feet square by three feet deep.

Page 21238; Section F 3.2.2.2 & 3.2.2.3 Delete all after second paragraph and table, and add:

Harvests by the Japanese in 1977 were restricted to a quota of 27,550,000 pounds (12,500 mt). Under the conditions of the preliminary fishery management plan for the eastern Bering Sea crab, the Japanese were permitted to harvest their quota in the area

west of 164° W. longitude and north of 56° N. latitude.

In 1978, the Japanese quota was 33 million pounds (15,000 mt) and in 1979 the quota remained the same with the provision that 2,500 mt of C. opilio from the Japanese quota of Tanner crab could be harvested south of 58° N. latitude and west of 173° W. longitude. That provision was also in effect for the remainder of the 1978 fishing season after July 3, 1978. The purpose of the measure was to allow the Japanese fishery to harvest the assigned TALFF without interference from ice conditions which might interfere with the harvest of the allowable catch.

In 1980, the TALFF was set at 7,500 mt, and foreign fishing was restricted to north of 58° N. latitude and west of 164° W. longitude. Most of the catch is expected to be C. opilio (88-92%) with incidentally caught C. bairdi allowed to be retained."

Page 21241; Section F.3.2.2.4. Delete "...and delivered daily to the factoryship." and add "...and delivered once or twice a day to the factoryship."; Delete last sentence in section.

Page 21241; Section F.3.3.1. Delete "...Alaska Department of Fish and Game manages the domestic" and add "...Alaska Department of Fish and Game has managed the domestic..."

Page 21241; Section F.3.3.2.1 Delete last line

Page 21241; Section Table 3 Delete

Page 21243; Section F.3.3.3 2nd paragraph, 17th line, change "are" to "were".

Page 21246; Section F.3.3.3.1. Last paragraph, delete "A pair of U.S. observers monitored catches of both Japanese...entire 1977 fishery." and add "....A pair of U.S. observers monitored catches of each of the Japanese...entire 1977, 1978 and 1979 fisheries."

Page 21246; Section F.3.5.1.1. After "...in 1976 was $4.4 million." add "In 1979, it was $32.7 million."

Page 21246; Section F.3.5.2. Before "Data for the Bering Sea..." add "Complete up-to-date ..."

Page 21246; Section F.3.5.2. After "...statewide section." add "U. S. catching capacity has been increasing rapidly for the last 3 years. In 1979, 240 boats engaged in the King crab fishery in this area, an increase of 20 from 1978. Most of the boats in the fishery are new combination trawler/crabbers with size increasing annually. Most new additions to the fleet are in the 110' to 160' range with increased fishing power from the older portion of the fleet which averages approximately 95' in length. The greatest proportional increase has been in the catcher/ processor category, from 3 in 1978, to 13 in 1979. Generally larger ships, 120'to 160' the catcher/processor remain on the grounds during the season, usually processing all of their catch by cooking and freezing in sections. It is expected that all of the ships in the King crab fishery, will engage in the Tanner crab fishery in 1980 with the exception of a few who will turn to bottomfish, plus some new construction entering the fleet since the King crab season. The influx of catcher/processors into this fishery adds a new dimension to management of this resource. Dockside inspection of catches to insure compliance with size and sea regulations will not be possible since the catch is butchered and processed at sea. Sex and size cannot be determined from the finished product."

Page 21246; Section F.3.5.3 delete last sentence.

Page 21246; Section F.4.2 delete 2nd sentence; insert: "Trawl surveys by NMFS indicate C. opilio is the most numerous of the two species." ; After "... C. bairdi being the..." add "...preferred...".

Page 21249; Section F.4.7 line 9, change "are" to "were". Change last sentence in first paragraph to read: "Trawl surveys for 1979 indicate C. bairdi pre-recruits down 38% from 1978 and C. opilio pre-recruits down 29%, with much reduced levels of harvestable males forecast by 1980 and continuing for several years thereafter."

Page 21249; Section F.4.7.1	2nd paragraph, delete all after 1st sentence: replace with the following: "However, the distribution of abundance is different between species. Almost all the stock of C. bairdi occurs south of 58° N. latitude. Large C. opilio extend somewhat farther north, with about 6 percent of the total stock surveyed during 1979 located north of 58° N. latitude. (Based on 1979 NMFS survey.)" delete 4th paragraph and replace as follows: "The estimated abundance of legal size (greater than 140 mm) male crab is 67 million pounds, (33,900 mt) with a range of 55-82 million pounds (24,950-37,200 mt). Applying an average annual exploitation rate of .4 to the abundance of legal size C. bairdi males gives an MSY of 27 million pounds (12,250 mt), with a range of 22-33 million pounds (9,980-14,970 mt). 5th paragraph, delete and replace as follows: The estimated MSY for C. opilio is calculated from the estimated abundance of males greater than 104 mm which is 218 million pounds (98,890 mt) with a range of 178-263 million pounds (80,740-119,300 mt). 6th paragraph, delete and replace as follows: "The calculated exploitation rate applied is 0.58 (Sumerton and Low, 1977) and results in an ABC of 126 million pounds (57,150 mt) for C. opilio, with a range of 103-153 million pounds (46,720-69,400 mt). Detailed calculations are given in Reeves, 1979. Six percent of this estimate is available from the area north of 58° N. latitude, where large C. bairdi occur only rarely.
Page 21247; Figure F3	Delete.
Page 21249; Table F5	Delete existing table; Insert new Table F5.
Page 21249; Section F.4.7.1	insert period; delete "(Figure F3)."
Page 21249; Section F.4.7.3	3rd line, change figures to 22-33 million pounds (9,980 - 14,970) mt, "126,000,000", "57,150".

TABLE F5 -- Estimates of maximum sustainable yield of male Tanner Crab in the Eastern Bering Sea.

Species	Size Group	Millions of crabs	Average Weight-Pounds	Millions of Pounds	Exploitation Rate	Millions of Pounds
C. bairdi	≥135*	28	2.40	(55-82) 67	0.40	(22-33) 27
C. opilio	>104	156	1.40	(178-263) 218	0.58	(103-153) 126

* The biological data are based on inside the spine measurements. The legal definition includes the spines in carapace measurements. Therefore, the legal interpretation of the size limit will allow the harvest of crab which are according to the biological measurement up to 5 mm smaller; as a result, when calculating an MSY based on 140 mm minimum size, all crab ≥ must be considered.

Page 21249; Section F.4.8

delete section, replace as follows:

"The 1979 NMFS survey indicates a continual decline in the stock of C. bairdi, with declining catches expected through 1981. The stock of C. opilio appears relatively stable. However, the abundance of pre-recruits was lower in the 1979 NMFS surveys and suggests lower catches in the future.

Page 21249; Section F.5.3

Delete section and replace as follows:

"The DAH for C. bairdi in the eastern Bering Sea is expected to equal the OY of 22-33 million pounds(9,980-14,970 mt.)

The DAH for C. opilio in the eastern Bering Sea is expected to be near the estimate of 113.4 million pounds (51,484 mt).

Page 21249; SectionF.6.1. Delete "...,and C. opilio in the Bering Sea." and add "...C. opilio in the Bering Sea is 103-153 million pounds expressed as a point estimate of 126 million pounds (57,150 mt). ABC is expressed as a point figure rather than a range to simplify the derivation of TALFF. While expression of ABC and OY as a range is probably sounder biologically considering the paucity of accurate information about this species, a point figure on the safe, or conservative side of a range will not adversely affect the stocks or impair the proposed fisheries. It greatly simplifies the derivation of TALFF in a fishery where some excess of OY is expected over DAH and is used in all FMP's where that condition exists."

Page 21250; Section F.6.2.d 2nd paragraph, 6-7th line, delete "during the 1977/78 season." 9th line, change figures to "51,484" and "113,470,000"; delete rest of sentence.

Page 21249; Section F.6.2.c. Change "... C. opilio population exceeds domestic industry size requirements, the U.S. fishery for Tanner crab is therefore primarily for C. bairdi." to "... C. opilio populations exceeds previous domestic industry size preferences, the U. S. fishery for Tanner crab has been primarily for C. bairdi."

Page 21249; Section F.6.2.c. After "...primarily for C. bairdi." add new paragraph

" Declining stocks of C. bairdi, expanding market opportunities for Tanner crab, and improved processing techniques for the smaller C. opilio are overcoming the U.S. processors reluctance to buy C. opilio. It is expected they will make up an increasingly larger proportion of the U.S. catch in the future. As noted earlier, the U.S. C. opilio catch increased from 1.8 million pounds in 1978 to 34 million pounds in 1979. On at least some markets, the two species of Tanner crab are interchangeable, larger C. opilio sections are indistinguishable from C. bairdi sections and the meat from both species in all size ranges is the same in all known tests.

Processor resistance to C. opilio in the part has been largely from the added costs of processing more crab for the same amount of product and some processing problems with small crab because of the configuration of existing processing machinery and procedures. That resistance is being overcome by price differentials to the fishermen between the two species and new processing equipment or adjustments to existing equipment and procedures."

Page 21250; Section F.6.2.f

delete 2nd paragraph, insert as follows:

Optimum yields for Tanner crab are prescribed as follows:
C. bairdi 22-33 million pounds - (10-15,000 mt)
C. opilio 130 million pounds - (58,984 mt).

Page 21250; Section F.7.0

1st paragraph, 3rd sentence, delete and replace as follows: "For this reason and in order to prevent gear conflicts and a foreign by-catch of C. bairdi crab, the foreign harvest of Tanner crab is restricted to the area north of 58° N. latitude.

Page 21250; Section F.7.0

2nd paragraph, 1st line, delete "approximately half", insert: "six percent", 5th line, delete "(Fig. F3)"
2nd paragraph, 6th line, delete "relatively".
2nd paragraph, 8th line, insert period (.) after "fishery" and delete remainder of sentence.
3rd paragraph, delete first sentence and insert as follows:

The record used to establish DAH for C. opilio at 113,470,000 pounds contains information on the capacity and intent of the U.S. fleet, its phenomenal 40% growth in new boats for 1980 and the availability of foreign and domestic markets. Insofar as a DAH of this magnitude would impact the Tanner crab markets and reduce the amount available for any foreign allocation, the resultant reduction in TALFF was also considered. TALFF was set equal to OY (130,000,000 pounds) - DAH (113,470,000 pounds) or 16,530,000 pounds (7,500 mt); a 50% reduction over 1979.

Page 21250; Section F.7.0. After the third paragraph, add "1979 NMFS surveys showed approximately 6% of the male C. opilio are greater than 104 mm, north of 58° N. latitude. Using an OY of 130,000,000 pounds (59,037 mt), this is only 7.800,000 pounds (3,542 mt), well under the 16,530,000 pounds (7,500 mt) established as TALFF. There is reason to believe the survey did not, for undetermined reasons, sample that northern area adequately. The Japanese fishery took over 12,000 metric tons in that area in 1979, with no appreciable drop in CPUE by the end of the season. The Japanese fishery also takes C. opilio to a size of 100 mm carapace width, one age class lower than used in preceding computations of ABC/OY. Considering these facts, it is probable that the 1980 fishery will be able to take the full 7,500 metric tons allocated without any harm to the resource. Even C. opilio of 100 mm carapace width have been breeding for two or more years. Heavy cropping of that and older age classes is not likely to affect the spawning success of the crab populations."

Page 21250; Section F.8.3.2 delete section and insert new material as follows:

See Statewide Section 8.3.2. Management measures governing foreign fishing are as follows:

(1) The total allowable foreign catch shall not exceed 7,500 mt of snow (Tanner crab) from that portion of the Bering Sea over which the United States exercises fishing jurisdiction. Foreign fishing is allowed only north of 58° N. latitude and west of 164 degrees W. longitude.

Page 21251; Section 10.0

Insert following Reeves:

Reeves, J.E., 1979. Report to the NPFMC, Oct. 5, 1979.

BILLING CODE 3510-22-C

PART 611—FOREIGN FISHING

A. *It is proposed to amend 50 CFR Part 611 as follows:*

§ 611.20 [Amended]

1. Appendix 1 to § 611.20 is amended to read:

	Species	Species code	Area	Optimun yield (OY) in mountain time	Domestic harvest (DAH) mountain time	Joint Venture (JVP) [1] mountain time	Reserve	TALFF
*	*	*	*	*	*	*	*	
Alaska Fisheries:								
*	*	*	*	*	*	*	*	
Tanner Crab Fishery:	*C. opilio* and hybrid	610 and 684	I, II, III and IV	58,984	51,484	0	N/A	7,500
	C. bairdi	501	I, II, III and IV	15,000	15,000	0	N/A	0
*	*	*	*	*	*	*	*	
*	*	*	*	*	*	*	*	

[1] TALFF of *C. opilio* Tanner crab may be taken only north of 58° N. latitude and west of 164° W. longitude. Any *C. bairdi* Tanner crab taken incidentally to the permitted harvest of *C. opilio* Tanner crab may be retained."

§ 611.91 [Amended]

2. Section 611.91 is amended as follows:

(a) Amend § 611.91(b)(2) to read:

(b) * * *

"(2) *TALFF.* The total allowable level of foreign fishing (TALFF) for Tanner crab is set forth in Appendix 1 to § 611.20."

* * * * *

(b) Amend § 611.91(d) to read:

* * * * *

(d) *Closed Areas.* No foreign vessel may engage in fishing for Tanner crab:

(1) Within twelve nautical miles of the baseline used to measure the U.S. territorial sea;

(2) South of 58° N. latitude; or

(3) East of 164° W. longitude.

* * * * *

(c) Amend § 611.91(f)(1) by deleting all of subparagraph (ii) and changing the numbering of subparagraph (iii) to (ii).

PART 671—TANNER CRAB OFF ALASKA

B. *It is proposed to amend 50 CFR Part 671 as follows:*

§ 671.4 [Amended]

1. Amend § 671.4(b) by striking "72 hours" in the two places where it appears, and substituting "one week".

2. Section 671.4 is amended by adding a new subsection (e) to read as follows:

* * * * *

(e) Any U.S. processor who receives Tanner crab by way of purchase, barter, trade, or sale from a U.S. fishing vessel or prior purchaser subject to this Part shall provide, when requested to do so by the Regional Director, but in no event more than twice a year, the following information by Tanner crab species:

(1) Actual plant capacity to process Tanner crab in the next fishing year, in terms of weight, and

(2) The estimated actual amount by weight of Tanner crabs to be processed in the coming fishing year.

§ 671.5 [Amended]

3. Section 671.5 is amended by adding the following at the end of § 671.5(a):

(a) * * * prohibited by this part; "except that *C. bairdi* Tanner crab taken incidentally to permitted fishing for *C. opilio* Tanner crab in the area north of 58° N. latitude and west of 164° W. longitude may be retained."

§ 671.21 [Amended]

4. Section 671.21 is amended as follows:

(a) Amend Table 1 in § 671.21(a) to read:

Registration area	Optimum yield (in metric tons) [1]	Species
* * * * *		
Registration Area J:		
Kodiak district	15,865	All.
* * * * *		
Bering Sea district	10,000–15,000	*C. bairdi.*
	58,984	*C. opilio.*
* * * * *		

(b) Amend § 671.21(b) to read:

* * * * *

(b) * * * in each respective area, "except that *C. bairdi* Tanner crab taken incidentally to permitted fishing for *C. opilio* Tanner crab in the area north of 58° N. latitude and west of 164° W. longitude may also be retained."

* * * * *

(c) Amend § 671.21(c) to read:

* * * * *

(c) *Field Orders.* Except as provided in § 671.21(b), if the Regional Director determines that the optimum yield for a particular species of Tanner crab in any geographic area specified in Table 1 will be reached, he shall issue a field order pursuant to § 671.27(a) prohibiting fishing for that particular species of Tanner crab in that geographic area. Fishing for prohibited species of Tanner crab by vessels of the United States in the applicable geographic area is prohibited from the effective date of the field order.

* * * * *

§ 671.26 [Amended]

5. Section 671.26(b)(3) is amended to read:

(b) * * *

(3) During any period when fishing for all species of Tanner crab is prohibited in any Federal registration area, all Tanner crab pots shall either be removed from the water or stored in less than 25 fathoms (46m) of water, with all doors secured fully open and all bait and bait containers removed, with the following exceptions;* * *"

6. Section 671.26(f)(3)(iv) is amended to read:

(f) * * *

(3) * * *

(iv) * * * except that Tanner crab other than *C. bairdi*, and *C. bairdi* taken incidentally in the area north of 58° N. latitude and west of 164° W. longitude, may be * * *"

7. Section 671.26(f)(4) is amended to read:

(f) * * *

(4) *Storage of gear.* During any period when fishing for all species of Tanner crab is prohibited in the applicable area, Tanner crab pots. * * *"

[FR Doc. 80-11397 Filed 4-14-80; 8:45 am]
BILLING CODE 3510-22-M

Notices

Federal Register
Vol. 45, No. 74
Tuesday, April 15, 1980

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Child Care Food Program; National Average Payment Factor for Reduced Price Lunches and Suppers, and Administrative Payment Factors and Food Service Payment Factors in Alaska for the Period May 1–June 30, 1980

AGENCY: Food and Nutrition Service, USDA.

ACTION: Notice.

Pursuant to Section 11 of the national School Lunch Act, as amended by Pub. L. 95–627, and § 226.4 of the regulations governing the Child Care Food Program (7 CFR Part 226) published on January 22, 1980, notice is hereby given of an adjustment in the national average payment factor for reduced price lunches and suppers served to children attending participating institutions in the Child Care Food Program. Section 4 of Pub. L. 95–627 amends Section 11(a) of the National School Lunch Act by changing the differential between the earning factor for free lunches and that for reduced price lunches from 10 to 20 cents. This provision applies to the Child Care Food Program because the rates of reimbursement under the Program are based on the National School Lunch Program rates. Furthermore, Congress intended that this provision would go into effect for the Program with implementation of the tiering system. Hence, the reduction in the reduced price levels does not go into effect until May 1, 1980. The national average payment factors for free and paid lunches and suppers served under the Program remain the same as those issued in the Child Care Food Program's reimbursement rate notice for the period January 1–June 30, 1980. (That rate notice was published in the **Federal Register** on January 11, 1980, 45 FR 2355.) Accordingly, the national average payment factor for reduced price lunches and suppers during the two-month period May 1–June 30, 1980, in all States except Alaska, shall be as follows.

For each lunch or supper served in the Program to children from families whose incomes meet the eligibility criteria for reduced-price school meals the national average payment factor will be 59.50 cents, making a total of 77.25 cents when added to the paid rate.

Pursuant to Section 12 of the National School Lunch Act, as amended by Section 10(a) of Pub. L. 95–627, and § 226.4, § 226.13, and § 226.14 of the aforementioned Child Care Food Program regulations, the Department has made adjustments for Alaska to the national average payment factor for reduced price lunches and suppers served to children attending participating institutions, the administrative payment factors for participating sonsoring organizations of day care homes, and the food service payment factors for meals served to children in participating day care homes. These adjustments were not included in the regulations published in the **Federal Register** of January 22, 1980.

In Alaska, these payment factors during the two month period May 1–June 30, 1980, shall be as follows:

For each lunch or supper served in the Program, in Alaska, to children from families whose incomes meet the eligibility criteria for reduced price school meals the national average payment factor will be 108.75 cents, making a total of 137.25 cents when added to the paid rate.

For sponsoring organizations of day care homes in the Program, in Alaska, the monthly administrative payment factors will be: (a) 73 dollars for each of the initial 25 day care homes; (b) 57 dollars for each of the next 50 day care homes; and (c) 49 dollars for each additional day care home.

For meals served in the Program, in Alaska, in day care homes the food service payment factors will be: (a) 75 cents for each breakfast served; (b) 146 cents for each lunch or supper served; and (c) 44 cents for each supplement served.

Definitions. The terms used in this notice shall have the meanings ascribed to them in the regulations governing the Child Care Food Program (7 CFR Part 226) published on January 22, 1980 at 45 FR 4960.

(Catalog of Federal Domestic Assistance Program No. 10.558)

(Section 2, Pub. L. 95–627, 92 Stat. 3603, 42 U.S.C. 1766; Section 4, Pub. L. 95–627, 92 Stat. 3619, 42 U.S.C. 1759a; Section 10, Pub. L. 95–627, 92 Stat. 3623, 42 U.S.C. 1760)

EFFECTIVE DATE: This notice shall be effective as of May 1, 1980.

Dated: April 11, 1980.

Carol Tucker Foreman,

Assistant Secretary for Food and Consumer Services.

[FR Doc. 80-11421 Filed 4-14-80; 8:45 am]

BILLING CODE 3410-30-M

Forest Service

1980 Spring Vegetation Management Program; Siuslaw National Forest, Benton, Douglas, Lane, Lincoln Tillamook, and Yamhill Counties, Oreg.; Finding of No Significant Impact

An environmental assessment has been prepared that discusses the Spring 1980 vegetation management program for site preparation, conifer release, control of noxious weeds, and tree nursery management, on the Alsea, Hebo, Mapleton, Waldport Ranger Districts and the Beaver Creek Nursery of the Siuslaw National Forest. The environmental assessment involves the control of competing vegetation on 4,692 acres. All proposed treatment areas are located on National Forest lands within Benton, Douglas, Lane, Lincoln, Tillamook and Yamhill Counties, Oregon. The assessment is available for public review at the Alsea Ranger District in Alsea, Oregon, Hebo Ranger District in Hebo, Oregon, Mapleton Ranger District in Mapleton, Oregon, Waldport Ranger District in Waldport, Oregon, and the Siuslaw National Forest Office in Corvallis, Oregon.

Under the preferred alternative, 2,640 acres are proposed to be treated for conifer release, 1,997 acres for site preparation, 47 acres for control of noxious weeds and 8 acres for management of Beaver Creek Nursery. Forty-two percent of proposed acreage will be treated by aerial application method, 35 percent by chemcial ground application, and 23 percent by manual methods.

The aerial application portion of this program is only those unfinished units

assessed in the Final Environmental Statement, Vegetation Management with Herbicides–USDA–FS–R6–FES (Adm) 75–13 (Revised).

I have determined through the environmental analysis that this is not a major Federal action that would significantly affect the quality of the human environment; therefore, an environmental impact statement is not needed. This determination was made considering the following factors, which are discussed in detail in the environmental assessment: (a) that the physical and biological effects of the proposed treatment are limited to the project area, (b) management requirements and constraints and mitigation measures ensures against the potential of significant adverse effects, (c) No irretrievable loss of timber production, (d) there are no apparent adverse cumulative or secondary effects, (e) no known threatened or endangered plants or animals within affected areas. This alternative has been determined to be environmentally preferable to the other alternatives considered in the assessment because it will provide a balance of environmental protection as well as goods and services for the public.

Some public concern has been expressed over the use of any chemical and the effects it has on water quality. The required mitigation measures and constraints on the implementation of the preferred alternative is designed to protect the water quality. State and Federal water quality standards will be met.

No action will be taken prior to 30 days from the date this finding is published in the **Federal Register.**

The responsible official is Larry A. Fellows, Forest Supervisor, Siuslaw National Forest, P.O. Box 1148, Corvallis, Oregon 97330.

Dated: April 3, 1980.

Jerald N. Hutchins,

Acting Forest Supervisor.

[FR Doc. 80-11334 Filed 4-14-80; 8:45 am]

BILLING CODE 3410-11-M

Rural Electrification Administration

South Mississippi Electric Power Association, Hattiesburg, Miss.; Proposed Loan Guarantee

Under the authority of Public Law 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 providing a guarantee supported by the full faith and credit of the United States of America for a loan in the approximate amount of $325,000,000 to South Mississippi Electric Power Association, of Hattiesburg, Mississippi. These loan funds will be used to finance the acquisition of approximately a 10 percent ownership interest in the Grand Gulf Nuclear Station with two generating units each having a nameplate rating of 1,250,000 kilowatts.

Legally organized lending agencies capable of making, holding and servicing the loan proposed to be guaranteed may obtain information on the proposed project, including the engineering and economic feasibility studies and the proposed schedule for the advances to the borrower of the guaranteed loan funds from Mr. George B. Taylor, Manager, South Mississippi Electric Power Association, P.O. Box 1589, Hattiesburg, Mississippi 39401.

In order to be considered, proposals must be submitted on or before May 15, 1980, to Mr. Taylor. The right is reserved to give such consideration and make such evaluation or other disposition of all proposals received, as South Mississippi Electric Power Association 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 7th day of April 1980.

Robert W. Feragen,

Administrator, Rural Electrification Administration.

[FR Doc. 80-11222 Filed 4-14-80; 8:45 am]

BILLING CODE 3410-15-M

ARMS CONTROL AND DISARMAMENT AGENCY

General Advisory Committee; Meeting

Notice is hereby given in accordance with Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. Appendix I (the Act) and paragraph 8.b. of Office of Management and Budget Circular No. A–63 (Revised March 27, 1974) (the OMB Circular), that a meeting of the General Advisory Committee (GAC) is scheduled to be held on May 8, 1980 from 10 a.m. to 6 p.m. and on May 9, 1980 from 8:30 a.m. to 2 p.m. at 2201 C Street NW., Washington, D.C., in Room 7219.

The purpose of the meeting is for the GAC to receive briefings and hold discussions concerning arms control and related issues which will involve national security matters classified in accordance with Executive Order 12065 dated June 28, 1978.

The meeting will be closed to the public in accordance with the determination of April 3, 1980 made by the Director of the U.S. Arms Control and Disarmament Agency pursuant to Section 10(d) of the Act and paragraph 8.d.(2) of the OMB Circular that the meeting will be concerned with matters of the type described in 5 U.S.C. 552 (b)(1). This determination was made pursuant to a delegation of authority from the Office of Management and Budget dated June 25, 1973, issued under the authority of Executive Order 11686 dated October 7, 1972 and continued by Executive Order 11769 dated February 21, 1974.

Dated: April 10, 1980.

Charles R. Oleszycki,

Advisory Committee Management Officer.

[FR Doc. 80-11360 Filed 4-14-80; 8:45 am]

BILLING CODE 6820-32-M

CIVIL AERONAUTICS BOARD

[Docket 37278]

American Airlines, Inc.; New York-San Juan Cargo Service; Enforcement Proceeding; Postponement of Hearing

By Notice dated March 18, 1980 (45 FR 18412, dated March 21, 1980), this proceeding was set to be heard April 23, 1980. At the request of the parties as stated at the prehearing conference heard April 8, 1980, the hearing is postponed pending further notice.

Dated at Washington, D.C., April 10, 1980.

Marvin H. Morse,

Administrative Law Judge.

[FR Doc. 80-11366 Filed 4-14-80; 8:45 am]

BILLING CODE 6320-01-M

[Docket 36595]

Competitive Marketing of Air Transportation; Supplemental Prehearing Conference

Notice is hereby given that a supplemental prehearing conference in the above-entitled matter is assigned to be held on April 29, 1980, at 10:00 a.m. (local time), in Room 1003, Hearing Room D, Universal Building North, 1875 Connecticut Avenue, N.W., Washington, D.C., before Administrative Law Judge William H. Dapper.

Dated at Washington, D.C., April 9, 1980.

William H. Dapper,

Administrative Law Judge.

[FR Doc. 80-11365 Filed 4-14-80; 8:45 am]

BILLING CODE 6320-01-M

[Dockets Nos. 33363, 36234]

Former Large Irregular Air Service Investigation; Application of Silvas Air Lines, Inc.; Reassignment of Proceeding

This proceeding, insofar as it involves the application of Silvas Air Lines, Inc., Docket 36234, has been reassigned to Administrative Law Judge Elias C. Rodriguez. Future communications should be addressed to Judge Rodriguez.

Dated at Washington, D.C., April 7, 1980.

Joseph J. Saunders,

Chief Administrative Law Judge.

[FR Doc. 80-11364 Filed 4-14-80; 8:45 am]

BILLING CODE 6320-01-M

DEPARTMENT OF COMMERCE

International Trade Administration

Exhibitors' Briefing for the U.S. National Exhibition—Beijing; Notice of Briefing

The Office of East-West Trade Development, International Trade Administration, U.S. Department of Commerce will hold an Exhibitors' Briefing on May 12, 1980 at 10:00 AM, in the Department of Commerce Main Auditorium. The purpose of this briefing is to inform the Exhibitors participating in the "U.S. National Exhibition—Beijing" (to be sponsored by the Department of Commerce in Beijing, China, on November 17–28) about subjects specifically relating to the Exhibition. The subjects to be covered at the briefing will be as follows:

Political Overview of the People's Republic of China (PRC);
Economic Overview of the PRC;
Market Promotion;
Exhibition Administration;
Design and Construction;
Freight Forwarding; and
Travel Arrangements and Accommodations.

All paid Exhibitors to the Exhibition have been invited. There will be a limited number of seats available to the public on a reservation basis. To reserve a seat, telephone Ursula Williams, (202) 377–2614, or write Ms. Williams at the Department of Commerce, Room 4815, 14th and Constitution Avenue, Washington, D.C. 20230.

Dated: April 10, 1980.

Steve Sind,

Office of East-West Trade Development, International Trade Administration, U.S. Department of Commerce.

[FR Doc. 80-11381 Filed 4-14-80; 8:45 am]

BILLING CODE 3510-25-M

Presbyterian-University Hospital, et al.; Applications for Duty-Free Entry of Scientific Articles

The following are notices of the receipt of applications for duty-free entry of scientific articles pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purposes for which the article is intended to be used is being manufactured in the United States. Such comments must be filed in triplicate with the Director, Statutory Import Programs Staff, U.S. Department of Commerce, Washington, D.C. 20230, within 20 calendar days after the date on which this notice of application is published in the **Federal Register.**

Regulations (15 CFR 301.9) issued under the cited Act prescribe the requirements for comments.

A copy of each application is on file, and may be examined between 8:30 a.m. and 5:00 p.m., Monday through Friday, in Room 735 at 666 11th Street NW., Washington, D.C.

Docket No. 80–00142. Applicant: Presbyterian-University Hospital, DeSoto at O'Hara, Pittsburgh, Pennsylvania 15213. Article: Automated Ultrasonic Body Scanner. Manufacturer: Ausonics, Ltd., Australia. Intended use of article: The article is intended to be used to provide consistent and high quality images of the body in the following applications:

(1) Use in the examination of female breast for identification of focal mass lesions and differentiation of benign from malignant masses so as to see what extent ultrasound can replace X-ray mammography.

(2) To study the brain in infants and young children to determine to what extent ultrasound can replace computerized tomographic scanning.

(3) To investigate the application of the article for rapid and automatic scanning of abdomen in order to reduce the time necessary for the performance of ultrasound exams and to improve the quality of images obtained.

In addition the article will be used to train residents, technologists, medical students, and staff radiologist in the more effective use of ultrasound for evaluating human disease. Application received by Commissioner of Customs: January 15, 1980.

Docket No. 80–00143. Applicant: University of California, Lawrence Berkeley Laboratory, One Cyclotron Road, Berkeley, CA 94720. Article: Electron Microscope, 1.5 MEV. Manufacturer: Kratos Incorporated, United Kingdom. Intended use of article: The article is intended to be used in performing the following experiments:

(1) Direct observation of gas-solid interaction in an environmental chamber, e.g., oxidation or corrosion of metals, reduction of oxides, gasification processes in coals,

(2) Examination of biological tissues in a hydrated state,

(3) Direct observation and simulation of radiation damage in materials for fusion and fission reactor applications, and

(4) Studies of thick sections of ceramics used in high temperature or waste-storage applications. Application received by Commissioner of Customs: January 17, 1980.

Docket No. 80–00144. Applicant: LSU Medical Center—Shreveport, 1501 Kings Highway, Shreveport, LA 71103. Article: Electron Microscope, Model EM 109 and Accessories. Manufacturer: Carl Zeiss, Inc., West Germany. Intended use of article: The article is intended to be used for studies of human and animal surgical and autopsy tissue with the following objectives:

(1) Investigation of the reactions of various tissues to injury.

(2) Delineation of normal fine structural appearance.

(3) More precise identification of undifferentiated tumors. The article will also be used in the course General Pathology/Systemic Pathology to teach basic pathologic processes to sophomore medical students. Application received by Commissioner of Customs: January 21, 1980.

Docket No. 80–00145. Applicant: University of California, Lawrence Livermore Laboratory, P.O. Box 5012, Livermore, CA 94550. Article: 14 Faraday Rotators. Manufacturer: Hoya Corporation, Japan. Intended use of article: The articles are intended to be used for the investigation of the feasibility of producing a thermonuclear microexplosion using a uniquely high intensity laser pulse. The articles are precision apparatus which are integrally incorporated into the laser beam chain to optically isolate the laser beam reflected back from the target, and to prevent the beam from traveling backwards in each amplifier chain

thereby destroying the components and apparatus in the forward part of the chain. Application received by Commissioner of Customs: January 21, 1980.

Docket No. 80–00146. Applicant: Papanicolaou Cancer Research Institute, 1155 N.W. 14th St., (POB 016188), Miami, Florida 33101. Article: NMR Spectrometer, Model FX–90Q and Accessories. Manufacturer: Jeol Ltd., Japan. Intended use of article: The article is intended to be used for studies in the general areas of biochemistry, biophysics, pharmacology and medicine. These studies will include:

(1) Microenvironmental Geometry of C–C Lyase Active Sites.

(2) Characterization of Biological Tissues by NMR.

(3) Studies of the Mechanisms of Aldolases and Ketolases.

(4) Studies of the Mechanism and Regulation of Lactose Synthase.

(5) Conformational Aspects and Dynamics of Ionophore Complexation.

(6) NMR Studies of the Conformation of Bradykinin. Application received by Commissioner of Customs: January 21, 1980.

Docket No. 80–00147. Applicant: Pennsylvania Hospital, Eighth and Spruce Streets, Philadelphia, PA 19107. Article: Electron Microscope, EM 109 and Accessories. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used primarily for study of biological specimens of human origin, i.e. kidney and muscle biopsies for diagnosis, tumor tissue for ultrastructural study to diagnose tumor type in doubtful cases, brain biopsy specimens for identification of virus particles in cases of encephalitis, and identification of some agents that cause occupational disease, such as asbestos fibers. The properties of the biological specimens to be studied are ultrastructural features such as the detailed microanatomy of renal glomerulus cell membranes, and organelles such as mitochondria, lysosomes, ribosomes, specific granules, Golgi apparatus, desmosomes, microfilaments and microtubules. The article will also be used in a training program to provide both theoretical and practical experience in diagnostic pathology. Application received by Commissioner of Customs: January 21, 1980.

Docket No. 80–00148. Applicant: University of Pennsylvania School of Medicine, 36th and Hamilton Walk, Philadelphia, PA 19104. Article: Electron Microscope, Model JEM–100CX and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used for continued investigation of the mechanism of action of insulin in adipocytes from its initial binding to the horomone receptor on the plasma membrane through and including its alteration of lipolysis, protein synthesis, calcium binding and distribution, plasma membrane ATPase activity and membrane phosphorylation. Application received by Commissioner of Customs: January 23, 1980.

Docket No. 80–00149. Applicant: U.S. Naval Research Laboratory, Washington, D.C. 20375. Article: Electron Microscope, Model JEM 200CX and Accessories. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used for simultaneous microstructural, chemical, and crystallographic analyses at resolutions in the range of 0.2 to 20 nm. These needs include:

(1) Identifications of chemical distributions and associated microstructures in ion-implanted materials;

(2) Determinations of crystal structures and chemical distribution associated with grain boundaries in ceramic materials;

(3) Structure-chemistry-property relationships in granular superconducting fibers;

(4) Studies of phase instabilities in alloys exposed in harsh service environments;

(5) Studies of the deformation structures surrounding crack tips in alloys and their relationships to fracture mechanisms. Application received by Commissioner of Customs: January 23, 1980.

Docket No. 80–00150. Applicant: University of Tennessee, Center for the Health Sciences, Stout Neuroscience Mass Spectrometry Laboratory, 800 Madison Avenue, Memphis, Tenn. 38163. Article: Mass Spectrometer, Model Varian 731. Manufacturer: Varian MAT, West Germany. Intended use of article: The article is intended to be used to analyze Oligopeptide fragments produced from the novel protein kinase AUT–PK–85 isolated from adrenocortical carcinoma, hypothalamic peptide hormones and vasoactive phospholipids. Secondarily, the article will be used to analyze leucotrienes, prostaglandins, thromboxanes, urinary organic acids, drug metabolities, steroids, saccharides, and other compound types. Investigations will be conducted to: (1) Obtain the amino acid sequence of an adrenocortical carcinoma protein kinase, (2) quantify endogenous amounts of biologically active, underivatized oligopeptides, and (3) elucidate structure of a vasoactive phospholipid. In addition, the article will be used in the course Mass Spectrometry of Biologically Important Compounds for educational purposes. Application received by Commissioner of Customs: January 23, 1980.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Acting Director, Statutory Import Programs Staff.

[FR Doc. 80–11335 Filed 4–14–80; 8:45 am]

BILLING CODE 3510–25–M

National Oceanic and Atmospheric Administration

Designate a Marine Sanctuary Offshore Point Reyes and the Farallon Islands, Calif.; Availability of Funds for Public Participation

AGENCY: Office of Coastal Zone Management (OCZM), National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: Pursuant to Title III of the Marine Protection, Research and Sanctuaries Act of 1972, 16 U.S.C. 1431–1434, OCZM is considering the designation of certain waters off the Coast of California, adjacent to Point Reyes and the Farallon Islands, as a marine sanctuary. A DEIS discussing this proposal was published in March 1980. Public hearings will be held in San Francisco on May 13, 1980, at 1:00 p.m. at the Jack Tarr Hotel, Cathedral Hill Room B–Mezzanine Level, 1101 Van Ness Avenue, and in Point Reyes Station on May 13, 1980, at 7:00 p.m. at the West Marin School Auditorium, Highway 1. Comments on the DEIS will be accepted until May 27, 1980.

In order to promote a full and fair determination of the issues involved, OCZM is making available $5,000 to compensate persons eligible under the criteria set forth in NOAA regulations (15 CFR Part 904) for their participation in this proceeding.

DATES: Closing date for the receipt of applications for compensation is May 5, 1980.

FOR FURTHER INFORMATION CONTACT: JoAnn Chandler, Director, Sanctuary Programs Office, Office of Coastal Zone Management, 3300 Whitehaven Street, N.W. Washington, D.C. 20235, 202/634–4236.

SUPPLEMENTAL INFORMATION: History of Proposal: In 1977 NOAA received several recommendations that waters offshore Point Reyes and surrounding the Farallon Islands should be designated as a marine sanctuary, the

recommendations varying somewhat as to the actual boundary. A public meeting was held in April 1978 to discuss these recommendations.

An Issue Paper was prepared and issued in December 1978 outlining alternative proposals for public review. Based on the responses to this paper, and consultation with other Federal agencies, the Pacific Regional Fishery Management Council, State and local governments, and interest group, NOAA prepared a draft environmental impact statement on which public comment is solicited. NOAA will hold public hearings in San Francisco and Point Reyes Station, California on May 13, 1980, to receive comments on the proposal and on the DEIS.

Issues Involved: The basic issues which will be analyzed by the DEIS and considered at the public hearings are:

What conservation, recreational, ecological, and esthetic resources are found in the general area under consideration?

Is designation of a marine sanctuary necessary to protect and manage these resources?

What size should a marine sanctuary be?

What regulatory and other measures should be taken within a sanctuary to ensure protection and proper management?

Available Fund: A total fund of $5,000 is availalble to compensate eligible applicants. This fund may be distributed among one or more applicants, or, at the discretion of the Administrator, not distributed at all.

Eligible Persons: In accordance with the criteria of 15 CFR 904.3 persons who represent an interest the presentation of which can reasonably be expected to contribute substantially to a fair determination of the issues described above may be eligible for compensation from these funds. In determining eligibility and the amount of compensation, the Administrator may take into account:

(a) Whether the interest will be adequately represented otherwise;

(b) The need to encourage participation by segments of the public who may have little economic incentive to participate;

(c) The importance of the representation to a fair balance of interests;

(d) The number and complexity of the issues presented;

(e) The importance of public participation; and

(f) The applicant's resources available for participation.

Eligible Costs: The Administrator may compensate eligible persons for some or all of the reasonable costs incurred in participating including:

(1) Salaries for participants or employees of participants;

(2) Fees for consultants, experts, contractual services, and attorneys;

(3) Travel and travel related costs such as lodging, meals, tipping, telephone calls, etc.; and

(4) Document reproduction, postage, etc.

Procedures for Applying: Applications must be filed with the Director, Sanctuary Programs Office, Office of Coastal Zone Management, NOAA, no later than May 5, 1980, and shall contain the information required by and be filed in accordance with the NOAA's financial participation regulations, 43 FR 17806 (April 26, 1978).

Dated: April 9, 1980.

Donald W. Fowler,

Acting Deputy Assistant Administrator, Office of Coastal Zone Management.

[FR Doc. 80-11238 Filed 4-14-80; 8:45 am]

BILLING CODE 3510-08-M

Office of the Secretary

Establishment and Membership of Departmental Performance Review Board

This notice announces the establishment of the Departmental Performance Review Board (PRB) in the Department of Commerce and the appointment of all its initial members. The Departmental PRB is responsible for reviewing performance appraisals and ratings of Senior Executive Service (SES) members and making written recommendations to the appropriate appointing authority on SES retention and compensation matters, including performance based pay adjustments, awarding of bonuses and amounts, and initial recommendations for potential rank awards. The Departmental PRB will review the performance of appointing authorities and their immediate deputies who are in the SES and other SES members whose ratings are initially prepared by their respective appointing authorities.

The appointment of the members of the Department PRB will be for a period of approximately 18 months and will officially begin on April 15, 1980.

The names of the 18 members of the Departmental PRB are set forth below:

Guy W. Chamberlin, Jr., Deputy Assistant Secretary for Administration, Office of the Secretary

Clifford J. Parker, Director, Office of Budget and Program Evaluation, Office of the Secretary

Joseph C. Brown, Deputy Director for Personnel Administration, Office of the Secretary

Daniel Levine, Deputy Director, Bureau of the Census, Office of the Chief Economist

Shirley Kallek, Associate Director, Economic Fields, Bureau of the Census, Office of the Chief Economist

Hal W. Williams, Deputy Assistant Secretary for Economic Development, Economic Development Administration

George W. Karras, Deputy Assistant Secretary for Operations, Economic Development Administration

William Skidmore, Acting Deputy General Counsel, Office of the General Counsel

John B. Roose, Director, Office of Export Promotion, Industry and Trade Administration

Frederick L. Montgomery, Acting Deputy Assistant Secretary for Trade Agreements, Industry and Trade Administration

Richard O. Thomas, Director, Office of Policy and Plans, Maritime Administration

Allan A. Stephenson, Deputy Director, Minority Business Development Agency

James W. Brennan, Deputy General Counsel, National Oceanic and Atmospheric Administration

Stanley I. Cohn, Deputy Administrator for Operations, National Telecommunications Information Administration

Lucy Falcone, Deputy Assistant Secretary for Domestic Economic Policy, Office of Policy

Edward L. Brady, Associate Director, International Affairs, National Bureau of Standards, Office of Science and Technology

Herbert C. Wamsley, Executive Assistant to the Commissioner, Patent and Trademark Office, Office of Science and Technology

Lee Wells, Acting Deputy Assistant Secretary, United States Travel Service

Persons desiring any further information about the Departmental PRB or its membership may contact Mr. John Innocenti, Executive Secretary to the Departmental Performance Review Board, Office of Personnel, Main Commerce Building, Room 5102, Washington, D.C. 20230, 202/377-2245.

Dated: March 26, 1980.

John Innocenti,

Executive Secretary, Departmental Performance Review Board, U.S. Department of Commerce.

[FR Doc. 80-11245 Filed 4-14-80; 8:45 am]

BILLING CODE 3510-17-M

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

Procurement List 1980; Additions

AGENCY: Committee for Purchase from the Blind and Other Severely Handicapped.

ACTION: Addition to Procurement List.

SUMMARY: This action adds to Procurement List 1980 commodities to be

produced by workshops for the blind and other severely handicapped.

EFFECTIVE DATE: April 15, 1980.

ADDRESS: Committee for Purchase from the Blind and Other Severely Handicapped, 2009 14th Street North, Suite 610, Arlington, Virginia 22201.

FOR FURTHER INFORMATION CONTACT: C. W. Fletcher, (703) 557–1145.

SUPPLEMENTARY INFORMATION: On February 8, 1980, the Committee for Purchase from the Blind and Other Severely Handicapped published notice (45 FR 8691) of proposed additions to Procurement List 1980, November 27, 1979 (44 FR 67925).

After consideration of the relevant matter presented, the Committee has determined that the commodities listed below are suitable for procurement by the Federal Government under 41 U.S.C. 46–48c, 85 Stat. 77.

Accordingly, the following commodities are hereby added to Procurement List 1980:

Class 8115

Box, Wood, Nailed, 8115–00–N00–0019, Requirements for Pine Bluff Arsenal, Pine Bluff, Arkansas only.

Class 3990

Pallet, Material Handling, 3990–00–935–7826, Requirements for Pine Bluff Arsenal, Pine Bluff, Arkansas only.

C. W. Fletcher,

Executive Director.

[FR Doc. 80–11237 Filed 4–14–80; 8:45 am]

BILLING CODE 6820–33–M

Economic Regulatory Administration

Powerplant and Industrial Fuel Use Act of 1978; Information Concerning Compliance Reports To Be Filed by Persons Owning, Operating, or Proposing To Operate One or More Existing Electric Powerplants

AGENCY: Economic Regulatory Administration, Department of Energy.

ACTION: Notice of requirement to file compliance reports.

SUMMARY: This notice is to call to the attention of electric utilities and to inform the public that pursuant to Section 712 of the Powerplant and Industrial Fuel Use Act of 1978 (42 U.S.C. 8301 *et seq.*), hereinafter "the Act" or "FUA", persons owning, operating or proposing to operate one or more existing electric powerplants required to come into compliance with the prohibitions of the Act were required to submit a report to the Department of Energy on or before January 1, 1980, and annually thereafter. Specifically, the reports must identify and furnish compliance related information for all existing powerplants which (1) are subject to the Section 301 statutory prohibitions on the use of natural gas; (2) are subject to a final prohibition order issued pursuant to Section 301; (3) are subject to the Section 405 prohibitions on the increased use of petroleum; and (4) were elected to be covered by the Electric Utility System Compliance Option pursuant to Title V of the Act.

DATES: Reports are to be filed by January 1, 1980, and annually thereafter.

FOR FURTHER INFORMATION CONTACT:

William L. Webb, Office of Public Information, Economic Regulatory Administration, Department of Energy, 2000 M Street, NW., Room B–110, Washington, D.C. 20461, Phone: (202) 653–4055.

James W. Workman, Director, Division of Existing Facilities Conversion, Economic Regulatory Administration, Department of Energy, 2000 M Street, NW., Room 3128, Washington, D.C. 20461, Phone: (202) 653–3637.

James Renjilian, Office of the General Counsel, Department of Energy, 1000 Independence Avenue, SW., Room 6G–087, Washington, D.C. 20585, Phone: (202) 252–2967.

SUPPLEMENTARY INFORMATION: Section 712 of the Powerplant and Industrial Fuel Use Act of 1978 reads as follows:

"Sec. 712. Compliance report.

Any person owning, operating, or proposing to operate one or more existing electric powerplants required to come into compliance with the prohibitions of this Act shall on or before January 1, 1980, and annually thereafter, submit to the Secretary a report identifying all such existing electric powerplants owned or operated by such person.

Such report shall—

(1) set forth the anticipated schedule for compliance with the applicable requirements and prohibitions by each such electric powerplant;

(2) indicate proposed or existing contracts or other commitments or good faith negotiations for such contracts or commitments for coal or another alternate fuel, equipment, or combinations thereof, which would enable such powerplant to comply with such prohibitions; and

(3) identify those electric powerplants, if any, for which application for temporary or permanent exemption from the prohibitions of this Act may be filed."

In filing documents required under Section 712 of FUA, the applicable provisions of Interim Rule Part 501, Subpart A (44 FR 28530, 28544; May 15, 1979) should be followed.

Issued in Washington, D.C., April 7, 1980.

Robert L. Davies,

Assistant Administrator for Fuels Conversion, Economic Regulatory Administration.

[FR Doc. 80–11254 Filed 4–14–80; 8:45 am]

BILLING CODE 6450–01–M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Projects Nos. 2994 and 3028]

Borough of Lehighton, Pa., et al.; Applications for Preliminary Permits

April 9, 1980.

Take notice that the Borough of Lehighton, Pennsylvania filed on November 5, 1979, and the Delaware River Basin Commission and the Commonwealth of Pennsylvania filed on January 29, 1980, competing applications [pursuant to the Federal Power Act, 16 U.S.C. Sections 791(a)–825(r)] for preliminary permits for a proposed hydroelectric power project that would be known as the Beltzville Hydroelectric Project, FERC Projects Nos. 2994 and 3004, respectively. The proposed project would be located at the U.S. Army Corps of Engineers' Beltzville Dam, on Pohopoco Creek in Carbon County, Pennsylvania. Correspondence with the Borough of Lehighton, Pennsylvania, should be directed to: Mr. Mort Smedley, Business Manager, Borough of Lehighton, Municipal Building, Lehighton, Pennsylvania 18235. Correspondence with the Delaware River Basin Commission and the Commonwealth of Pennsylvania should be directed to: Mr. Gerald M. Hansler, Executive Director, Delaware River Basin Commission, 25 State Police Drive, West Trenton, New Jersey 08628; and to Mr. Clifford Jones, Secretary, Department of Environmental Resources, Commonwealth of Pennsylvania, Evangelical Press Building, Harrisburg, Pennsylvania 17120.

Purpose of Project—Project energy developed from Project No. 2994 would be sold to Applicant's retail customers. Project energy developed from Project No. 3028 would be sold by the Applicants to public utilities or local municipalities and institutions.

Proposed Scope and Cost of Studies under Permit—Each Applicant seeks issuance of a preliminary permit for a period of three years, during which time it would conduct surveys, an engineering feasibility study, and an economic and environmental assessment of the proposed project. Depending upon the outcome of the

studies, each of the Applicants would decide whether to proceed with an application for license. The Borough of Lehighton estimates that the cost of studies under the permit would be $75,000. The Delaware River Basin Commission and the Commonwealth of Pennsylvania estimate the cost of studies under the permit would be at least $50,000.

Project Descriptions—Each Applicant would utilize the U.S. Army Corps of Engineers' Beltzville Dam and Reservoir on Pohopoco Creek, and each project would consist of: (1) a powerhouse to be located at the end of an existing outlet tunnel; (2) turbines and generators to be installed in the powerhouse; and (3) appurtenant facilities.

The Borough of Lehighton, Pennsylvania, intends to install turbine-generators having a total capacity of 3,500 kW. The estimated average annual energy output is 15,000,000 kWh.

The Delaware River Basin Commission and the Commonwealth of Pennsylvania intends to install turbine-generators having a total capacity of between 2,000 and 5,000 kW. The estimated average annual energy output is from 10,000,000 to 20,000,000 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 power, and all other information necessary 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 applications for preliminary permit. (A copy of the applications may be obtained directly from the Applicants.) 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 an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desirng to file a competing application must submit to the Commission, on or before June 9, 1980, either the competing application itself or a notice of intent to file a competing application. Submission of a timely notice of intent allows an interested person to file the competing application no later than August 8, 1980. A notice of intent must conform with the requirements of 18 C.F.R. 4.33(b) and (c), (*as amended* 44 FR 61328, October 25, 1979). A competing application must conform with the requirements of 18 CFR, 4.33(a) and (d), (*as amended* 44 FR 61328, October 25, 1979.)

Comments, Protests, or Petitions to Intervene—Anyone desiring to be heard or to make any protests about these applications 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, protest, or petition to intervene must be filed on or before June 9, 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. 80-11405 Filed 4-14-80; 8:45 am]

BILLING CODE 6450-85-M

[Project No. 3026]

Delaware River Basin Commission and the Commonwealth of Pennsylvania; Application for Preliminary Permit

April 9, 1980.

Take notice that an application was filed January 28, 1980, under the Federal Power Act, 16 U.S.C. § 791(a)–825(r), by the Delaware River Basin Commission and the Commonwealth of Pennsylvania, for a preliminary permit for a proposed water power project to be known as the Blue Marsh Dam Project, FERC No. 3026. The project would be located on the Tulpehocken Creek (a tributary of the Schuylkill River) in Berks County, Pennsylvania. The proposed project would utilize Federal lands and a Federal dam under the jurisdiction of the U.S. Army Corps of Engineers. Correspondence with the Applicant should be directed to: Delaware River Basin Commission, 25 State Police Drive, West Trenton, New Jersey 08628; and Department of Environmental Resources, Commonwealth of Pennsylvania, Evangelical Press Building, Harrisburg, Pennsylvania 17120.

Purpose of Project—Project energy would be sold to public utilities or to local industries and institutions.

Proposed Scope and Cost of Studies Under Permit—Applicants seek issuance of a preliminary permit for a period of three years, during which time they would assess economic and environmental features of the proposed project, as well as conduct surveys and an engineering feasibility study. Depending upon the outcome of the studies, the Applicants would decide whether to proceed with an application for license. Applicants estimate that the cost of studies under the permit would be at least $50,000.

Project Description—The proposed project would utilize the U.S. Army Corps of Engineers' (Corps) existing Blue Marsh Dam and Reservoir. The project would consist of: (1) a powerhouse to be constructed at the downstream terminus of the existing outlet tunnel, and (2) appurtenant facilities. The installed capacity would be between 800 and 2,000 kW. It is estimated that the average annual energy output would be between 7,000 and 16,000 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 power, and all other information necessary 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 an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before June 9, 1980 either the competing application itself or a notice of intent to file a competing application. Submission

of a timely notice of intent allows an interested person to file the competing application no later than August 8, 1980. A notice of intent must conform with the requirements of 18 CFR 4.33(b) and (c), (*as amended* 44 FR 61328, October 25, 1979). A competing application must conform with the requirements of 18 CFR 4.33(a) and (d), (*as amended,* 44 FR 61328, October 25, 1979.)

Comments, Protest, or 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, § 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, protest, or petition to intervene must be filed on or before June 9, 1980. The Commission's address is: 825 N. Capitol Street, NE., Washington, D.C. 20426. The application is on file with the Commission and is available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-11406 Filed 4-14-80; 8:45 am]

BILLING CODE 6450-85-M

[Project No. 3027]

Delaware River Basin Commission and the Commonwealth of Pennsylvania; Application for Preliminary Permit

April 9, 1980.

Take notice that an application was filed January 29, 1980, under the Federal Power Act, 16 U.S.C. 791(a)–825(r), by the Delaware River Basin Commission and the Commonwealth of Pennsylvania, for a preliminary permit for a proposed water power project to be known as the Prompton Dam Project, FERC No. 3027. The project would be located on the Lackawaxen River (a tributary of the Delaware River) in Wayne County, Pennsylvania. The proposed project would utilize Federal lands and a Federal dam under the jurisdiction of the U.S. Army Corps of Engineers. Correspondence with the Applicant should be directed to: Delaware River Basin Commission, 25 State Police Drive, West Trenton, New Jersey 08628; and Department of Environmental Resources, Commonwealth of Pennsyvania, Evangelical Press Building, Harrisburg, Pennsylvania 17120.

Purpose of Project—Project energy would be sold to public utilities or to local industries and institutions.

Proposed Scope and Cost of Studies Under Permit—Applicants seek issuance of a preliminary permit for a period of three years, during which time they would conduct surveys, an engineering feasibility study, and an economic and environmental assessment of the proposed project. Depending upon the outcome of the studies, the Applicants would decide whether to proceed with an application for license. Applicants estimate the cost of studies under the permit would be at least $50,000.

Project Description—The proposed project would utilize the U.S. Army Corps of Engineers' (Corps) existing Prompton Dam and Reservoir which, under existing Congressional authorization, would be raised 2 feet by the Corps. The project would consist of (1) a powerhouse to be constructed at the end of an existing outlet tunnel; and (2) appurtenant facilities. The installed capacity would be between 500 and 2,000 kW, with an average annual energy production of between 4,000 and 15,000 MWh.

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 feasbility of the proposed project, the market for power, and all other information necessary 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 an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications—Anyone desiring to file a competing application must submit to the Commission, on or before June 9, 1980 either the competing application itself or a notice of intent to file a competing application. Submission of a timely notice of intent allows an interested person to file the competing application no later than August 8, 1980. A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c), (*as amended* 44 FR 61328, October 25, 1979). A competing application must conform with the requirements of 18 CFR, 4.33 (a) and (d), (*as amended,* 44 FR 61328, October 25, 1979.)

Comments, Protests, or 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, § 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 June 9, 1980. The Commission's address is: 825 N. Capitol Street, NE., Washington, D.C. 20426. The application is on file with the Commission and is available for public inspection.

Kennety F. Plumb,

Secretary.

[FR Doc. 80-11407 Filed 4-14-80; 8:45 am]

BILLING CODE 6450-85-M

[Project No. 3094]

New Hampshire Hydro Associates; Application for Preliminary Permit

April 10, 1980.

Take notice that on March 21, 1980, New Hampshire Hydro Associates filed an application for preliminary permit [pursuant to the Federal Power Act, 16 U.S.C. 791(a)–825(r)] for the proposed Moore's Falls Project, FERC No. 3094, that would be located on the Merrimack River in Hillsboro County, New Hampshire. Correspondence with the Applicant should be addressed to: Attorney David B. Ward, Case and Ward, P.C., 1050 17th St. N.W., Suite 510, Washington, D.C. 20036.

Purpose of the Project

Power generated by the project would be sold to either Concord Electric Company, Public Service Company of New Hampshire, or New Hampshire Electric Cooperative, Inc. for distribution to their customers.

Proposed Scope and Cost of Studies Under Permit

The work proposed under the preliminary permit would include an economic analysis, preparation of preliminary engineering plans, and a study of environmental impacts. Based on results of these studies, Applicant would decide whether to proceed with more detailed studies and the preparation of an application for license to construct and operate the project. Applicant estimates that the cost of the work to be performed under the preliminary permit would be up to $100,000.

Project Description

The Moore's Falls Project would consist of: (1) A 70-foot high, 600-foot long concrete dam; (2) and 800-acre reservior with a usable storage capacity of 2,000 acre feet; (3) a powerhouse containing two tubular turbine/generator units with a total rated capacity of 14.8 MW; (4) a 120-foot wide, 250-foot long tailrace channel; (5) a 6,500-foot long, 34-kV transmission line; and (6) appurtenant facilities. The estimated annual output of the project is 85,000,000 kWh that would save the equivalent of 140,000 barrels of oil or 40,000 tons of coal annually.

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 power, and all other necessary information for inclusion in an application for a license. In this instance, the Applicant seeks an 18-month permit.

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 an agency does not file comments within the time set below, it will be presumed to have no comments.

Competing Applications

Anyone desiring to file a competing application must submit to the Commission, on or before June 13, 1980, either the competing application itself or a notice of intent to file a competing application. Submission of a timely notice of intent allows an interested person to file the competing application no later than August 12, 1980. A notice of intent must conform with the requirements of 18 CFR 4.33 (b) and (c), (*as amended* 44 FR 61328, October 25, 1979). A competing application must conform with the requirements of 18 CFR 4.33 (a) and (d), (*as amended,* 44 FR 61328, October 25, 1979.)

Comments, Protests, or Petitions To Intervene

Anyone desiring to be heard or to make any protests 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 Section 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 June 13, 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. 80-11408 Filed 4-14-80; 8:45 am]

BILLING CODE 6450-85-M

[Project No. 2752]

Northern Lights, Inc.; Availability of Staff Draft Environmental Impact Statement

April 10, 1980.

Notice is hereby given in the captioned Project, that on or about April 18, 1980, as required by 18 CFR 2.81(b), a draft environmental impact statement prepared by the staff of the Federal Energy Regulatory Commission was made available for comments. This statement deals with the environmental impact of the issuance of a Federal Energy Regulatory Commission license to Northern Lights, Inc. for the construction, operation, and maintenance of the proposed Kootenai Falls Hydroelectric Project, FERC No. 2752, consisting of: One diversion structure and reservoir on the Kootenai River; intake and outlet structures; underground powerstation and switchyard; new and improved recreation facilites; and associated tunnels, transmission facilities, and access road.

This statement has been circulated for comments to Federal, State, and local agencies, has been placed in the public files of the Commission, and is available for public inspection both in the Commission's Office of Public Information, Room 1000, 825 North Capitol Street, NE, Washington, DC 20426 and its San Francisco Regional Office located at 333 Market Street, 6th Floor, San Francisco, California.

Copies may be ordered from the Commission's Office of Public Information, Washington, DC 20426.

Any person who wishes to do so may file comments on the staff draft statement for the Commission's consideration. All comments must be filed on or before June 2, 1980.

Any person who wishes to present evidence regarding environmental matters in this proceeding must file with the Commission a petition to intervene pursuant to 18 CFR 1.8. Petitioners must also file timely comments on the draft statement in accordance with 18 CFR 2.81(c).

All petitions to intervene must be filed on or before June 2, 1980.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-11409 Filed 4-14-80; 8:45 am]

BILLING CODE 6450-85-M

[Project Nos. 3105 and 3106]

The Power Authority of the State of New York; Applications for Exemption for Small Conduit Hydroelectric Facilities

April 10, 1980.

Take notice that on March 27, 1980, the Power Authority of the State of New York (PASNY) filed, pursuant to 30 of the Federal Power Act [16 U.S.C. 823(a)], applications for exemption from licensing for two separate, proposed, small conduit hydroelectric facilities.

The proposed hydroelectric facilities (FERC Projects Nos. 3105 and 3106) would be located on the City of New York's (City) existing water distribution system in Ulster and Westchester Counties, New York. Water flowing in the conduits is obtained through aqueducts from the Ashokan and Kensico Reservoirs. Correspondence with the Applicant should be directed to Mr. Thomas R. Frey, Vice President and General Counsel, Power Authority of the State of New York, 10 Columbus Circle, New York, New York 10019.

Purpose of Project

Power from the project would be sold to the City of New York for municipal use.

Project Description

The proposed facilities are: (1) the Ashokan development (Project No. 3105) to be located along the headworks of the existing Catskill Aqueduct down-aqueduct from Ashokan Reservoir, in the Township of Olive, in Ulster County. The facilities to be constructed include (a) a 240-foot long, 10-foot diameter penstock; (b) a 60-foot by 20-foot semi-underground powerhouse which would contain (c) two turbine-generators with a rated capacity of 2,375 kW, each; and (d) a tailrace to the existing aerator chamber outlet channel; (2) the Kensico development (Project No. 3106) to be located along the headworks of the lower Catskill Aqueduct down-aqueduct from Kensico Reservoir in the Town of Mount Pleasant in Westchester County. The facilities would consist of (a) three new turbine-generator units each having a rated capacity of 1,000 kW installed in existing bays within the lower aqueduct effluent chamber.

Agency Comments

The U.S. Fish and Wildlife Service and the New York Department of Environmental Conservation are requested pursuant to Section 30 of the Federal Power Act, to submit appropriate terms and conditions to protect any fish and wildlife resources. Other Federal, State, and local agencies that receive this notice through direct mailing from the Commission are requested to provide any comments they may have in accordance with their duties and responsibilities. No other formal requests for comments will be made.

Comments should be confined to substantive issues relevant to the granting of an exemption. If an agency does not file comments within the time set below, it will be presumed to have no comments.

Comments, Protests, or Petitions To Intervene

Anyone desiring to be heard or to make any protests about these applications 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 1.10 (1979). Comments not in the nature of a protest may also be submitted by conforming to the procedures specified in Section 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, protest, or petition to intervene must be filed on or before May 22, 1980. The Commission's address is: 825 North Capitol Street, N.E., Washington, D.C. 20426. The applications are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80-11410 Filed 4-14-80; 8:45 am]

BILLING CODE 6450-85-M

Office of Hearings and Appeals

Cases Filed; Week of February 22 Through February 29, 1980

Notice is hereby given that during the week of February 22, 1980 through February 29, 1980, the appeals and applications for exception or other relief listed in the Appendix to this Notice were filed with the Office of Hearings and Appeals of the Department of Energy.

Under the DOE's procedural regulations, 10 CFR, Part 205, any person who will be aggrieved by the DOE action sought in such cases may file with the DOE written comments on the application within ten days of service of notice, as prescribed in the procedural regulations. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. All such comments shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20461.

Melvin Goldstein,

Director, Office of Hearings and Appeals.

April 10, 1980.

List of Cases Received by the Office of Hearings and Appeals.

[Week of Feb. 22 through 29, 1980]

Date	Name and location of applicant	Case No.	Type of submission
Feb. 22, 1980	R. D. Smith Oil Company, Highland, Illinois	BEE-0910	Allocation Exception. If granted: R. D. Smith Oil Company would receive an exception from the provisions of 10 CFR 211 which would permit the firm to receive an increased allocation of unleaded motor gasoline for the purpose of blending gasohol.
Feb. 25, 1980	A. J. Oil Company, Hanna City, Illinois	BEE-0916	Allocation Exception. If granted: A. J. Oil Company would receive an exception from the provisions of 10 CFR 211 which would permit the firm to receive an increased allocation of unleaded motor gasoline for the purpose of blending gasohol.
Feb. 25, 1980	Corn Belt FS, Inc., Decatur, Illinois	BEE-0915	Allocation Exception. If granted: Corn Belt FS, Inc. would receive an exception from the provisions of 10 CFR 211 which would permit the firm to receive an increased allocation of unleaded motor gasoline for the purpose of blending gasohol.
Feb. 25, 1980	Exxon Company, U.S.A., et al., Washington, D.C.	BEA-0210, BEA-0214-0223.	Appeal of an Assignment Order. If granted: The January 7, 1980, Assignment Order issued to Setgo Products, Ltd. by the Economic Regulatory Administration, Region V, regarding the firm's supply obligations to Service Oil Company, Inc. would be rescinded.
Feb. 25, 1980	Interstate Truck Stops, Inc., Blue Springs, MS	BEA-0238	Appeal of an Assignment Order. If granted: The Assignment Order issued to Speedway Petroleum by the Economic Regulatory Administration, Region V, regarding the firm's supply obligations would be rescinded.
Feb. 25, 1980	Mike's Shell Service, et al., Daleville, IN	BEA-0224 thru BEA-0237.	Appeal of an Assignment Order. If granted: The Assignment Order issued to Speedway Petroleum by the Economic Regulatory Administration, Region, V, regarding the firm's supply obligations would be rescinded.
Feb. 25, 1980	Port-O-Call Mobil, Indianapolis, IN	BEA-0242	Appeal of an Assignment Order. If granted: The Assignment Order issued to Speedway Petroleum by the Economic Regulatory Administration, Region, V, regarding the firm's supply obligations would be rescinded.

List of Cases Received by the Office of Hearings and Appeals.—Continued

[Week of Feb. 22 through 29, 1980]

Date	Name and location of applicant	Case No.	Type of submission
Feb. 25, 1980	Quaker State Oil/Gulf Oil Corporation, Washington, D.C.	BEJ-0052	Motion for Protective Order. If granted: Quaker State Oil and Gulf Oil Corporation would enter into a Protective Order with respect to Quaker State's Application for Exception (Case No. BEE-0795).
Feb. 25, 1980	Quaker State Oil/Marathon Oil Company, Washington, D.C.	BEJ-0048	Motion for Protective Order. If granted: Quaker State Oil Refining Corporation and Marathon Oil Company would enter into a Protective Order regarding confidential information to be exchanged by the firms.
Feb. 25, 1980	S & W Engine Supply, Oklahoma County, Oklahoma.	BXE-0918	Extension of relief granted in S & W Engine Supply, —— DOE Par. (November 8, 1979). If granted: S & W Engine Supply would be permitted to continue to sell the crude oil produced from the Baker Townsend Lease located in Oklahoma County, Oklahoma at upper tier ceiling prices.
Feb. 26, 1980	Alger Oil Co., Rising Sun, Maryland	BEE-0920	Allocation Exception. If granted: Alger Oil Co. would receive an exception from the provisions of 10 CFR 211 which would permit the firm to receive an increased allocation of unleaded motor gasoline for the purpose of blending gasohol.
Feb. 26, 1980	Exeter Shell Service, Manchester, NH	BRD, BRH-0820.	Motion for Discovery; Motion for Evidentiary Hearing. If granted: Discovery would be granted and a evidentiary hearing would be covened in connection with the Statement of Objections submitted in response to the Proposed Remedial Order (Case No. BRO-0820) issued to Exeter Shell Service.
Feb. 26, 1980	Shell Oil Company, Houston, TX	BEA-0204	Appeal of a Buy/Sell Order. If granted: The February 5, 1980, Buy/Sell Order issued to Commonwealth Oil Refining Company, Inc. by the ERA would be modified.
Feb. 26, 1980	Southwestern States Marketing Corporation, Abilene, TX.	BFA-0205	Appeal of a Freedom of Information Denial. If granted: The January 18, 1980, Information Request Denial issued by the Economic Regulatory Administration, Region VI, would be modified and Southwestern States Marketing Corp. would receive access to certain DOE information.
Feb. 27, 1980	Doub and Muntzing, Washington, D.C.	BFA-0206	Appeal of a Freedom of Information Denial. If granted: The January 25, 1980, Information Request Denial issued by the DOE Office of Policy, Procurement and Contracts Management Directorate, would be rescinded and Doub and Muntzing would receive access to the Logistics Management Institute Report.
Feb. 27, 1980	Exxon Company, U.S.A., Houston, TX	BEA-0208	Appeal of an Assignment Order. If granted: The January 28, 1980, Assignment Order issued to Exxon Company, U.S.A. by the Economic Regulatory Administration, Region IV, regarding Exxon's supply obligations to Cosmo Oil Company, Inc. would be rescinded.
Feb. 27, 1980	La Gloria Oil & Gas Company, Houston, TX	BEA, BES-0207	Appeal and Stay of an Assignment Order. If granted: The February 1, 1980, Assignment Order issued to La Gloria Oil and Gas Company by the Economic Regulatory Administration, Region V, regarding La Gloria's supply obligations to Busler Enterprises, Inc. would be rescinded and La Gloria would receive a Stay of the order pending a final determination on its Appeal.
Feb. 27, 1980	National Oil Jobbers Council, Washington, D.C.	BEH-0012	Motion for Evidentiary Hearing. If granted: An evidentiary hearing would be convened in connection with National Oil Jobbers Council's Application for Temporary Stay and Stay (Case Nos. BST, BES-0060).
Feb. 27, 1980	Office of Enforcement, Washington, D.C.	BRR, BRS-0064.	Request for Stay; Request for Modification. If granted: The Office of Enforcement would receive a Stay of the January 11, 1980, Remedial Order Appeal issued to Shenandoah Oil Corp. Pending a final determination on its Application for Modification.
Feb. 28, 1980	Aminoil USA, Inc., Houston, TX	BXE-0921	Extention of Relief Granted in Aminoil USA, Inc. 2 DOE Par. 81,114 (October 24, 1978). If granted: Aminoil USA, Inc. would be permitted to continue to sell the crude oil produced from the California State Lease 392 located in Huntington Beach, California at upper tier ceiling prices.
Feb. 28, 1980	Eastern Oil Company, Tampa, FL	BRA-0213	Appeal of Remedial Order. If granted: The January 18, 1980, Revised Remedial Order issued to Eastern Oil Company by the Economic Regulatory Administration, Region IV, would be rescinded.
Feb. 28, 1980	Exxon Company, U.S.A., Houston, TX	BEA-0211	Appeal of an assignment Order. If granted: The January 28, 1980, Assignment Order issued to Exxon Co. USA by the Economic Regulatory Administration, Region IV, regarding Exxon's supply obligations to Major Oil would be rescinded.
Feb. 28, 1980	Exxon Company, U.S.A., Houston, TX	BEA, BES-0212	Appeal of an Assignment Order; Request for Stay. If granted: The January 29, 1980, Assignment Order issued to Exxon Company, U.S.A. by the Economic Regulatory Administration, Region IV, regarding Exxon's supply obligations to Marine Oil Company would be rescinded and the firm would receive a stay of the order pending a final determination in its Appeal.
Feb. 28, 1980	Marathon Oil Company, Findlay, Ohio	BEA-0209	Appeal of an Assignment Order. If granted: The January 28, 1980, Assignment Order issued to Quarry Self Serve by the Economic Regulatory Administration, Region V, regarding Marathon Oil Company's supply obligations to Quarry Self Serve would be rescinded.
Feb. 28, 1980	Pester Refining Company, Washington, D.C.	BES-0258	Request for Stay. If granted: Pester Refining Company would receive a stay of the January 29, 1980, Assignment Order issued to the firm by the Economic Regulatory Administration, Region VII, pending a final determination on its Appeal which the firm intends to file.
Feb. 28, 1980	Texaco, Inc., White Plains, NY	BED, BEJ-0049	Motion for Discovery and Protective Order. If granted: Discovery would be granted to Texaco, Inc. in connection with Laketon Asphalt Refining, Inc.'s Application for Exception (Case No. DXE-6986) and the two firms would enter into a Protective Order regarding information concerning the case.
Feb. 29, 1980	Champlin Petroleum Company, Tulsa, Oklahoma	BEA-0240, BES-0240.	Appeal of Assignment Order. If granted: The February 1, 1980, Temporary Assignment Order Issued to Busler Enterprises, Inc. by the Economic Regulatory Administration, Region V, regarding Champlin Petroleum Company's supply obligations to Busler would be rescinded.
Feb. 29, 1980	Chevron U.S.A., Inc., San Francisco, California	BEJ-0050	Motion for Protective Order. If granted: Chevron U.S.A., Inc. and Pride Refining, Inc. would enter into a Protective Order regarding documents in connection with Pride's Application for Exception (Case No. BEE-0651).
Feb. 29, 1980	DOE-Economic Regulatory Administration (Long Point Marina), Washington, D.C..	BRR-0027	Modification/Rescission of Remedial Order. If granted: The February 20, 1980, Final Remedial Order issued by the DOE (Case No. BRW-0013) to Long Point Marina would be rescinded.
Feb. 29, 1980	National Oil Jobbers Council, Washington, D.C.	BSG-0016	Request for Special Redress. If granted: The Special Report Orders issued by The Office of Enforcement to petroleum jobbers would be modified.
Feb. 29, 1980	Vickers Petroleum Corporation, Wichita, KN	BES-0051, BEA-0239.	Request for Stay, Appeal of an Entitlement Notice. If granted: The December 1979, Entitlement Notice would be modified with respect to Vickers Petroleum Corp.'s entitlements purchase obligations and the firm would receive a stay of the obligations pending final determination on its Appeal.

Notices of Objection Received

[Week of Feb. 22, 1980, to Feb. 29, 1980]

Date	Name and location of applicant	Case No.
2/25/80	Cunningham Oil Co., Columbus, Ga.	DEE-3490
2/21/80	Marty's Amoco, Laurel, Md.	DEE-7354
2/25/80	Gold Oil Co., Houston, Tex.	BXE-0454
2/25/80	Tropicana Petroleum Ltd., Paramount, Calif.	BEE-0426
2/26/80	Pennant Petroleum Co., Tulsa, Okla	DEE-3931
2/26/80	Big D&W Refining & Solvents	DEE-7895
2/26/80	Petroleum Products Corp., Harrisburg, Pa.	DEE-2888
2/27/80	Coggin Oil Co., Caraway, Ark.	BEE-0400
2/22/80	Seaview Exxon	DEE-6834
2/22/80	Mohammed Abzakh	DEE-5762

List of Cases Involving the Standby Petroleum Product Allocation Regulations for Motor Gasoline

Week of February 22 Through February 29, 1980

If granted: The following firms would be granted relief which would increase their base period allocation of motor gasoline.

February 22, 1980

Daigh Automotive Engineering, BXE-0914, California.
Isiminger's Arco, BEE-0903, Pennsylvania.
R&R Texaco (Strother), BXE-0904, Louisiana.
Sumner's Amoco, BEE-0911, Virginia

February 25, 1980

Belle Haven Sunoco, BEE-0912, District of Columbia.
Dow Jones & Co., Inc., BEE-0506, New Jersey.
Engel Oil Co., Inc., BEE-0909, Minnesota.
L.H. Smith Oil Corp., BEE-0913, Indiana.

February 26, 1980

Lyons Oil Co., BEE-0919, Wisconsin.

February 27, 1980

Cone Oil Co., Inc., BEE-0545, Tennessee.
Peninsula Transportation, BEE-0928, Virginia.

February 29, 1980

Allen's Fairway, BEE-0940, Mississippi.
Gluth Oil Co., BEE-0941, Michigan.
Wilson's Arco, Inc., BEE-0924, Rhode Island.
Wilson's Arco, Inc., BEE-0923, Rhode Island.

Items retrieved—15.

[FR Doc. 80-11395 Filed 4-14-80; 8:45 am]

BILLING CODE 6450-01-M

Issuance of Proposed Decisions and Orders; February 25 Through February 29, 1980

Notice is hereby given that during the period February 25 through February 29, 1980, the Proposed Decisions and Orders which are summarized below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to Applications for Exception which had been filed with that Office.

Under the procedures which govern the filing and consideration of exception applications (10 CFR, Part 205, Subpart D), any person who will be aggrieved by the issuance of the Proposed Decision and Order in final form may file a written Notice of Objection within ten days of service. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this Notice or the date of receipt by an aggrieved person of actual notice, whichever occurs first. The applicable procedures also specify that if a Notice of Objection is not received from any aggrieved party within the time period specified in the regulations, the party will be deemed to consent to the issuance of the Proposed Decision and Order in final form. Any aggrieved party that wishes to contest any finding or conclusion contained in a Proposed Decision and Order must also file a detailed Statement of Objections within 30 days of the date of service of the Proposed Decision and Order. In that Statement of Objections an aggrieved party must specify each issue of fact or law contained in the Proposed Decision and Order which it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these Proposed Decisions and Orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street NW., Washington, D.C. 20461, Monday through Friday, between the hours of 1 p.m. and 5 p.m., e.s.t., except Federal holidays.

Melvin Goldstein,

Director, Office of Hearings and Appeals.

April 10, 1980.

Proposed Decision and Order

C & C Oil Co., Inc., Huntington, Ind., BEE-0401, gasohol.

The C & C Oil Company, Inc. filed an Application for Exception from the provisions of 10 CFR, Part 211. The exception request, if granted, would increase the firm's allocation of unleaded motor gasoline so that it could blend and sell gasohol. On February 26, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be granted.

Church & Son Oil Co., Clayton, Ga., BEE-0377, gasohol.

Church & Son Oil Company filed an Application for Exception from the provisions of 10 CFR, Part 211. The exception request, if granted, would increase the firm's allocation of unleaded motor gasoline so that it could blend and sell gasohol. On February 26, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be granted.

D. Gilliam Production Co., El Dorado, Ark., DEE-0412, crude oil.

D. Gilliam Production Company filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit the firm to sell a certain portion of the crude oil produced for the benefit of the working interest owners from the Cook-Gilliam Lease at market prices. On February 29, 1980, the DOE issued a Proposed Decision and Order and tentatively determined that exception request should be denied.

Foeman Shelton Distributor, Inc., Morganfield, Ky., DEE-8268, gasohol.

Foeman Shelton Distributor, Inc. filed an Application for Exception from the provisions of 10 CFR, Part 211. The exception request, if granted, would increase the firm's allocation of unleaded motor gasoline so that it could blend and sell gasohol. On February 29, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be granted.

General Machine Corp., Duo-Matic Olsen, Inc., Emmaus, Pa., Park Forest South, Ill., BEE-0422, BEE-0648, testing requirements.

General Machine Corporation and Duo-Matic Olsen, Inc. filed Applications for Exception from the provisions of 10 CFR, Part 430, the Energy Conservation Program for Consumer Products. If the exception requests are granted, the applicants will not be required to perform energy efficiency and consumption tests on their combination fuel furnances and boilers. On February 26, 1980, the Department of Energy issued a Proposed Decision and Order in which it tentatively determined that General Machine's and Duo-Matic Olsen's exception applications be granted.

Hobart Corp., Cleveland, Ohio, DEE-4459, dishwasher.

On September 5, 1979, Hobart Corporation filed an Application for Exception from the provisions of Appendix C Subpart B of 10 CFR 430. The exception request, if granted, would permit Hobart to test the Kitchen Aid dishwasher Model KD-19 using 120°F inlet water instead of 140°F inlet water. On February 26, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be granted.

Kern County Refinery, Inc., Bakersfield, Calif., DXE-0098, crude oil.

In accordance with Decisions and Orders issued to Kern County Refinery, Inc. which granted the firm exception relief from the provisions of 10 CFR 211.67 (the Entitlements Program) the firm submitted actual financial data for its fiscal year ended March 31, 1978. On February 25, 1980, after reviewing the level of exception relief granted to Kern under the applicable standards, the DOE issued a Proposed Decision and Order which determined that Kern should purchase $2,182,113 of entitlements.

Stubbs Oil Co., Inc., Statesboro, Ga., BEE-0459, gasohol.

Stubbs Oil Co., Inc. filed an Application for Exception from the provisions of 10 CFR Part 211. The exception request, if granted, would permit Stubbs to receive an increased allocation of unleaded motor gasoline for the purpose of blending and marketing gasohol. On February 26, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be granted.

Zenith Oil Co., Minneapolis, Minn., DEE-2556, No. 2 heating oil.

Zenith Oil Company (Zenith) filed an Application for Exception from the provisions of the Mandatory Petroleum Price Regulations. The exception request, if granted, would permit Zenith to be relieved of its obligation to comply with the terms of a Remedial Order which the Regional Administrator of FEA Region V had issued to the firm on August 10, 1977. On February 26, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

Petitions Involving the Motor Gasoline Allocation Regulations

The following firms filed Application for Exception from the provisions of the Motor Gasoline Allocation Regulations. The exception requests, if granted, would result in an increase in the firms' base period allocation of motor gasoline. The DOE issued Proposed Decisions and Orders which determined that the exception requests be granted.

Company Name, Case Number, and Location

Bosar Enterprises, DEE-7870; DEL-7870; DES-7870, New York, NY.
Earl Wilkins, DEE-6041, Reform, AL.
Larry Mills Exxon, DEE-7105, Olancha, CA.
Surry Lane Service, DEE-6566, Hempstead, NY.

Petitions Involving the Motor Gasoline Allocation Regulations

The following firms filed Applications for Exception from the provisions of the Motor Gasoline Allocation Regulations. The exception requests, if granted, would result in an increase in the firms' base period allocation of motor gasoline. The DOE issued Proposed Decisions and Orders which determined that the exception requests be denied.

Company Name, Case Number, and Location

"F" Street Mobil, DEE-6668, Philadelphia, PA.
General Dynamics Corp., DEE-7152, Groton, CT.
Joe's 66 Service, DEE-4033, Columbus, NB.
Pomperaug Shell, DEE-7402, Woodbury, CT.
Regan's Service, DEE-7111, Newton, MA.
Richard's R. Wheeler, Inc., DEE-5364, Worcester, MA.
Rockside and 21 Shell, DEE-6559, Independence, OH.
Russell Distributing, DEE-4174, Rector, AR.
Steamboat Springs Station No. 1, DEE-7534, Washington, DC.
Valley Exxon, DEE-7158, Yountville, CA.

[FR Doc. 80-11396 Filed 4-14-80; 8:45 am]
BILLING CODE 6450-01-M

Office of Assistant Secretary for International Affairs

Proposed Subsequent Arrangement

Pursuant to Section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160), notice is hereby given of a proposed "subsequent arrangement" under the Additional Agreement Between the Government of the United States of America and the European Atomic Energy Community (EURATOM) Concerning the Peaceful Uses of Atomic Energy and the Agreement for Cooperation Between the Government of the United States of America and the Government of Switzerland.

The subsequent arrangements to be carried out under the above mentioned agreements involve approval of the following retransfer:

RTD/SD(EU)-28, from West Germany to Switzerland, 473.12 grams of uranium, containing 431.0 grams of U-235 (91.10%) to be irradiated in the SAPHIR reactor for production of Molybdenum 99. It is intended that the irradiated material will be retransfered to West Germany for separation of the uranium and molybdenum.

In accordance with Section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that approval of this retransfer will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

For the Department of Energy.

Dated: April 9, 1980.

Harold D. Bengelsdorf,

Director for Nuclear Affairs, International Nuclear and Technical Programs.

[FR Doc. 80-11250 Filed 4-14-80; 8:45 am]
BILLING CODE 6450-01-M

Proposed Subsequent Arrangement

Pursuant to Section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160), notice is hereby given of a proposed "subsequent arrangement" under the Additional Agreement Between the Government of the United States of America and the European Atomic Energy Community (EURATOM) Concerning the Peaceful Uses of Atomic Energy.

The subsequent arrangement to be carried out under the above mentioned agreement involves approval of the following sale:

S-EU-638, United States to United Kingdom, 500 micrograms of Plutonium-242 (greater than 99.96%) to be used as radio tracer for Pu-238 and Pu-239 in the analysis of bioassay and environmental samples.

In accordance with Section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that the furnishing of the nuclear material will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than fifteen days after the date of publication of this notice.

For the Department of Energy.

Dated: April 9, 1980.

Harold D. Bengelsdorf,

Director for Nuclear Affairs, International Nuclear and Technical Programs.

[FR Doc. 80-11251 Filed 4-14-80; 8:45 am]
BILLING CODE 6450-01-M

Proposed Subsequent Arrangement

Pursuant to section 131 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2160) notice is hereby given of a proposed "subsequent arrangement" under the Additional Agreement Between the Government of the United States of America and the European Atomic Energy Community (EURATOM) Concerning the Peaceful Uses of Atomic Energy and the Agreement for Cooperation Between the Government of the United States of America and the Government of Japan.

The subsequent arrangement to be carried out under the above mentioned agreements involves the approval of the following retransfer:

RTD/EU(JA)-34, from Japan to West Germany, one fission counter, containing 0.40 grams of uranium, enriched to 93.16% in U-235, to be used for neutron flux measurements for the study of high temperature gas cooled reactors.

In accordance with section 131 of the Atomic Energy Act of 1954, as amended, it has been determined that approval of this retransfer will not be inimical to the common defense and security.

This subsequent arrangement will take effect no sooner than April 30, 1980.

For the Department of Energy.

Dated: April 9, 1980.

Harold D. Bengelsdorf,

Director for Nuclear Affairs, International Nuclear and Technical Programs.

[FR Doc. 80-11252 Filed 4-14-80; 8:45 am]
BILLING CODE 6450-01-M

Office of the Special Counsel for Compliance

Action on Consent Order With Exxon Corp.

AGENCY: Department of Energy (DOE).

ACTION: Adoption of proposed consent order as final.

SUMMARY: The Office of the Special Counsel for Compliance (OSC) hereby gives the notice required by 10 CFR § 205.199J that it has adopted the consent order with Exxon Corporation (Exxon), executed on and published for comment in 45 FR 9993 on February 14,

1980. The consent order resolves all issues of compliance with the DOE Mandatory Petroleum Price Regulations, at §§ 212.83(b) and 212.84, concerning the pricing of imported crude oil in interaffiliate transactions in the period August 1973 through May 1975. In the consent order, Exxon agrees to a $377,200.00 reduction in increased costs of crude oil allocated to gasoline.

As required by regulation OSC received comments on the consent order for a period of not less than 30 days following publication of the notice of the consent order. One comment was received. OSC considered that comment and determined that the consent order should be made final without modification. The consent order is effective as an order of the Department of Energy (DOE) on April 15, 1980.

FOR FURTHER INFORMATION CONTACT: Marcell R. Anthony, Assistant Solicitor to the Special Counsel for Compliance, Department of Energy, 1200 Pennsylvania Avenue, N.W., Room 3109, Washington, D.C. 20461, 202–633–8292.

Copies of the consent order may be received free of charge by written request to: Exxon Consent Order Request, Office of Special Counsel, Department of Energy, 1200 Pennsylvania Avenue, N.W., Rm. 3109, Washington, D.C. 20461.

Copies may also be obtained in person at the same address or at the Freedom of Information Reading Room, Forrestal Building, 100 Independence Avenue, S.W., Washington, D.C., Room GB-145.

SUPPLEMENTARY INFORMATION:

The Consent Order

On February 14, 1980, OSC published notice in the **Federal Register** at page 9993, announcing the execution of a consent order between Exxon and OSC. In compliance with DOE regulations, that notice, and a press release issued on February 4, 1980, briefly summarized the consent order and the facts behind it. The notice and press release also gave instructions for obtaining copies of the consent order.

The consent order can be summarized as follows:

1. The consent order resolves a Notice of Proposed Disallowance issued to Exxon by the Federal Energy Administration.

2. The raised issues in the Notice were resolved by a reduction of Exxon's increased costs of crude oil allocated to gasoline by $377,200.00.

3. The provisions of 10 CFR § 205.199J are applicable to the Consent Order.

Comment Received

One comment was received. This comment was submitted by a trade association representing wholesale-consumer interests in a product which is not currently covered. It states that the consent order fails to bring relief on a volumes-purchased basis directly to consumers of that product, jet fuel, who have been overcharged during the period in question.

The comment does not take cognizance of the fact that the amount in question is relatively small to permit any meaningful partition or allocation. Thus, any allocation of the remedy over all products would result in negligible impact upon the prices of those products, particularly the prices of products like jet fuel which are not currently covered under the regulations. Moreover, the amount represents a crude *cost* contested as excessive, rather than an alleged overcharge, as advanced in the comment. Clearly, there is no overcharge to be allocated. Given this fact, the reduction in current crude oil costs allocated to gasoline provides a tangible benefit whereas the allocation of costs among all products would have virtually no effect in this case.

OSC has considered the comment submitted, and as a result has found no reason to modity or reject the consent order. Accordingly OSC has determined that the proposed consent order with Exxon should be made final, effective April 15, 1980.

Issued in Washington, D.C., March 26, 1980.

Paul L. Bloom,

Special Counsel for Compliance.

[FR Doc. 80-11394 Filed 4-14-80; 8:45 am]

BILLING CODE 6450-01-M

ENVIRONMENTAL PROTECTION AGENCY

[80P-67; FRL 1462-3]

ICI Americas, Inc.; Renewal of Temporary Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has renewed the temporary tolerance for residues of the insecticide permethrin, the *cis* and *trans* isomers of (3-phenoxyphenyl) methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclorpropanecarboxylate), in or on the raw agricultural commodity celery at 5 parts per million (ppm).

DATE: This temporary tolerance expires on January 25, 1981.

FOR FURTHER INFORMATION CONTACT: Franklin D. R. Gee, Product Manager (PM) 17, Room E-341 (TS-767), Office of Pesticide Programs, Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460, (202–426–9417).

SUPPLEMENTARY INFORMATION: In the **Federal Register** of March 7, 1979 (44 FR 12493) EPA announced the establishment of a temporary tolerance for residues of the insecticide permethrin (*cis* and *trans* isomers of (3-phenoxyphenyl) methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclorpropanecarboxylate) in or on the raw agricultural commodity celery at 5 ppm. The tolerance was established in response to a pesticide petition (PP 8G 2029) submitted by ICI Americas, Inc. That temporary tolerance permitted the marketing of the celery treated in accordance with experimental use permit 10182–EUP–9. It expired January 25, 1980.

ICI Americas, Inc requested a one-year extension of this temporary tolerance to permit continued testing to obtain additional data and to permit the marketing of the above raw agricultural commodity when treated in accordance with the provisions of experimental use permit 10182–EUP–9 which has been extended under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended in 1972, 1975, and 1978 (92 Stat. 819; 7 U.S.C. 136).

The scientific data reported and all other relevant material were evaluated, and it was determined that extension of the temporary tolerance would protect the public health. Therefore, the temporary tolerance has been extended on condition that the experimental use permit be used with the following provisions:

1. The total amount of active ingredient to be used will not exceed the quantity authorized by the experimental use permit; and

2. ICI Americas, Inc., will immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The firm will also keep records of production, distribution, and performance and upon request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This temporary tolerance expires January 25, 1981. Residues not in excess of this temporary tolerance remaining in or on the raw agricultural commodity celery after expiration of this tolerance 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 any scientific data or experience with this pesticide indicate such revocation is necessary to protect the public health.

(Sec. 408(j), 68 Stat. 561; (21 U.S.C. 346a(j)))

Dated: April 9, 1980.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 80-11401 Filed 4-14-80; 8:45 am]

BILLING CODE 6560-01-M

[OPP-50463A; FRL 1462-2]

Issuance of Experimental Use Permit; Correction

On Tuesday, March 18, 1980 in FR Doc. 80-8196 (45 FR 17201), information appeared pertaining to the issuance of an experimental use permit, No. 476-EUP-97, to Stauffer Chemical Co. In the title, Summary and Supplementary Information sections the active ingredient should have read "S-propyl dipropylthiocarbamate alternate formula containing R-29148". (PM-25, Robert J. Taylor, Rm. E-359, Telephone: 202/755-2196.

Dated: April 9, 1980.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 80-11402 Filed 4-14-80; 8:45 am]

BILLING CODE 6560-01-M

[OPP-50464A, FRL 1462-1]

Issuance of Experimental Use Permit; Correction

On Tuesday, March 18, 1980 in FR Doc. 80-8197 (45 FR 17201), information appeared pertaining to the issuance of an experimental use permit, No. 476-EUP-99, to Stauffer Chemical Co. In the title, SUMMARY, and SUPPLEMENTARY INFORMATION sections the active ingredient should have read "S-ethyl dipropylthiocarbamate alternate formula contining R-29148". (PM-25, Robert J. Taylor, Rm. E-359, Telephone: 202/755-2196)

Dated: April 9, 1980.

Douglas D. Campt,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 80-11403 Filed 4-14-80; 8:45 am]

BILLING CODE 6560-01-M

FEDERAL COMMUNICATIONS COMMISSION

[BC Dockets Nos. 80-140, 80-141; Files Nos. BPH-10922, BPH-780831AL]

Broadcasting Enterprises, Inc. and Logan County Broadcasting Co.; Hearing Designation Order

Adopted: March 28, 1980.

Released: April 10, 1980.

In re Applications of Broadcasting Enterprises, Inc., Caulksville, Arkansas, Req. 95.3 MHz, Channel 237 0.68 kW (H&V), 568.5 feet, BC Docket No. 80-140, File No. BPH-10922; Gordon Hixson tr/as Logan County Broadcasting Company, Paris, Arkansas, Req: 95.3 MHz, Channel 237 0.7 kW (H&V), 562 feet, BC Docket No. 80-141, File No. BPH-780831AL; for construction permits for a new FM station.

1. The Commission, by the Chief, Broadcast Bureau, acting pursuant to delegated authority, has under consideration the above-captioned mutually exclusive applications.

2. Logan's ascertainment survey appears deficient. Logan failed to provide a racial or ethnic demographic breakdown of the community of Paris; it does not appear that Logan interviewed leaders of women's groups, minority groups, the elderly, youth, public safety, health and welfare, and recreation; Logan failed to indicate when the community leader and the general public surveys took place; and Logan did not state who conducted the community leader interviews. An ascertainment issue will be specified.

3. The respective proposals, although for different communities, would serve substantial areas in common. Consequently, in addition to determining, pursuant to Section 307(b) of the Communication's Act of 1934, as amended, which of the proposals would better provide a fair, efficient and equitable distribution of radio service, a contingent comparative issue will also be specified.

4. Except as indicated by the issues specified below, the applicants are qualified to construct and operate as proposed. However, since the proposals are mutually exclusive, they must be designated for hearing in a consolidated proceeding.

5. Accordingly, It Is Ordered, That, pursuant to Section 309(a) of the Communications Act of 1934, as amended, the applications are designated for hearing in a consolidated proceeding, at a time and place to be specified in a subsequent Order, upon the following issues:

1. To determine the areas and populations which would receive primary aural service (1.0 mV/m or greater in the case of FM) from the proposals and the availability of other primary service to such areas and populations.

2. To determine the efforts of Logan to ascertain the needs and problems of the area to be served and the means by which the applicant proposes to meet those needs and problems.

3. To determine, in the light of Section 307(b) of the Communications Act of 1934, as amended, which of the proposals would provide a fair, efficient, and equitable distribution of radio service.

4. To determine, in the event it is concluded that a choice between the applicants should not be based solely on considerations relating to Section 307(b), which of the proposals would, on a comparative basis, best serve the public interest.

5. To determine, in the light of the evidence adduced pursuant to the foregoing issues, which, if any, of the applications should be granted.

6. It Is Further Ordered, That, prior to the grant of the construction permit, the presiding Administrative Law Judge shall determine whether the winning applicant would be one mile short-spaced with a proposed operation in Springdale, Arkansas (RM-3373), and if so, whether the winning applicant has shown that a waiver of § 73.207 of the Commisison's Rules is warranted.

7. It Is Further Ordered, That, to avail themselves of the opportunity to be heard, the applicants herein shall, pursuant to § 1.221(c) of the Commission's Rules, in person or by attorney, within 20 days of the mailing of this Order, file with the Commission in triplicate a written appearance stating an intention to appear on the date fixed for the hearing and to present evidence on the issues specified in this Order.

8. It Is Further Ordered, That the applicants herein shall, pursuant to Section 311(a)(2) of the Communications Act of 1934, as amended, and § 73.3594 of the Commission's Rules, give notice of the hearing (either individually or, if feasible and consistent with the Rules, jointly) within the time and in the manner prescribed in such Rule, and shall advise the Commission of the publication of such notice as required by § 73.3594(g) of the Rules.

Federal Communications Commission.

Jerold L. Jacobs,

Chief, Broadcast Facilities Division.

[FR Doc. 80-11276 Filed 4-14-80; 8:45 am]

BILLING CODE 6712-01-M

[Report No. B-5]

TV Broadcast Applications Accepted for Filing and Notification of Cutoff Date

Released: April 4, 1980.

Cutoff date: May 27, 1980.

Notice is hereby given that the applications listed below are accepted for filing. Because the applications listed below are in conflict with applications which were accepted for filing and listed previously as subject to a cut-off date for conflicting applications, no application which would be in conflict with any application listed below will be accepted for filing.

Petitions to deny the applications listed below and minor amendments thereto must be on file with the Commission not later than the close of business on May 27, 1980. Any application previously accepted for filing and in conflict with any application listed below may also be amended as a matter of right not later than the close of business on May 27, 1980. Amendments filed pursuant to this notice are subject to the provisions of § 73.3572(b) of the Commission's rules.

BPCT-791026KJ (new), Spokane, Washington, Frontier Media, Inc., Channel 22. ERP: Vis. 1197 kW; HAAT: 1707 feet.

BPCT-791026KF (new), Austin, Texas, Mountain Laurel Broadcasting, Inc., Channel 42. ERP: Vis. 5000 kW; HAAT: 1172 feet.

BPCT-791026KG (new), Austin, Texas, Television Corporation of Central Texas, Channel 42. ERP: Vis. 5000 kW; HAAT: 1393 feet.

BPCT-791026KH (new), Austin, Texas, Pappas Telecasting, Inc., Channel 42. ERP: Vis. 5000 kW; HAAT: 1288 feet.

BPCT-791025KE (new), Austin, Texas, Austin Telecasting Co., Channel 42. ERP: Vis. 5000 kW; HAAT: 1293 feet.

BPCT-791026KM (new), Tacoma, Washington, Tacoma Community TV, Inc., Channel 20. ERP: Vis. 5000 kW; HAAT: 1730 feet.

BPCT-791026KL (new), Tacoma, Washington, Family Broadcasting Company, Channel 20. ERP: Vis. 2094 kW; HAAT: 800 feet.

BPCT-791026LB (new), Omaha, Nebraska, Pappas Telecasting, Inc., Channel 42. ERP: Vis. 78.8 kW; HAAT: 511.5 feet.

BPCT-791129KM (new), Salt Lake City, Utah, Golden West Broadcasters, Channel 14. ERP: Vis. 1585 kW; HAAT: 3944 feet.

BPCT-791130LB (new), Salt Lake City, Utah, Salt Lake Broadcasters, Inc., Channel 14. ERP: Vis. 1750 kW; HAAT: 3688 feet.

BPCT-790910KE (new), Omaha, Nebraska, Katz Broadcasting Corp. of Omaha, Channel 15. ERP: Vis. 3020 kW; HAAT: 1316 feet.

BPCT-791026KN (new), Omaha, Nebraska, Mid-America Broadcasting, Inc., Channel 15. ERP: Vis. 5000 kW; HAAT: 1143 feet.

Federal Communications Commission.

William J. Tricarico,

Secretary.

[FR Doc. 80-11275 Filed 4-14-80; 8:45 am]

BILLING CODE 6712-01-M

FEDERAL MARITIME COMMISSION

Independent Ocean Freight Forwarder License Applicants

Notice is hereby given that the following applicants have filed with the Federal Maritime Commission applications for licenses as independent ocean freight forwarders pursuant to section 44(a) of the Shipping Act, 1916 (75 Stat. 522 and 46 U.S.C. 841(b)).

Persons knowing of any reason why any of the following applicants should not receive a license are requested to communicate with the Director, Bureau of Certification and Licensing, Federal Maritime Commission, Washington, D.C. 20573.

D. T. Maley, Assoc. (Donald T. Maley, dba), 195 Hempstead Ave., Rockville Center, NY 11570.

Concord International Forwarders, Inc., 5529 NW 84th Avenue, Miami, FL 33166.
Officers: Olga Fernandez, President/Secretary, Eduardo Leon, Vice President/Treasurer.

Expeditors International of Washington, Inc., 119 First Ave., South, Seattle, WA 98104.
Officers: John M. Kaiser, President, Mike Krummel, Vice President, Susan R. Kaiser, Secretary/Treasurer.

Rical Express Inc., 10420 La Cienega Blvd., Inglewood, CA 90304.
Officers: Ernest So, President, Calvin Ng, Vice President, Ricky Leung, Secretary, Francis So, Treasurer, Leung Choy Yuk Tsang, Director.

Aurora International Forwarding Inc., 5060 Shawline Drive, San Diego, CA 92111.
Officers: Paul H. Comtois, President, John C. Beima, Vice President, Judith Brewer, Secretary/Treasurer.

Louis A. Segarra, dba A.A.A. Customs Brokers, Calla Marina 151, San Juan, PR 00901.

Omni Express International Inc., 5305 West 102nd Street, Los Angeles, CA 90045.
Officers: Linda R. Ruoff, President, Isobel Pritchard, Vice President.

Horizon International (Earl E. Egan, Ronald J. Will, Samuel E. Millender, dba), 201 Napoleon Avenue, New Orleans, LA 70115.

Continental Forwarding Co. (John D. Cioffi, dba), P.O. Box 81222 AMF, Cleveland, OH 44181.

J. F. Lumpkin, CHB (Jimmy Franklin Lumpkin and Elizabeth Ann Lumpkin, dba), P.O. Box 4189, North Little Rock, AR 72116.

Jodari International Freight Forwarding Inc., 10216 SW First Street, Sweetwater, FL 33174.
Officers: Jorge Machado, President, Clara Y. Machado, Director.

IBEX International Forwarding Corp., 33-19 170th Street, Flushing, NY 11358.
Officer: Kenneth Carroll, President.

Chicago Cargo Corp., 5665 North Gage Street, Rm. 201, Rosemont, IL 60018.
Officers: Wm. D. Dean, President, Jeffrey W. Pearson, Secretary/Treasurer, Louwanne M. Sheftic, Director.

Whaling City Trucking Incorporated, dba Associated North American, 95 Cranston Street, Cranston, RI 02920.
Officers: Leonard Fishkin, President/Director, Joseph Samson, Vice President/General Manager, Betty McCarthy, Treasurer/Director, Clement A. Poulin, Secretary/Director.

Roger Alfonso, 5945 N.W. 113th Terrace, Hialeah, FL 33012.

Finsec Export Inc., 137-09 Eastgate Plaza, Springfield Gardens, NY 11413.
Officer: Robert F. Stalling, President/Secretary/Treasurer.

By the Federal Maritime Commission.

Dated: April 10, 1980.

Francis C. Hurney,

Secretary.

[FR Doc. 80-11369 Filed 4-14-80; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Banco Real International, Inc.

Corporation To Do Business Under Section 25(a) of the Federal Reserve Act; Establishment of U.S. Branch of a Corporation To Be Organized Under Section 25(a)

An application has been submitted for the Board's approval of the organization of a corporation to do business under section 25(a) of the Federal Reserve Act ("Edge Corporation"), to be known as Banco Real International, Inc., Chicago, Illinois. Banco Real International, Inc. would operate as a subsidiary of Banco Real S.A., Sao Paulo, Brazil. The proposed corporation has also applied for the Board's approval under section 211.4(c)(1) of Regulation K (12 CFR 211.4(c)(1)), to establish a branch in Houston, Texas. The factors that are to be considered in acting on these applications are set forth in section 211.4(a) of the Board's Regulation K (12 CFR 211.4(a)).

The applications may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of New York. Any person wishing to comment on the applications should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20051 to be received no later than May 8, 1980. 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, identify specifically any questions of fact that are in dispute, and summarize the

evidence that would be presented at a hearing.

Board of Governors of the Federal Reserve System, April 8, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-11288 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

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 engaged *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, increase 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, except as noted, received by the appropriate Federal Reserve Bank not later than May 3, 1980.

A. *Federal Reserve Bank of Cleveland* (Harry W. Hunning, Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

Banc One Corporation, Columbus, Ohio (financing activities; Ohio): to engage, through a subsidiary, Banc One Financial Corporation in the activities of making, acquiring, and selling, for its own account and for the account of others, loans and other extensions of credit including loans to finance agricultural production, commercial and industrial loans, and loans to individuals for household, family, and other personal expenditures; and servicing such loans and other extensions of credit for itself and for non-affiliated banks and for institutional investors. These activities will be performed from offices located at 100 East Broad Street, Columbus, Ohio and at 8060 Montgomery Road, Cincinnati, Ohio. The geographic area to be served from such offices will be Ohio.

B. *Federal Reserve Bank of San Francisco* (Harry W. Green, Vice President) 400 Sansome Street, San Francisco, California 94120:

Imperial Bancorp, Inglewood, California (commercial finance activities; Alaska, Arizona, California, Nevada and Oregon): to engage through its subsidiary, Imperial Credit Corporation, in the activities of making, acquiring or servicing loans and other extensions of credit for its own account and for the account of others as an insurance premium finance company, primarily engaged in insurance premium financing consisting of financing of premiums relating to both commercial and consumer property and casualty insurance. These activities will be conducted from offices in Los Angeles and Costa Mesa, California, serving Alaska, Arizona, California, Nevada, and Oregon. Comments on this application must be received by April 25, 1980.

C. *Federal Reserve Bank of Boston,* (Richard E. Randall, Vice President) 30 Pearl Street, Boston, Massachusetts 02106:

1. Multibank Financial Corp., Quincy Massachusetts, (data processing services; Massachusetts): to engage, through its direct subsidiary, Multibank Computer Corp., in processing bank related financial data. This activity would be conducted from an existing office in Auburn, Massachusetts, and would be performed for a single company located in Massachusetts. Comments on this application must be received by May 5, 1980.

2. Multibank Financial Corp., Quincy, Massachusetts (data processing services; Massachusetts): to engage, through its direct subsidiary, Multibank Computer Corp., in data processing services for customers of affiliated banks. These activities, which include demand deposit accounting, installment loan accounting and time deposit accounting, would be conducted from an existing office in Auburn, Massachusetts, servicing customers located throughout Massachusetts, Rhode Island, northern Connecticut, eastern New York, southern New Hampshire and southern Vermont. Comments on this application must be received by May 5, 1980.

D. *Other Federal Reserve Banks:* None.

Board of Governors of the Federal Reserve System, April 4, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11281 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

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, except as noted, received by the appropriate Federal Reserve Bank not later than May 8, 1980.

A. *Federal Reserve Bank of Atlanta* (Robert E. Heck, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

Barnett Banks of Florida, Inc., Jacksonville, Florida (check verification services; North Carolina and South Carolina): to engage through its subsidiary, Verifications, Inc., in offering check verification services including

authorizing subscribing merchants to accept certain personal purchase money checks and obligating Verifications, Inc. to purchase any properly verified checks which are subsequently dishonored. These activities will be conducted from the principal office of Verifications, Inc. located in Jacksonville, Florida, and will be offered throughout the States of North Carolina and South Carolina. Comments on this application must be received by April 29, 1980.

B. *Federal Reserve Bank of Kansas City* (John F. Zoellner, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

BBJ Incorporated, Ord, Nebraska (insurance activities; Nebraska): to continue to engage in general insurance activities, including the sale of fire and casualty, credit, life,and accident insurance, in a community with a population not exceeding 5,000. These activities would continue to be conducted from an office in Ord, Nebraska, serving Ord, Nebraska.

C. *Other Federal Reserve Banks:* None.

Board of Governors of the Federal Reserve System, April 8, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-11289 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Blackwater Bancshares, Inc.; Formation of Bank Holding Company

Blackwater Bancshares, Inc., Blackwater, Missouri, 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 Farmers Stock Bank, Blackwater, Missouri. 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, to be received not later than May 6, 1980. 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, April 7, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11285 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Elba State Co.; Formation of Bank Holding Company

Elba State Company, Elba, Nebraska, has applied for the Board's approval under § 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 (less directors' qualifying shares) of the voting shares of Elba State Bank, Elba, Nebraska. The factors that are considered in acting on the application are set forth in § 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, to be received not later than May 8, 1980. 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, April 8, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11280 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

First International Bancshares, Inc.; Proposed Acquisition of Silner Factors, Inc.

First International Bancshares, Inc., Dallas, Texas, has 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 substantially all of the assets of Silner Factors, Inc., Beverly Hills, California.

Applicant states that the proposed subsidiary would engage in the activities of wholesale factoring. These activities would be performed from offices of Applicant's subsidiary in Beverly Hills, California, and the geographic area to be served is the Los Angeles, California metropolitan area. 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 Dallas.

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 May 7, 1980.

Board of Governors of the Federal Reserve System, April 4, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11282 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Hibernia Bancshares Corp.; Formation of Bank Holding Comany

Hibernia Bancshares Corporation, San Francisco, California, has applied for the Board's approval under § 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 The Hibernia Bank. The factors that are considered in acting on the application are set forth in § 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 San Francisco. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than May 8, 1980. 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, April 8, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11284 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Indiana National Corp.; Proposed Retention of the Monument Life Insurance Co.

The Indiana National Corporation, Indianapolis, Indiana, has 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 retain voting shares of The Monument Life Insurance Company, Phoenix, Arizona.

Applicant states that the proposed subsidiary would continue to engage in the activities of underwriting as reinsurer credit life and credit accident and health insurance directly related to extensions of consumer credit by Applicant's subsidiaries. These activities would continue to be performed from offices of Applicant's subsidiary in Indianapolis, Indiana, and the geographic areas to be served are the eight counties comprising the Indianapolis SMSA. 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 Chicago.

Any views or requests for hearing should be submitted in writing and received by the Reserve Bank not later than May 8, 1980.

Board of Governors of the Federal Reserve System, April 8, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11287 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

K.B.J. Enterprises, Inc.; Acquisition of Bank

K.B.J. Enterprises, Inc., Sibley, Iowa, has applied for the Board's approval under section 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 19.98 percent of the voting shares of The Viking Corporation, Denison, Iowa, and indirectly acquiring Crawford County Trust and Savings Bank, Denison, 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 May 7, 1980. 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, April 7, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11283 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Lloyds Bank Limited; the Royal Bank of Scotland Group Limited; the Royal Bank of Scotland Limited; Proposed Acquisition of James Talcott Factors, Inc.

Lloyds Bank Limited, London, England, and The Royal Bank of Scotland Group Limited and The Royal Bank of Scotland Limited, both of Edinburgh, Scotland, 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)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission for their subsidiary Lloyds and Scottish Limited, Edinburgh, Scotland to acquire through its subsidiary Lloyds and Scottish America Corporation, all of the shares of James Talcott Factors, Inc., New York, New York.

Each applicant states that the proposed subsidiary would engage in the activity of factoring accounts receivable in both the retail and wholesale textile, apparel and related industries. These activities would be performed from offices of the proposed subsidiary in New York, New York, serving the thirty one most eastern states, and in Los Angeles, California, serving the nineteen most western states. 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 New York.

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 May 7, 1980.

Board of Governors of the Federal Reserve System, April 7, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11278 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Old Canal Bankshares II, Inc.; Formation of Bank Holding Company

Old Canal Bankshares II, Inc., Lockport, 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 100 per cent of the voting shares of Old Canal Bankshares, Inc., Lockport, Illinois, and thereby indirectly acquiring 80.04 per

cent of the voting shares of Heritage First National Bank of Lockport, Lockport, 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 May 8, 1980. 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, April 8, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11279 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Van Dyke Bank Holding Corp.; Formation of Bank Holding Company

Van Dyke Bank Holding Corp., Sioux City, 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 88.8 percent of the voting shares of First Trust and Savings Bank, Alta, 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 May 8, 1980. 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, April 8, 1980.

Griffith L. Garwood,

Deputy Secretary of the Board.

[FR Doc. 80-11286 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Central Bancorp; Formation of Bank Holding Company

Central Bancorp, Central City, Nebraska, has applied for the Board's approval under 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 90 percent or more of the voting shares of Central Bank, Central City, Nebraska. The factors that are considered in acting on the application are set forth in 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, to be received not later than April 30, 1980. 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, April 9, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-11376 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Citizens Security Bancshares, Inc.; Formation of Bank Holding Company

Citizens Security Bancshares, Inc., Bixby, Oklahoma, has applies for the Board's approval under 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 Citizens Security Bank and Trust Company, Bixby, Oklahoma. The factors that are considered in acting on the application are set forth in 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, to be received not later than May 9, 1980. 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, April 9, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-11377 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

Coronado Bancshares, Inc.; Formation of Bank Holding Company

Coronado Banchares, Inc., El Paso, Texas, has applied for the Board' approval under 3(a)(1) of the Bank Holding Compnay Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 84 percent or more of the voting shares of Coronado State Bank, EL Paso, Texas. The factors that are considered in acting on the application are set forth in 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 Reserve Bank, to be received not later than May 7, 1980. 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, April 9, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-11378 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

LeRoy Bancshares, Inc.; Formation of Bank Holding Company

LeRoy Bancshares, Inc., LeRoy, Kansas, 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 The First National Bank, LeRoy, Kansas. 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, to be received not later than May 9, 1980. 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, April 9, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-11379 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

National City Corp.; Acquisition of Bank

National City Corporation, Cleveland, Ohio, has applied for the Board's approval under 3(a)(3) of the Bank Holding Company Act (12 U.S.C. 1842(a)(3)) to acquire 100 per cent (less director's qualifying shares) of the voting shares of The Henry County Bank, Napoleon, Ohio. The factors that are considered in acting on the application are set forth in 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 Cleveland. Any person wishing to comment on the application should submit views in writing to the Reserve Bank to be received not later than May 9, 1980. 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, April 9, 1980.

Cathy L. Petryshyn,

Assistant Secretary of the Board.

[FR Doc. 80-11380 Filed 4-14-80; 8:45 am]

BILLING CODE 6210-01-M

GENERAL SERVICES ADMINISTRATION

Programmatic Environmental Impact Statement; Intent To Prepare

The General Services Administration (GSA) Region 8 intends to prepare a Programmatic Environmental Impact Statement that will address Federal agency space requirements in the Denver-Boulder Standard Metropolitan Statistical Area through the year 2000. This EIS will address the space needs generated by the anticipated growth of Federal agencies housed by GSA in the SMSA; the various alternatives of housing these agencies and all impacts associated with this growth.

The scoping process for this EIS will consist of a request for Federal, state and local agencies to assist GSA in identifying the appropriate scope of this EIS. The agencies contacted will be those normally consulted under the Intergovernmental Cooperation Act and OMB Circular A-95 procedures. Other organizations who have expressed interest in GSA programs will also be invited to identify the appropriate scope of this EIS. A scoping meeting will be held.

Suggestions or questions should be directed to Mr. Dean L. Frohardt, GSA Region 8 (8 PRG), Bldg. 41, Denver Federal Center, Denver, CO 80225. Telephone (303) 234-4357.

Dated: April 4, 1980.

P. J. Menardi,

Acting Regional Administrator.

[FR Doc. 80-11241 Filed 4-14-80; 8:45 am]

BILLING CODE 6820-23-M

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Office of Education

Advisory Council on Developing Institutions; Meeting

AGENCY: Advisory Council on Developing Institutions.

ACTION: Notice of meeting.

SUMMARY: This Notice sets forth the schedule and proposed agenda of a forthcoming meeting of the Advisory Council on Developing Institutions. This Notice also describes the functions of the Council. Notice of this meeting is required under the Federal Advisory Committee Act (Pub. L. 92-463, Sec. 10(a)(2)).

DATE: April 29, 1980; 9:00 a.m. to 5:00 p.m.

ADDRESS: Conference Room 3652, Regional Office Building 3, 7th and D Streets, SW., Washington, D.C. 20202.

FOR FURTHER INFORMATION CONTACT: Dr. Paul H. Carnell, Executive Director, Advisory Council on Developing Institutions, Regional Office Building 3, 7th and D Streets, SW., Washington, D.C. 20202 (202/245-9862).

SUPPLEMENTARY INFORMATION: The Advisory Council on Developing Institutions is established under Section 303 of the Higher Education Act of 1965, as amended (20 U.S.C. 1051-1056), unless otherwise noted. The Council is directed to:

Assist the Commissioner—

In identifying developing institutions through which the purposes of this title may be achieved; and

In establishing the priorities and criteria to be used in making grants under Section 304(a); and

In determining, for a Professor Emeritus Grant exceeding two academic years, the period of the additional award; and

In determining the stipend and dependency allowance for a Professor Emeritus Grant for each academic year of teaching or research.

The meeting of the Council shall be open to the public.

The proposed agenda includes: Preparation of the annual report to Congress; and other administrative matters and related business.

Records shall be kept of all Council proceedings, and shall be available for public inspection at the Office of the Executive Director of the Advisory Council on Developing Institutions, Room 3905, Regional Office Building 3, 7th and D Streets SW., Washington, D.C. 20202.

Signed at Washington, D.C., on April 10, 1980.

Paul H. Carnell,

Executive Director, Advisory Council on Developing Institutions.

[FR Doc. 80-11345 Filed 4-14-80; 8:45 am]

BILLING CODE 4110-02-M

Food and Drug Administration

Advisory Committees; Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also sets forth a summary of the procedures governing committee meetings and methods by which interested persons may participate in open public hearings conducted by the committees and is issued under section 10(a) (1) and (2) of the Federal Advisory Committee Act (Pub. L. 92-463, 86 Stat. 770-776 (5 U.S.C. App. I)), and FDA regulations (21 CFR Part 14) relating to advisory committees. The following advisory committee meetings are announced:

Committee name	Date, time, and place	Type of meeting and contact person
1. Anesthesiology Devices Section of the Respiratory and Nervous System Devices Panel.	May 15, 9 a.m., Rm. 425, 8757 Georgia Ave., Silver Spring, MD.	Closed committee discussion of trade secret data 9 a.m. to 10 a.m.; open public hearing 10 a.m. to 11 a.m.; open committee discussion 11 a.m. to 4 p.m.; David S. Shindell (HFK-430), 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7226

General function of the Committee. The Committee reviews and evaluates available data concerning the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons are encouraged to present information pertinent to the classification of anesthesia and respiratory therapy devices. Submission of data relative to tentative classification findings is also invited. Those desiring to make formal presentations should notify David S. Shindell by May 1, 1980, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, references to any data to be relied on, and also an indication of the approximate time required to make their comments.

Open committee discussion. The Committee will discuss the comments received in response to the proposed classification regulations for anesthesia and respiratory therapy devices, and it will review and discuss the safety and effectiveness data in a premarket approval application.

Closed committee discussion. The panel will review trade secret information in premarket approval application #P800003. This portion of the meeting will be closed to permit discussion of trade secret data (5 U.S.C. 552b(c)(4)).

Committee name	Date, time, and place	Type of meeting and contact person
2. General and Plastic Surgery Devices Section of the Surgical and Rehabilitation Devices Panel.	May 23, Rm. 525–529, H. H. Humphrey Bldg., 200 Independence Ave., SW., Washington, DC.	Open public hearing 8 a.m. to 9 a.m.; open committee discussion 9 a.m. to 9:30 a.m; closed committee discussion of trade secret data 9:30 a.m. to 11 a.m.; open committee discussion 11 a.m. to 4 p.m., Mark F. Parrish (HFK–410), 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7238

General function of the Committee. The Committee reviews and evaluates available data concerning the safety and effectiveness of devices currently in use and makes recommendations for their regulation.

Agenda—Open public hearing. Interested parties are encouraged to present information pertinent to the classification of the devices listed below to Mark Parrish. Submission of data relative to tentative classification findings is also invited. Those desiring to make formal presentations should notify Mark Parrish by May 16, 1980, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, references to any data to be relied on, and also an indication of the approximate time required to make their comments.

Open committee discussion. The panel will review a premarket approval application for an absorbable hemostatic agent, including in vitro studies, animal studies, and clinical evaluations of the agent; classify sunlamp tanning booths, silicone adhesives for use with implanted prosthetic devices, and cargile membrane; and review its previous classification recommendations for wound-dressing devices and materials.

Closed committee discussion. The panel will review trade secret information in a premarket approval application for an absorbable hemostatic agent. This portion of the meeting will be closed to permit discussion of trade secret data (5 U.S.C. 552b(c)(4)).

Each public advisory committee meeting listed above may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. The dates and times reserved for the separate portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairman determines will facilitate the committee's work.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this **Federal Register** notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairman's discretion.

Persons interested in specific agenda items to be discussed in open session may ascertain from the contact person the approximate time of discussion.

A list of committee members and summary minutes of meetings may be obtained from the Public Records and Documents Center (HFC–18), 5600 Fishers Lane, Rockville, MD 20857, between the hours of 9 a.m. and 4 p.m., Monday through Friday. The FDA regulations relating to public advisory committees may be found in 21 CFR Part 14.

The Commissioner, with the concurrence of the Chief Counsel, has determined for the reasons stated that those portions of the advisory committee meetings so designated in the notice shall be closed. The Federal Advisory Committee Act (FACA), as amended by the Government in the Sunshine Act (Pub. L. 94–409), permit such closed advisory committee meetings in certain circumstances. Those portions of a meeting designating as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information or a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files

compiled for law enforcement purposes; information the premature disclosure of which would would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necesary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, notably, deliberative sessions to formulate advice and recommendations to the agency on matters that do not independently justify closing.

Applications for reimbursement for participation in the meetings listed above should be sent to Ronald Wylie (HF-70), Office of Consumer Affairs, Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, rather than to the Hearing Clerk as prescribed in § 10.210 of the regulations (21 CFR 10.210). If you wish to submit an application, please call Ron Wylie at 301–443–2932. The time limits for applying for such reimbursement are as follows:

Committee meeting	Meeting date	Reimbursement applications must be received by
1. Anesthesiology Devices Section of the Respiratory and Nervous System Devices Panel.	May 15.....	April 30.
2. General and Plastic Surgery Devices Section of the Surgical and Rehabilitation Devices Panel.	May 23.....	May 2.

FDA has established expedited procedures for review of any application for reimbursement for participation in the meeting(s) announced in this notice. The Office of Consumer Affairs, FDA, will file any applications for reimbursement for participation in the meeting(s) announced in this notice in the docket for this notice.

Dated: April 8, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80-11056 Filed 4-14-80; 8:45 am]

BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming consumer exchange meeting to be chaired by LeRoy M. Gomez, District Director, Denver District Office, Denver, CO.

DATE: The meeting will be held at 9:30 a.m., Wednesday, April 23, 1980.

ADDRESS: The meeting will be held at the State Capitol Bldg., Rm. 305, Salt Lake City, UT 84114.

FOR FURTHER INFORMATION CONTACT: Kathy Brunner, Consumer Affairs Officer, Food and Drug Administration, Department of Health, Education, and Welfare, 500 U.S. Customhouse, Denver, CO 80202, 303–837–4915.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's Denver District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: April 8, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11058 Filed 4-14-80; 8:45 am]

BILLING CODE 4110-03-M

Consumer Participation; Open Meeting

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming consumer exchange meeting to be chaired by Alan L. Hoeting, District Director, Detroit District Office, Detroit, MI.

DATE: The meeting will be held at 9:30 a.m., Tuesday, May 6, 1980.

ADDRESS: The meeting will be held at the George Potter Larrick Building, Conference Room, 1560 E. Jefferson, Detroit MI.

FOR FURTHER INFORMATION CONTACT: Diane M. Place, Consumer Affairs Officer, Food and Drug Administration, Department of Health, Education, and Welfare, 1560 E. Jeffersson, Detroit MI 48207, 313–226–6260.

SUPPLEMENTARY INFORMATION: The purpose of this meeting is to encourage dialogue between consumers and FDA officials, to identify and set priorities for current and future health concerns, to enhance relationships between local consumers and FDA's Detroit District Office, and to contribute to the agency's policymaking decisions on vital issues.

Dated: April 8, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11059 Filed 4-14-80; 8:45 am]

BILLING CODE 4110-03-M

Medical Device Panels; Request for Nominations for Nonvoting Representatives of Consumer and Industry Interests on Public Advisory Panels

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This document invites nominations for nonvoting consumer and industry representatives to serve on certain public advisory panels of the Bureau of Medical Devices. Nominations will be accepted for current vacancies and for those that will or may occur on the panels or sections during the next 12 months. The Food and Drug Administration (FDA) has a special interest in ensuring that women, minority groups, the physically handicapped, and small businesses are adequately represented on advisory committees and, therefore, extends particular encouragement to nominations for appropriately qualified female and minority candidates, the physically handicapped, and nominations from small businesses that manufacture medical devices subject to the regulations.

DATE: Nominations should be received on or before May 15, 1980 for vacancies listed in this notice.

ADDRESS: All nominations and curricula vitae for consumer representatives must be submitted in writing to the Associate Commissioner for Consumer Affairs (HF–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. All nominations and curricula vitae for industry representatives must be submitted in writing to Kay A. Levin, Bureau of Medical Devices (HFK–50), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910.

FOR FURTHER INFORMATION CONTACT: For consumer interests: Naomi Kulakow, Office of Consumer Affairs (HF–70), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5006. For industry interests: Robert S. Kennedy, Bureau of Medical Devices (HFK–400), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7230.

SUPPLEMENTARY INFORMATION: FDA requests nominations for nonvoting members representing consumer and industry interests for the following panels or sections.

Device panel section	Approximate date representative needed	
	Consumer	Industry
1. Surgical and rehabilitation devices panel:		
a. Orthopedic devices section	8/31/80	NA
b. Physical medicine devices section	NA	8/31/80
2. Ophthalmic; ear, nose, and throat; and dental devices panel: a. Ear, nose, and throat devices section	10/31/80	NA
3. Respiratory and nervous system devices panel: a. Neurological devices section	11/30/80	11/30/80
4. General medical devices panel: a. Gastroenterology-urology devices section	NA	12/31/80
5. Obstetrics-gynecology and radiologic devices panel: a. Obstetrics-gynecology devices section	1/31/81	NA
6. Clinical chemistry and hematology devices panel:		
a. Clinical chemistry section	NA	2/28/81
b. Clinical toxicology section	NA	2/28/81
7. Immunology and microbiology devices panel:		
a. Immunology devices section	NA	2/28/81
b. Microbiology devices section	NA	2/28/81

In accordance with the Medical Device Amendments of 1976 (Pub. L. 94–295, 90 Stat. 539–583), the functions of the panels and sections listed above are to (1) review and evaluate available data concerning the safety and effectiveness of devices currently in use, (2) advise the Commissioner of Food and Drugs regarding recommended classification of these devices into one of three regulatory categories, (3) recommend the assignment of a priority for the application of regulatory requirements for devices classified in the standards or premarket approval category, (4) advise on any possible risks to health associated with the use of devices, (5) advise on formulation of product development protocols and review premarket approval applications for those devices classified in the premarket approval category, (6) review classification of devices to recommend changes in classification as appropriate, (7) recommend exemption of certain devices from the application of portions of the act, (8) advise on the necessity to ban a device, (9) and respond to requests from the agency to review and make recommendations on specific issues or problems concerning the safety and effectiveness of devices.

Section 513 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) provides that each medical device panel include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Each of the sections identified in this notice will have a representative of consumer interests and a representative of industry interests.

Any interested person may nominate one or more qualified persons as a nonvoting member of a particular advisory panel or section to represent consumer interests as identified in this notice. Any organization in the medical device manufacturing industry ("industry interests") wishing to participate in the selection of an appropriate nonvoting member of a particular panel or section may nominate one or more qualified persons to represent industry interests.

Nominations shall state that the nominee is aware of the nomination, is willing to serve as a member of an advisory panel, and, in the case of a consumer representative, appears to have no conflict of interest. The nomination should state whether the nominee is interested only in a particular advisory panel or section or in any advisory panel or section. A complete curriculum vitae of each nominee shall be included. The term of office is approximately 3 years.

The agency has instituted, on a trial basis, a new selection process for members representing consumer interests. This process temporarily replaces the procedures set out in 21 CFR 14.84(c). The voting groups that have previously elected consumer representatives have selected a consortium of consumer organizations. This consortium will recommend two candidates to the agency, and agency staff will make the final selection.

Regarding nominations for members representing the interests of the device manufacturing industry, a letter will be sent to each organization that has made a nomination, together with a complete list of all such organizations and the nominees. This letter will state that it is the responsibility of each organization to consult with the others in selecting a single nonvoting member representing industry interests for that particular committee within 30 days after receipt of the letter.

This notice is issued under the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770–776 (5 U.S.C. App. I)) and 21 CFR Part 14, relating to advisory committees.

Dated: April 8, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11057 Filed 4–14–80; 8:45 am]

BILLING CODE 4110–03–M

Public Health Service

Health Maintenance Organizations

AGENCY: Public Health Service, HEW.

ACTION: Notice, continued regulation of health maintenance organizations: determination of noncompliance.

SUMMARY: On September 25, 1979, the Director of the Office of Health Maintenance Organizations determined that Manhattan Health Plan, (MHP), 425 East 61st Street, New York, New York 10021, a federally qualified health maintenance organization (HMO), was not in compliance with the assurance it had provided to the Secretary that it would maintain a fiscally sound operation. The determination of noncompliance does not itself affect the status of MHP as a federally qualified HMO. Rather, MHP has been given the opportunity to and has, in fact, initiated corrective action to bring itself into compliance with the assurances it gave the Secretary.

FOR FURTHER INFORMATION CONTACT: Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443–4106.

SUPPLEMENTARY INFORMATION: Under Section 1312(b)(1) of the Public Health Service Act (42 U.S.C. 300e–11(b)(1)) (the Act), if the Secretary makes a determination under Section 1312(a) that a qualified HMO which provided assurances to the Secretary under

section 1310(d)(1) is not organized or operated in the manner prescribed by section 1301(c), then he shall (1) notify the HMO in writing of the determination, (2) direct the HMO to initiate such action as may be necessary to bring it into compliance with the assurances, and (3) publish the determination in the **Federal Register.**

Dated: April 7, 1980.

Howard R. Veit,

Director, Office of Health Maintenance Organizations.

[FR Doc. 80-11336 Filed 4-14-80; 8:45 am]

BILLING CODE 4110-85-M

Health Maintenance Organizations

AGENCY: Public Health Service, HEW.

ACTION: Notice, continued regulation of health maintenance organizations: determination of noncompliance.

SUMMARY: On August 24, 1979, the Director of the Office of Health Maintenance Organizations determined that American Health Plan, Inc. (AHP), 1701 Northeast 164th Street, North Miami Beach, Florida 33162, a federally qualified health maintenance organization (HMO), was not in compliance with the assurance it had provided to the Secretary that it would maintain a fiscally sound operation. The determination of noncompliance does not itself affect the status of AHP as a federally qualified HMO. Rather, AHP has been given the opportunity to and has, in fact, initiated corrective action to bring itself into compliance with the assurances it gave the Secretary.

FOR FURTHER INFORMATION CONTACT: Howard R. Veit, Director, Office of Health Maintenance Organizations, Park Building, 3rd Floor, 12420 Parklawn Drive, Rockville, Maryland 20857, 301/443-4106.

SUPPLEMENTARY INFORMATION: Under Section 1312(b)(1) of the Public Health Service Act (42 U.S.C. 300e-11(b)(1)) (the Act), if the Secretary makes a determination under Section 1312(a) that a qualified HMO which provided assurances to the Secretary under section 1310(d)(1) is not organized or operated in the manner prescribed by section 1301(c), then he shall (1) notify the HMO in writing of the determination, (2) direct the HMO to initiate such action as may be necessary to bring it into compliance with the assurances, and (3) publish the determination in the **Federal Register.**

Dated: April 7, 1980.

Howard R. Veit,

Director, Office of Health Maintenance Organizations.

[FR Doc. 80-11337 Filed 4-14-80; 8:45 am]

BILLING CODE 4110-85-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Goshute Indians; Plan for the Use and Distribution of Goshute Indians' Judgment Funds Awarded in Dockets 326-B and 326-J Before the Indian Claims Commission

April 2, 1980.

This notice is published in exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary for Indian Affairs by 209 DM 8.

The Act of October 19, 1973 (Pub. L. 93-134, 87 Stat. 466), requires that a plan be prepared and submitted to Congress for the use or distribution of funds appropriated to pay a judgment of the Indian Claims Commission or Court of Claims to any Indian tribe. Funds were appropriated by the Act of December 18, 1975, 89 Stat. 826, in satisfaction of the award granted to the Goshute Indians in Indian Claims Commission Dockets 326-B and J. The plan for the use and distribution of the funds was submitted to the Congress with a letter dated July 12, 1979, and was received (as recorded in the Congressional Record) by the House of Representatives on July 17, 1979, and the Senate on July 19, 1979. Congress not having adopted a resolution disapproving it, the plan became effective on October 19, 1979, as provided by Section 5 of the 1973 Act, *supra.*

Publication of this plan has been delayed pending passage of S.J. Resolution 108 (which became Pub. L. 96-194 on February 21, 1980) to validate plans submitted after the deadlines specified in the 1973 Act, *supra.*

The plan reads as follows:

"The funds appropriated by the Act of December 18, 1975, 89 Stat. 826, in satisfaction of an award granted to the Goshute Indians in Dockets 326-B and J before the Indian Claims Commission, less attorney fees and litigation expenses, and including all interest and investment income accrued, shall be used and distributed as provided herein.

The funds shall be divided by the Secretary of the Interior (hereinafter 'Secretary') on the basis of the respective tribal rolls of the Confederated Tribes of the Goshute Reservation (hereinafter 'Goshute Tribe') and the Skull Valley Tribe of Utah (hereinafter 'Skull Valley Tribe') developed pursuant to this plan.

Goshute and Skull Valley Tribal Rolls

To effect the division of the funds the Secretary shall prepare, in cooperation with the respective tribal governing bodies and enrollment committees, tribal rolls containing the names of all eligible persons born on or prior to and living on the effective date of this plan.

In order to prepare an official roll for the Goshute Tribe the Secretary shall utilize as the tribal base roll the Agency Census of January 1, 1939, as corrected by the Agency Census of January 31, 1941, and including those whose names were not removed by November 24, 1941, and criteria and procedures for enrollment specified in the tribe's constitution and bylaws and Ordinance no. 76-G-13, as amended October 16, 1976.

In order to prepare an official roll of the Skull Valley Tribe the Secretary shall utilize the tribal enrollment ordinance of June 28, 1956.

Any additional enrollment procedures required for either tribe shall be promulgated by the Secretary. The decision of the Secretary concerning eligibility to appear on the Goshute tribal base roll or on the Goshute and Skull Valley tribal rolls brought current to the effective date of this plan shall be final.

Share of the Goshute Tribe

Per Capita Payment Aspect (50 Percent)

Subsequent to the preparation and approval of the membership roll referred to above, the Secretary shall make a per capita distribution of fifty (50) percent of the share, in a sum as equal as possible, to each tribal enrollee.

Programing Aspect

1. *Education and Training Program (Ten Percent).* Ten (10) percent of the share, and any amounts remaining after the per capita payment provided above, shall be invested by the Secretary and shall not be expended, and the interest and investment income accrued shall be utilized on an annual budgetary basis, subject to the approval of the Secretary, to fund an Education and Training Program. Said program shall consist of scholarships and other educational assistance and vocational training. The tribal governing body shall develop a suitable code to administer the program, including the screening of applicants, with preference extended to off-reservation members of the tribe.

2. *Tribal Administration (Twenty Percent).* Twenty (20) percent of the share shall be invested by the Secretary and shall not be expended, and the interest and investment income accrued shall be utilized on an annual budgetary basis, subject to the approval of the Secretary, for tribal administrative needs. Such needs and projects shall include, but not be limited to, the establishment and maintenance of the position of Tribal Manager, reimbursement of tribal council members in the conducting of tribal business and maintenance and protection of a community building and other tribal or community facilities.

3. *Economic Development and Land Consolidation Program (Ten Percent).* Ten (10) percent of the share shall be invested by the Secretary, and such funds and all interest and investment income accrued shall be expended for land purchase and consolidation and for the securing of water rights. Such purchases shall be utilized for livestock and other tribal enterprises designed to employ and train tribal members and to produce revenue for the tribe. The tribal governing body shall develop an appropriate ordinance and code of operations to govern this program. Any profits derived shall, with the approval of the Secretary, be added on an annual budgetary basis to the Dividend Payments Program provided for below.

4. *Dividend Payments Program (Ten Percent).* Ten (10) percent of the share shall be invested by the Secretary and shall not be expended, and the interest and investment income accrued shall be utilized for periodic dividend payments to the members of the tribe. Such dividend payments shall be determined by the tribal governing body on an annual budgetary basis with the approval of the Secretary.

Share of the Skull Valley Tribe

Per Capita Payment Aspect (67 Percent)

Subsequent to the preparation and approval of the membership roll referred to above, the Secretary shall make a per capita distribution of sixty-seven (67) percent of the share, in a sum as equal as possible, to each tribal enrollee.

Programing Aspect

1. *Dividend Payment and Tribal Operations Program (Twenty-Four Percent).* Twenty-four (24) percent of the funds, and any amounts remaining after the per capita payment provided above, shall be invested by the Secretary and shall not be expended. Sixty-six (66) percent of the interest and investment income accrued shall be utilized for periodic dividend payments to the members of the tribe. Such dividend payments shall be determined by the tribal governing body on an annual budgetary basis, with the approval of the Secretary, and shall continue for a period of at least ten years from the effective date of this plan. Subsequent to the end of the ten-year period the tribal governing body may reprogram the sixty-six percent portion of the funds with the approval of the Secretary.

Thirty-four (34) percent of the interest and investment income accrued shall be utilized on an annual budgetary basis, subject to the approval of the Secretary, for the following purposes: the management and maintenance of a community building; a funeral fund to supplement Federal and State programs; and the management of the tribal water system on the Skull Valley Reservation and for other tribal operations.

2. *Community Building and Other Capital Improvements (Three Percent).* Three (3) percent of the funds shall be invested by the Secretary and shall not be expended, and the interest and investment income accrued shall be utilized as matching funds for the construction of a community building and other capital improvements as needed. In the event that full grants for construction are available, the funds shall be designated on an annual budgetary basis, with the approval of the Secretary, for maintenance of the facilities.

3. *Farm Enterprise (Six Percent).* Six (6) percent of the funds shall be invested by the Secretary and shall not be expended, and the interest and investment income accrued shall be utilized by the tribal governing body on an annual budgetary basis for the development of a tribal farming enterprise. The expenditure of such funds shall be contingent upon the acceptance by the Secretary of a tribal plan of operations for this enterprise.

General Provisions

The per capita shares and dividend payments of living competent adults shall be paid directly to them. Shares and payments of deceased individual beneficiaries shall be determined and distributed in accordance with 43 CFR, Part 4, Subpart D. Shares and payments of legal incompetents shall be handled pursuant to 25 CFR 104.5. Shares and payments of minors shall be handled pursuant ot 25 CFR 60.10(a) and (b)(1) and 104.4.

Should any funds in any of the above-cited general program categories not be needed or be found in excess of programing goals in any given annual budget, such funds may be transferred by the affected tribal governing body, with the approval of the Secretary, to another of the above-cited general program categories.

None of the funds distributed per capita or made available under the programing aspects of this plan shall be subject to Federal or State income taxes or be considered income or resources in determining eligibility for assistance under Federal, State or local programs.

Rick Lavis,

Deputy Assistant Secretary, Indian Affairs.

[FR Doc. 80-11338 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-02-M

Nisqually Indian Reservation, Wash.; Proclaiming Certain Lands as Part of Indian Reservation; Correction

April 3, 1980.

In FR Doc. 80-1282, appearing at page 2910 in the issue for Tuesday, January 15, 1980, the land description is hereby corrected by deleting the period on the last line of the land description and adding "; lying Northerly of the North right-of-way line of Secondary State Highway No. 5-1."

Rick Lavis,

Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 80-11342 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-02-M

Receipt of Petition for Reassumption of Jurisdiction, Spokane Tribe of the Spokane Reservation

April 3, 1980.

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.

The Indian Child Welfare Act of 1978 provides, subject to certain specified conditions, that Indian tribes may petition the Secretary of the Interior for reassumption of jurisdiction over Indian child custody proceedings.

This is notice that a petition has been received by the Secretary from the Spokane Tribe of the Spokane Reservation, for the tribal reassumption of jurisdiction over child custody proceedings. The petition is under review, and may be inspected and copied at the Spokane Agency Office, Bureau of Indian Affairs, Wellpinit, Washington.

Rick Lavis,

Deputy Assistant Secretary, Indian Affairs.

[FR Doc. 80-11246 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-02-M

Bureau of Land Management

[NM 33740]

Amcoal, Inc., Invitation for Coal Exploration Program

April 7, 1980.

U.S. Department of the Interior, Bureau of Land Management, Santa Fe, New Mexico 87501. Pursuant to coal exploration license application NM 33740, qualified members of the public are hereby invited to participate with Amcoal, Inc., on a pro rata cost sharing basis in a program for the exploration of coal deposits owned by the United States of America in the S½ Sec. 8, T. 14 N., R. 17 W., NMPM, McKinley County, New Mexico.

Any party electing to participate in this exploration program shall notify, in writing, both the State Director, Bureau of Land Management, P.O. Box 1449, Santa Fe, New Mexico 87501 and Amcoal, Inc., P.O. Box 376, Fort Wingate, New Mexico 87316. Such written notice must be received no later than 30 calendar days after the publication of this notice in the Federal Register.

This proposed exploration program is for the purpose of determining the quality and quantity of the coal in the area and is fully described and will be conducted pursuant to an exploration plan to be approved by the U.S. Geological Survey and the Bureau of Land Management. A copy of the exploration plan as submitted by Amcoal, Inc., may be examined at the Bureau of Land Management, State Office, Room 3031, U.S. Post Office and Federal Building, South Federal Place, Santa Fe, New Mexico.

Larry L. Woodard,

Acting State Director.

[FR Doc. 80-11244 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

[N-2158]

Nevada; Classification Partially Revoked and Lands Open To Entry

April 7, 1980.

On February 6, 1970 (FR, Vol. 35, No. 30, Page 2901) the following described land was classified for multiple use management under the Act of September 19, 1964 and segregated from appropriation under the agricultural land laws and from sale under R.S. 2455:

Mount Diablo Meridian, Nevada

T. 21 N., R. 34 E.
Sec. 27, SE¼;
Sec. 34, NW¼.

The land described aggregates 320 acres.

Review and evaluation of the land use capabilities of the above described land indicates that the classification is no longer valid and it is hereby revoked.

The land is now open to the operation of the public land laws, subject to valid existing rights and the requirements of applicable law. The land has been open continually to the mining laws and to applications and offers under the mineral leasing laws. All valid applications received at or before 10 a.m. on May 16, 1980 shall be considered as simultaneously fied at that time. Those received therafter shall be considered in the order of filing.

Inquiries concerning this land should be addressed to Chief, Division of Technical Services, Bureau of Land Management, 300 Booth Street, P.O. Box 12000, Reno, NV 89520.

Wm. J. Malencik,

Chief, Division of Technical Services.

[FR Doc. 80-11242 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

[N-21759]

Nevada; Realty Action, Sale of Public Lands in Washoe County, Nev.

April 7, 1980.

The following described land has been examined and identified for disposal by public auction under the Authority of Section 203 of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1716, at no less than fair market value which has been determined to be $160,000.00.

Mount Diablo Meridian, Nevada

T. 20 N., R. 24 E.,
Sec. 2, S½S½.

Comprising 160 acres.

The sale will be held on Friday, April 25, 1980, at the BLM Winnemucca District Office, 705 East Fourth Street, Winnemucca, Nevada. Registration of bidders will begin at 8:00 a.m. and the sale will start at 9:00 a.m.

The land is being offered for sale to provide public lands for industrial expansion, private enterprise. The sale is consistent with the Bureau's planning. Public interest will be well served by making these lands available for public sale.

Patent, when issued, will contain the following reservations to the United States:

1. A right-of-way thereon for ditches and canals constructed by the authority of the United States. Act of August 30, 1890, 26 Stat. 391; 43 U.S.C. 945.

2. All mineral deposits in the lands so patented, and to it, or persons authorized by it, the right to prospect, mine, and remove such deposits from the same under applicable law and such regulations as the Secretary of the Interior may prescribe.

And will be subject to:

1. Those rights for communication line purposes which have been granted to Bell Telephone Company of Nevada, its successors or assigns on August 18, 1958 for a period of 50 years, under the Act of March 4, 1911, 36 Stat. 1253; 43 U.S.C. 961. (Nev-030375)

2. Those rights for power distribution line purposes which have been granted to Sierra Pacific Power Company, its successors or assigns, on June 27, 1967 for a 50 year period, under the Act of March 4, 1911, 36 Stat. 1253; 43 U.S.C. 961. (N-661)

3. An easement 50 feet in width will be reserved along the eastern boundary of the parcel, to assure continued ingress and egress to adjacent land.

Detailed information concerning the sale, including the planning documents, environmental assessment and the record of the public discussions, is available for review at the Bureau of Land Management, Winnemucca District Office, 705 East Fourth Street, Winnemucca, Nevada 89445. No bid will be accepted for less than the appraised price and bids for a parcel must include all the land in the parcel. Federal law requires that bidders be U.S. citizens or, in the case of corporations, subject to the laws of any state or the United States.

Bids must be made by a principal or his agent, either by sealed bid mailed or delivered to the Bureau of Land Management, Winnemucca District Office, or by oral bidding at the sale. Bids delivered or sent by mail will be considered only if received at the Bureau of Land Management, Winnemucca District Office, 705 East Fourth Street, Winnemucca, Nevada 89445 prior to 4:30 p.m. on Thursday, April 24, 1980. Each bid must be in a sealed envelope accompanied by a certified check, postal money order, bank draft or cashier's check, made payable to the Bureau of Land Management for not less than one-fifth of the amount of the bid. The envelopes must be marked in the lower left-hand corner as follows: "Bid Parcel No. N-21759; Sale to be Held April 25, 1980." The highest sealed bid on the parcel will determine the base of the oral bidding conducted the day of the sale. If two or more envelopes are received containing valid bids of the same amount, the determination of which is to be considered the highest bid will be by drawing. The highest qualifying sealed bid will be publicly declared on the day of the sale and oral bids will then be invited. After oral bids, if any, are received, the highest qualifying bid will be declared by the authorized officer. The person declared to have entered the highest qualifying oral bid shall submit payment by cash, personal check, bank draft, money order, or any combination for not less than one-fifth of the amount of the bid immediately following the close of the sale. The successful bidder shall submit the remainder of the full bid price within 30 days of the sale. Failure to submit the full bid price within 30 days shall result in cancellation of the sale of the parcel and the deposit shall be forfeited and disposed of as other receipts of sale. All bids will be either returned, accepted, or rejected in writing within 30 days of the sale date.

Wm. J. Malencik,

Chief, Division of Technical Services.

[FR Doc. 80-11243 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

Potassium Lease Offering by Sealed Bid

April 4, 1980.

U.S. Department of the Interior, Bureau of Land Management, New Mexico State Office, P.O. Box 1449, Santa Fe, New Mexico 87501. Notice is hereby given that certain potassium resources in the lands hereinafter described will be offered for lease by sealed bid to the qualified bidder of the highest cash amount per acre or fraction thereof in accordance with the provisions of the Act of February 7, 1927 (44 Stat. 1057), as amended. The minimum acceptable bid is $25 per acre. The sale will be held at 2:00 p.m., local time, May 1, 1980, in room 3A, Sweeney Convention Center, corner of Marcy and Grant, Santa Fe, New Mexico. Sealed bids may not be modified or withdrawn unless such modification or withdrawal is received before the date, time and place set for opening of such bids.

Potassium Offered: The potassium resource to be offered is located in southeastern New Mexico in Eddy County about 20 miles east of Carlsbad. The lands are entirely within the Carlsbad Known Potash Leasing Area and are described as follows:

T. 21 S., R. 30 E., New Mexico Principal Meridian
*Sec. 9, E½;
Sec. 10, N½, SW¼;
Containing 800.0 acres.

Potash in the area is contained in the Salado Formation within the McNutt potash zone. The 10th, 8th, 7th, 5th, and 4th ore zones contain an estimated 31.07 million tons in place or 19.22 million tons recoverable at 13.1% K_2O. However, only the 5th and 7th ore zones containing 8.25 million tons in place or 7.01 million tons recoverable are of current economic interest.

Public Comments: The public is invited to submit written comments concerning fair market value of the offered potassium reserves to the Bureau of Land Management and the U.S. Geological Survey. These comments will be reviewed and taken into consideration in the determination of fair market value of the potassium of the offered lands. Should any information submitted as comments be considered to be proprietary by the commenter, the information should be labeled as such and stated in the first page of the submission. Comments should be sent to the State Director, Bureau of Land Management, P.O. Box 1449, Santa Fe, New Mexico 87501 and to the Regional Conservation Manager, Conservation Division, Geological Survey, P.O. Box 25046, Mail Stop 609, Denver Federal Center, Denver, Colorado 80225, to arrive no later than April 28, 1980.

Notice of Availability: Bidding instructions are included in the detailed statement of lease sale. The detailed statement, all case file documents and written comments submitted by the public on fair market value or royalty rates, except those portions identified as proprietary by the commenter and meeting the exemptions stated in the Freedom of Information Act, are available for public inspection in Room 3031, U.S. Post Office and Federal Building, South Federal Place, Santa Fe, New Mexico 87501.

The successful bidder is obligated to pay for the newspaper publications of this notice.

Arthur W. Zimmerman,

State Director.

[FR Doc. 80-11320 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

*No surface disturbing activities will be allowed in the NE¼NE¼, W½NE¼, N½SE¼NE¼, NW¼SE¼, W½SW¼SE¼, Sec. 9, in order to protect known archeological values.

Wilderness Meeting in Eureka, Nev.; Changed Location

In the **Federal Register** of April 1, 1980, page 21356, the BLM announed a series of meetings in Nevada concerning its proposals on wilderness study areas on public lands. One of those sessions is planned for Eureka, Nevada on April 16, 1980. The notice said that the afternoon session (from 1 to 4:30 p.m.) was to be held at the Eureka Courthouse. That meeting has been changed to the BLM's Eureka office. The evening session (from 7 to 9 p.m.) will still be held at the Eureka Courthouse.

Dated: April 8, 1980.

Edward F. Spang,

State Director, Nevada.

[FR Doc. 80-11416 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

Koochiching Bog Units 42 and 45, Minnesota; Final Wilderness Inventory Decision

In the February 19, 1980 **Federal Register**, the Bureau of Land Management (BLM) announced its final intensive wilderness inventory decision on two units known as Koochiching Bog Units 42 and 45, encompassing 21,407.22 acres of public lands in Koochiching County, Minnesota.

The decision provided that, unless timely protests were received by the BLM Eastern States Director, 350 South Pickett Street, Alexandria, Virginia 22304, within a thirty-day period ending at 4:00 p.m., Eastern Standard Time, March 24, 1980 the decision would become *final.* No protests were received.

Under the authority of Section 603 of the Federal Land Policy and Management Act and in accordance with the guidelines in the September 27, 1978 BLM *Wilderness Inventory Handbook* and Organic Act Directive No. 78-61, Change 3, the final intensive wilderness inventory decision for the

following units became effective March 24, 1980:

Unit	Acres
Koochiching Bog Unit 42	10,394.72
Koochiching Bog Unit 45	11,012.50
Total acreage	21,407.22

The above public lands are no longer subject to BLM wilderness review and the management restrictions imposed by Section 603 of the Federal Land Policy and Management Act no longer apply.

Roger L. Hildebeidel,

Director, Eastern States.

[FR Doc. 80-11277 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

[INT DEIS 80-20]

Owyhee Grazing Draft Environmental Impact Statement; Public Hearings and DEIS Availability

AGENCY: Bureau of Land Management, Interior.

ACTION: Public hearings on Owyhee grazing DEIS.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared a draft environmental impact statement for a proposed grazing management program for the Owyhee Resource Area of the Boise District in southwestern Idaho. The proposal involves changes in initial stocking rates, implementing improved grazing systems and installation of range improvements. Approximately 1 million acres of public lands are involved. Copies of the draft environmental impact statement are available for inspection at the following locations:

Boise District Office, Bureau of Land Management, 230 Collins Road, Boise, Idaho 83702. Telephone: (208) 334–1582.

Idaho State Office, Bureau of Land Management, Federal Building, 500 W. Fort Street, Boise, Idaho 83724. Telephone: (208) 334–1770.

Public Affairs, Bureau of Land Management, Interior Building, 18th and G Street, NW., Washington, D.C. 20240.

A limited number of single copies may be obtained from the Idaho State Director or the Boise District Manager, Bureau of Land Management, at the above addresses.

Notice is hereby given that the draft environmental impact statement will be available for public review and comment for 60 days from the date filed with the Environmental Protection Agency. The Department of the Interior invites written comments on the adequacy of the draft statement to be submitted by June 10, 1980.

Notice is also given that public hearings will be held at: (1) The Red Lion Inn, Boise, Idaho, May 28, 1980, at 7 p.m.; and (2) Marsing Grade School, Marsing, Idaho, May 29, 1980, at 3 and 7 p.m.

DATES: May 28, 1980—Public hearing in Boise. May 29, 1980—Public hearing in Marsing. June 10, 1980—Deadline for receiving written testimony.

ADDRESS: Written comments on the Draft EIS should be sent to: Owyhee Grazing EIS, BLM Boise District Office, 230 Collins Road, Boise, Idaho 83702.

FOR FURTHER INFORMATION CONTACT: Ted Milesnick or Oscar Anderson, BLM Boise District Office, Telephone: (208) 334–1290.

SUPPLEMENTARY INFORMATION: Individuals wishing to testify may do so by appearing at a hearing place as previously specified. Persons wishing to give testimony will be limited to 10 minutes, with written submissions invited. Prior to giving testimony at public hearings, individuals or spokesmen are requested to complete a hearing registration form. Registration forms may be obtained by contacting the Boise District Manager at the above address.

Dated: April 9, 1980.

Ed Hastey,

Associate Director.

[FR Doc. 80-11357 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

Utah and Colorado; Adoption of Regional Leasing Target

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: Under the Federal coal management regulations (43 CFR 3420.3–2(j)), the Secretary of the Interior has the responsibility for establishing a Federal coal leasing target for each of the Federal coal production regions. This notice is to inform the public that, on March 28, 1980, the Secretary adopted a leasing target of 322 million tons of in-place Federal coal for the Uinta-Southwestern Utah Federal Coal Production Region. The target is to achieve 1985 through 1990 production levels and to promote competition in the region.

The target was arrived at after analyzing potential production from coal mines in the region, after extensive public hearings, and after consultation with State and local officials and the Departments of Energy and Justice. The approval of the Intermountain Power Project and the proposed exchange of preference right lease applications held by Utah Power and Light Company were key factors considered in deriving the leasing target.

FOR FURTHER INFORMATION CONTACT: Edward F. Spang, Regional Coal Team Chairperson, at the Bureau of Land Management, Federal Building, Room 3008, 300 Booth Street, Reno, Nevada 89509, or call (702) 784–5451.

Dated: April 9, 1980.

Ed Hastey,

Associate Director.

[FR Doc. 80-11293 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

Fish and Wildlife Service

Endangered Species Permit; Receipt of Application

Applicant: Mammal Division (Philip Myers), Museum of Zoology, University of Michigan, Ann Arbor, Michigan 48109.

The applicant requests a permit to import 6 skulls from tapir (*Tapirus terrestris*), 2 skeletons from black-throated piping guan (*Pipile jacutinga*) and 1 skeleton from solitary tinamou (*Tinamus solitarius*) for scientific purposes.

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 2–6467. Interested persons may comment on this application on or before May 15, 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: April 10, 1980.

Fred Bolwahnn,

Acting Chief, Permit Branch, Federal Wildlife Permit Office, U.S. Fish and Wildlife Service.

[FR Doc. 80-11367 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

Geological Survey

Oil and Gas and Sulphur Operations in the Outer Continental Shelf

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of the receipt of a proposed development and production plan.

SUMMARY: Notice is hereby given that ARCO Oil and Gas Company has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS–G 2834, Block 238, West Cameron Area.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that it is available for public review at the offices of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: U.S. Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised § 250.34 of Title 30 of the Code of Federal Regulations.

Dated: April 7, 1980.

Lowell G. Hammons,

Conservation Manager, Gulf of Mexico OCS Region.

[FR Doc. 80–11294 Filed 4–14–80; 8:45 am]

BILLING CODE 4310–31–M

Oil and Gas and Sulphur Operations in the Outer Continental Shelf

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of the receipt of a proposed developent and production plan.

SUMMARY: Notice is hereby given that ARCO Oil and Gas Company has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS–G 2919, Block 91, Ship Shoal Area.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that it is available for public review at the offices of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana.

FOR FURTHER INFORMATION CONTACT: U.S Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Cuaseway Blvd., Metairie, Louisiana 70002, Phone 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979 (44 FR 53685). Those practices and procedures are set out in a revised 250.34 of Title 30 of the Code of Federal Regulations.

Dated: April 7, 1980.

Lowell G. Hammons,

Conservation Manager, Gulf of Mexico OCS Region.

[FR Doc. 80–11295 Filed 4–14–80; 8:45 am]

BILLING CODE 4310–31–M

Oil and Gas and Sulphur Operations in the Outer Continental Shelf

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of the receipt of a proposed development and production plan.

SUMMARY: Notice is hereby given that Kerr-McGee Corporation has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS–G 1025, Block 239, Ship Shoal Area.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that it is available for public review at the offices of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: U.S. Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised § 250.34 of Title 30 of the Code of Federal Regulations.

Dated: April 7, 1980.

Lowell G. Hammons,

Conservation Manager, Gulf of Mexico OCS Region.

[FR Doc. 80–11296 Filed 4–14–80; 8:45 am]

BILLING CODE 4310–31–M

Oil and Gas and Sulphur Operations in the Outer Continental Shelf

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of the receipt of a proposed development and production plan.

SUMMARY: Notice is hereby given that Ocean Production Company has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS–G 1023, Block 224, Ship Shoal Area.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that it is available for public review at the offices of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: U.S. Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised § 250.34 of Title 30 of the Code of Federal Regulations.

Dated: April 7, 1980.

Lowell G. Hammons,

Conservation Manager, Gulf of Mexico OCS Region.

[FR Doc. 80–11297 Filed 4–14–80; 8:45 am]

BILLING CODE 4310–31–M

Oil and Gas and Sulphur Operations in the Outer Continental Shelf

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of the receipt of a proposed development and production plan.

SUMMARY: Notice is hereby given that Pennzoil Company has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS–G 3118, Block A–499, High Island Area.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that is available for public review at the offices of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: U.S. Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised § 250.34 of Title 30 of the Code of Federal Regulations.

Dated: April 7, 1980.

Lowell G. Hammons,

Conservation Manager, Gulf of Mexico OCS Region.

[FR Doc. 80–11298 Filed 4–14–80; 8:45 am]

BILLING CODE 4310–31–M

Oil and Gas and Sulphur Operations in the Outer Continental Shelf

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of the receipt of a proposed development and production plan.

SUMMARY: Notice is hereby given that Samedan Oil Corporation has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS–G 2659, Block A–28, Brazos Area.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that it is available for public review at the offices of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: U.S. Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m., 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised Section 250.34 of Title 30 of the Code of Federal Regulations.

Dated: April 8, 1980.

Lowell G. Hammons,

Conservation Manager, Gulf of Mexico OCS Region.

[FR Doc. 80–11859 Filed 4–16–80; 8:45 am]

BILLING CODE 4310–31–M

Oil and Gas and Sulphur Operations in the Outer Continental Shelf

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of the receipt of a proposed development and production plan.

SUMMARY: Notice is hereby given that Gulf Oil Exploration and Production Company has submitted a Development and Production Plan describing the activities it proposes to conduct on Lease OCS, 0453, Block 130, Ship Shoal Area, offshore Louisiana.

The purpose of this Notice is to inform the public, pursuant to Section 25 of the OCS Lands Act Amendments of 1978, that the Geological Survey is considering approval of the Plan and that it is available for public review at the offices of the Conservation Manager, Gulf of Mexico OCS Region, U.S. Geological Survey, 3301 North Causeway Blvd., Room 147, Metairie, Louisiana 70002.

FOR FURTHER INFORMATION CONTACT: U.S. Geological Survey, Public Records, Room 147, open weekdays 9 a.m. to 3:30 p.m. 3301 North Causeway Blvd., Metairie, Louisiana 70002, Phone 837–4720, Ext. 226.

SUPPLEMENTARY INFORMATION: Revised rules governing practices and procedures under which the U.S. Geological Survey makes information contained in Development and Production Plans available to affected States, executives of affected local governments, and other interested parties became effective December 13, 1979, (44 FR 53685). Those practices and procedures are set out in a revised Section 250.34 of Title 30 of the Code of Federal Regulations.

Dated: April 8, 1980.

Lowell G. Hammons,

Conservation Manager, Gulf of Mexico OCS Region.

[FR Doc. 80–11859 Filed 4–16–80; 8:45 am]

BILLING CODE 4310–31–M

Heritage Conservation and Recreation Service

National Register of Historic Places; 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 April 4, 1980. Pursuant to section 1202.13 of 36 CFR Part 1202, 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 should be submitted by April 30, 1980.

Carol Shull,

Acting Keeper of the National Register.

ARKANSAS

Drew County

Monticello, *Hardy, Robert Lee, House,* 207 S. Main St.

Pulaski County

Little Rock, *Compton-Wood House,* 800 High St.

CALIFORNIA

Inyo County

Little Lake vicinity, *Fossil Falls Archeological District,* N of Little Lake off CA 395

San Francisco County

San Francisco, *Fort Miley Military Reservation (Point Lobos Military Reservation),* Off CA 1

IOWA

Black Hawk County

Cedar Falls, *Forrest Milling Company Oatmeal Mill*, N. Main St.

Linn County

Mount Vernon, *Cornell College-Mount Vernon Historic District*, Roughly bounded by RR tracks, College Blvd., N. 10th, N. 8th, and S. 3rd Aves., N. 2nd and S. 4th Sts.

KENTUCKY

Anderson County

Lawrenceburg, *Hanks, Thomas H., House*, 516 E. Woodford St.

Jefferson County

Louisville, *Old U.S. Customshouse and Post Office and Fireproof Storage Company Warehouse*, 300–314 W. Liberty St.
Louisville, *Parkland Historic District*, Roughly bounded by RR tracks, Hale Ave., S. 26th and S. 30th Sts.
Louisville, *Russell Historic District*, Roughly bounded by S. 15th, S. 26th, Congress and W. Broadway Sts.

Kenton County

Covington, *Seminary Square Historic District*, Roughly bounded by RR tracks, Holman, 9th and 12th Sts.

Ohio County

Hartford, *Hill, Samuel E., House*, 519 E. Union St.

Union County

Morganfield, *Hughes, Daniel H., House*, 213 W. O'Bannon St.

LOUISIANA

Concordia Parish

Frogmore, *Gillespie*, U.S. 84

East Feliciana Parish

Clinton, *Boatner House*, Plank and Taylor Sts.

Iberville Parish

Plaquemine, *Iberville Parish Courthouse (Plaquemine City Hall)*, 209 Main St.

Lafourche Parish

Thibodaux, *Rienzi Plantation House*, LA 308

Tangipahoa Parish

Amite, *Greenlawn*, 200 E. Chestnut St.
Ponchatoula vicinity, *Nichols House*, 2 mi. W of Ponchatoula on LA 22

Washington Parish

Mount Hermon, *Magee, Nehemiah, House*, SW of Mount Hermon

MASSACHUSETTS

Berkshire County

Pittsfield, *Allen, William Russell, House*, 359 East St.

Suffolk County

Boston, *New England Conservatory of Music*, 290 Huntington Ave.

Worcester County

Uxbridge, *Farnum, Coronet John, House*, Mendon St.

MICHIGAN

Cheboygan County

Mackinaw City, *Stimpson, Forrest J., House (Mackinaw City Marine Recording Station)* 516 N. Huron Blvd.

Clinton County

St. Johns, *East Ward School*, 106 N. Traver St.
St. Johns, *Union School*, 205 W. Baldwin St.

Genesee County

Fenton, *Vermont House and Fenton Grain Elevator*, 302 and 234 N. Leroy St.
Flint, *Whaley, Robert J., House*, 624 E. Kearsley St.

Houghton County

Houghton, *College Club House and Gymnasium*, 1416 College Ave.

Jackson County

Jackson, *Michigan Theater*, 124 N. Mechanic St.
Springport vicinity, *Jameson, James M., Farm*, E of Springport at 10220 N. Parma Rd.

Kalamazoo County

Kalamazoo, *Masonic Temple Building*, 309 N. Rose St.

St. Joseph County

Constantine, *Art Gallery Building*, 156 S. Washington St.

Shiawassee County

Corunna, *Ingersoll, John N., House*, 570 W. Corunna Ave.

MISSISSIPPI

Chickasaw County

Okolona, *Elliott-Donaldson House*, 109 Church St.

Leflore County

Greenwood, *Cotton Row Historic District*, Cotton, Front, Fulton, Howard, Main, and Market Sts.

Wilkinson County

Woodville, *Hampton Hall*, MS 61

NEW MEXICO

Eddy County

Hope vicinity, *Pope's Artesian Well Camp No. 3*

Luna County

Deming vicinity, *Fort Cummings Historic District*, NE of Deming

NORTH CAROLINA

Madison County

Hot Springs, *Sunnybank*, NC 209

OHIO

Clark County

Enon vicinity, *Pickaway Settlement Battlesite*, N of Enon

Franklin County

Columbus, *Near Northside Historic District*, Off U.S. 23

PENNSYLVANIA

Berks County

Kutztown, *Kutztown 1892 Public School Building*, White Oak and Normal Ave.

Bucks County

Wrightstown vicinity, *Wrightstown Octagonal School House*, SW of Wrightstown off PA 232

Centre County

Bellefonte, *McAllister-Beaver House*, 817 E. Bishop St.

Franklin County

Upton vicinity, *McCoy-Shoemaker Farm*, SW of Upton on PA 995
Waynesboro, *Hamilton, Alexander, House*, 45 E. Main St.

Lackawanna County

Scranton, *Watkins-Maxey House*, 520 Monroe Ave.

Lehigh County

Egypt, *Troxell-Steckel House*, 4229 Reliance St.

Montgomery County

Penllyn, *Foulke Mansion*, Penllyn and Blue Bell Pike

SOUTH DAKOTA

Brookings County

Brookings, *Carnegie Public Library*, 524 4th St.
Brookings, *Wenona Hall and Wecota Hall*, Medary Ave.

Brown County

Aberdeen, *Masonic Temple*, 503 S. Main St.

Edmunds County

Ipswich, *Parmley, J. W., House*, 4th St. and 4th Ave.

Fall River County

Hot Springs, *Hot Springs High School*, 146 N. 16th St.

Hughes County

Pierre, *St. Charles Hotel*, 207 E. Capitol Ave.
Pierre vicinity, *Oahe Chapel*, NW of Pierre

Kingsbury County

Oldham, *Peterson-Loriks House*

Lawrence County

St. Onge, *St. Onge Schoolhouse*, Off SD 24

Minnehaha County

Renner, *Renner Lutheran Sanctuary*, Off U.S. 77
Sioux Falls, *Central Fire Station*, 100 S. Minnesota Ave.

Potter County

Hoven, *St. Bernard's Catholic Church*, SD 20

Todd County

Rosebud, *Rosebud Agency*, 1 Main St.
Rosebud, *Rosebud Hotel (Old Club)* 7 Circle Dr.
Rosebud vicinity, *Spotted Tail Gravesite*

Yankton County

Yankton, *Trierweiler, Dr. John, House,* 301 Spruce St.

TENNESSEE

Haywood County

Brownsville, *College Hill Historic District,* TN 19 and U.S. 70/79

TEXAS

COMMERCIAL STRUCTURES OF EL PASO BY HENRY C. TROST THEMATIC RESOURCES. Reference—see individual listings under El Paso County.

Anderson County

Palestine, *Link House,* 925 N. Link St.

El Paso County

El Paso, *Abdou Building, (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 115 N. Mesa St.
El Paso, *Bassett, O. T., Tower (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 301 Texas Ave.
El Paso, *Caples, Richard, Building (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 300 E. San Antonio Ave.
El Paso, *Columbia Furniture (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 216 E. Overland Ave.
El Paso, *El Paso International Building (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 125 N. Stanton St.
El Paso, *Hills, W. S., Commercial Structure (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 215–219 San Antonio Ave.
El Paso, *Hotel Cortez (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 300 N. Mesa St.
El Paso, *Hotel Paso del Norte (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 115 S. El Paso St.
El Paso, *Newberry, J. J., Company (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 201–205 N. Stanton St.
El Paso, *Palace Theatre (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 209 S. El Paso St.
El Paso, *Plaza Hotel (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* Oregon and Mills Sts.
El Paso, *Popular Department Store (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 102 N. Mesa St.
El Paso, *Roberts-Banner Building (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 215 N. Mesa St.
El Paso, *Singer Sewing Company (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 211 Texas Ave.
El Paso, *State National Bank (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 114 E. San Antonio Ave.
El Paso, *Union Bank and Trust (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 104–106 San Antonio Ave.
El Paso, *White House Department Store and Hotel McCoy (Commercial Structures of El Paso by Henry C. Trost Thematic Resources)* 109 Pioneer Plaza

Llano County

Llano, *Badu Building,* 601 Bessemer Ave.

Starr County

Rio Grande City, *LaBorde House, Store and Hotel,* 601 E. Main St.

UTAH

Garfield County

Panguitch vicinity, *Pole Hollow Archeological Site*

Juab County

Callao vicinity, *Fish Springs Caves Archeological District*

Salt Lake County

Salt Lake City, *Armstrong, Francis, House,* 667 E. 1st South St.

San Juan County

Aneth Vicinity, *Aneth Terrace Archeological District*

Utah County

American Fork, *American Fork Presbyterian Church,* 75 N. 1st East St.

VIRGINIA

Danville (independent city)

Danville Tobacco Warehouse and Residential District, Off U.S. 58

WISCONSIN

Adams County

Friendship vicinity, *Roche-a-Cri Petroglyphs*

Iron County

Montreal, *Montreal Company Location Historic District,* WI 77

Oconto County

Oconto, *Oconto Main Post Office,* 141 Congress St.

Rock County

Beloit, *Pearsons Hall of Science,* Beloit College campus
Milton, *Milton College Historic District,* College St.
Orfordville vicinity, *West Luther Valley Lutheran Church,* SW of Orfordville on W. Church Rd.

[FR Doc. 80-10935 Filed 4-14-80; 8:45 am]
BILLING CODE 4310-03-M

Bureau of Land Management

[INT DEIS 80-19]

Availability of the Draft Environmental Impact Statement, Anaconda Nevada Moly Project

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability of the draft environmental impact statement (DEIS) on the Anaconda Copper Company's proposed Nevada Moly project.

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior has prepared a DEIS concerning the Anaconda Copper Company's proposal to develop, mine, and mill a deposit of molybdenum ore. A major part of the proposal is the proposed construction of a 86 mile long 230 kV powerline by the Sierra Pacific Power Company to provide power for the mine/mill complex. The DEIS analyzes the impacts of the proposal, alternate routing of the powerline and a range of materials for its construction, as well as alternative means of milling the ore.

DATE: Comments by June 2, 1980.

ADDRESS: Comments should be sent to: State Director, Bureau of Land Management, Federal Building, 300 Booth Street, P.O. Box 12000, Reno, Nevada 89520.

Comments will be available for public review at the above address during regular business hours (7:30–4:15) Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Pat Clason, Division of Rights-of-Way and Project Review (332), Bureau of Land Management, 18th and C Streets NW., Washington, D.C. 20240, (202) 343–5441; or Mike Walker, Bureau of Land Management, Environmental Coordination Branch, Federal Building, 300 Booth Street, Reno, Nevada 89520, (702) 784–5602.

SUPPLEMENTARY INFORMATION: A limited number of copies of the DEIS are available upon request at the following offices:

Battle Mountain District Office, P.O. Box 194, Battle Mountain, Nevada 89820.
Tonopah Resource Area Hdqrs Bldg., 102 Old Radar Base, Tonopah, Nevada 89049.
Bureau of Land Management, Nevada State Office, Federal Building, 300 Booth Street, Reno, Nevada 89520.

Also, copies are available for review at public libraries in: Tonopah, Battle Mountain and Reno, Nevada.

Dated: April 10, 1980.

Guy R. Martin,
Assistant Secretary of the Interior.

[FR Doc. 80-11321 Filed 4-14-80; 8:45 am]
BILLING CODE 4310-84-M

[INT FEIS 80-13]

Superior Oil Co. Land Exchange and Oil Shale Resource Development

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice of availability of the final environmental impact statement (FEIS).

SUMMARY: Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior (DOI) has prepared a FEIS on a proposed land exchange with Superior Oil Company and subsequent oil shale development project.

SUPPLEMENTARY INFORMATION: The DOI (BLM) has prepared a FEIS on a land exchange proposed by Superior Oil Company which would involve the exchange of 2,045 acres of public land for 2,572 acres of Superior Oil Company land. As a result of the land exchange, Superior Oil Company could mine approximately 26,000 tons of oil shale per day.

The oil shale would be processed on site and produce approximately 11,500 barrels of shale oil, 4,800 tons of nahcolite, 1,000 tons of soda ash, and 580 tons of alumina per day. The FEIS analyzes the impacts that would result from the mining and processing operations. The FEIS also analyzes the alternative of leasing these public lands for oil shale development.

FOR FURTHER INFORMATION CONTACT: Mel Berg, Bureau of Land Management, 18th and C Streets NW., Washington, D.C. 20240, (202) 343–5441.

Copies of the FEIS will be available for inspection at the following locations:

Bureau of Land Management, Public Affairs, Interior Building, 18th and C Streets, NW., Washington, D.C. 20240, (202) 343–6011.

Bureau of Land Management, Craig District Office, 455 Emerson Street, Craig, Colorado 81625, (303) 824–3417.

Bureau of Land Management, Colorado State Office, Room 700, Colorado State Bank Building, 1600 Broadway, Denver, Colorado 80202, (303) 837–3515.

Bureau of Land Management, White River Resource Area, 317 E. Market, Meeker, Colorado 81641, (303) 878–5084.

Public Libraries

Public Library of Craig, Craig, Colorado 81625
Rifle Public Library, Rifle, Colorado 81650
Meeker Public Library, 200 Main, Meeker, Colorado 81641
Rangely Public Library, 109 E. Main St., Rangely, Colorado 81648
Conservation Library, Denver Public Library, 1537 Broadway, Denver, Colorado 80206

County Courthouses

Moffat County, Craig, Colorado 81625
Garfield County, Glenwood Springs, Colorado 81601.

A limited number of single copies of the FEIS can be obtained from the District Manager, Craig District Office or the State Director, Colorado State Office, at the addresses listed above.

Dated: April 10, 1980.

Larry E. Meierotto,

Assistant Secretary of the Interior.

[FR Doc. 80-11322 Filed 4-14-80; 8:45 am]

BILLING CODE 4310-84-M

INTERNATIONAL COMMUNICATION AGENCY

Culturally Significant Objects Imported for Exhibition; Amendment of Notice

Pursuant to the authority vested in me by the act of October 19, 1965 (79 Stat. 985, 22 U.S.C. 2459) and Executive Order 12047 of March 27, 1978 (43 FR 13359, March 29, 1978), I hereby amend the second sentence of the notice relating to the exhibit, "Post-Impressionism: Crosscurrents in European and American Paintings, 1880–1906," published in the **Federal Register** on March 31, 1980 (45 FR 21061), to read as follows: These objects are imported pursuant to an agreement on packing, transportation, and catalogue publication between the National Gallery of Art, Washington, D.C. and the Royal Academy of Arts, London, England, and pursuant to loan agreements between the National Gallery of Art and the foreign owner of each painting.

Notice of this amendment is ordered to be published in the **Federal Register**.

Dated April 10, 1980.

Charles W. Bray III,

Acting Director, International Communication Agency.

[FR Doc. 80-11358 Filed 4-14-80; 8:45 am]

BILLING CODE 8230-01-M

INTERSTATE COMMERCE COMMISSION

[Notice 177]

Assignment of Hearings

April 8, 1980.

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 42487 (Sub-916F), Consolidated Freightways Corporation of Delaware, now assigned for hearing on May 19, 1980 (1 week) at Omaha, NE in Omaha Hilton Hotel, 16th & Dodge Street.

MC 4963 (Sub-67F), Jones Motor Co., Inc., now assigned for Prehearing Conference on April 15, 1980 at the Offices of the Interstate Commerce Commission, Washington, DC.

FD–28934, Chicago and North Western Transportation Company Construction and Operation of a Line of Railroad in Niobrara and Goshen Counties, WY and in Sioux and Scotts Bluff Counties, NE, FD–29066, Chicago and North western Transportation Company-Construction, now assigned for further Prehearing Conference on April 18, 1980 at the Offices of the Interstate Commerce Commission, Washington, DC.

MC 80443 (Sub-23F), Overnite Express, Inc., now assigned for hearing on May 19, 1980 (2 days) at Minneapolis, MN in a hearing room to be later designated.

MC–F–14166F, Refrigerated Transport Co., Inc.-Purchase (Portion)-Dakota Express, Inc., and LTL Perishables, Inc., now assigned for hearing on May 21, 1980 (3 days) at Minnepalis, MN in a hearing room to be later designated.

MC 120981 (Sub-29F), Bestway Express, Inc., now assigned for continued hearing on April 7, 1980 (2 days) at Montgomery, AL will be held at the Ramada Inn, East, 1355 East Boulevard, and continued to April 10, 1980 (2 days) at Mobile, AL will be held at the Ramada Inn, Airport, 165 and Airport Boulevard, 600 Beltline Highway, South and continued to May 5, 1980 (2 days) at Birmingham, AL in a hearing room to be later designated.

MC 100666 (Sub-463F), Melton Truck Lines, Inc., now assigned for hearing on July 8, 1980 (9 days) at Birmingham, AL in a hearing room to be later designated.

MC 116400 (sub-7F), Lawrence Transfer & Storage Corporation, transferred to Modified Procedure.

MC 139960 (Sub-1F), Western Pacific Transport Company, now assigned for hearing on July 7, 1980 (2 weeks) at San Francisco, CA, in a hearing room to be later designated.

MC 65802 (Sub-66F), Lynden Transport, Inc., now assigned for hearing on June 5, 1980 (2 days) at Seattle, WA is advanced to June 2, 1980 (5 days) at Seattle, WA, in a hearing room to be later designated.

MC 85811 (Sub-12F), AMSCO Transportation, Inc., now being assigned for hearing on June 25, 1980 (3 days), at Kansas city, Mo, in a hearing room to be designated later.

MC 108633 (Sub-17F), Barnes Freight Line, Inc., now assigned for hearing on April 14, 1980 will be held in Room No. 401, 1776 Peachtree Street, N.W., Atlanta, GA., continued to April 17, 1980 at the Holiday Inn-Capitol, 924 Madison Avenue, Montgomery, AL., continued to April 21, 1980 at the Ramada Inn Airport, Airport Highway, Birmingham, AL., and continued to April 23, 1980 at the Holiday Inn, 3810 University Drive, Huntsville, AL.

MC 5623 (Sub-44F), Arrow Trucking Company, now assigned for hearing on April 15 thru 18, 1980 will be held at the Securities and Exchange Commission, Building 410, Seventeenth Street, Denver,

CO, and continued to April 21 thru 25, 1980 in Room No. 158, U.S. Customs House, 721 19th Street, Denver, CO. No. MC 145441 (Sub-29F), A.C.B. Trucking, Inc., Application Dismissed.

MC-FC-77914, American Tank Transport, Inc., Baltimore, MD Transferee and Secon Service System, Inc., New York, NY. Transferor now being assigned for hearing on June 10, 1980 (4 days), at New York, NY. in a hearing room to be designated later.

MC 116457 (Sub-45F), General Transportation, Inc., transferred to Modified Procedure.

MC 118044 (Sub-3F), Keeshin Charter Service, Inc., now being assigned for hearing on June 11, 1980 (3 Days), at Chicago, IL, in a hearing room to be designated later.

MC 145441 (Sub-38F), A.C.B. Trucking, Inc., now being assigned for hearing on June 2, 1980 (2 Days), at Los Angeles, CA, in a hearing room to be designated later.

MC 129857 (Sub-8F), G.R.M., Inc. d.b.a. Port Terminal Transport, Inc., now being assigned for hearing on June 4, 1980 (3 Days), at Los Angeles, CA, in a hearing room to be designated later.

AB-6 (Sub-73F), Burlington Northern, Inc. Abandonment Near Laclede and Unionville, MO, now assigned for hearing on April 29, 1980 will be held in the Circuit Court Room, County Court House, Unionville, MO.

MC 125368 (Sub-63F), Continental Coast Trucking Company, Inc., now being assigned for hearing on June 17, 1980 (1 Day), at Omaha, NE, in a hearing room to be designated later.

MC 95540 (Sub-1057F), Watkins Motor Lines, Inc., now being assigned for hearing on June 18, 1980 (3 Days), at Omaha, NE, in a hearing room to be designated later.

MC 119493 (Sub-298F), Monkem Company, Inc., now being assigned for hearing on June 23, 1980 (2 Days), at Kansas City, MO, in a hearing room to be designated later.

MC C-10331, Pennsylvania Public Utility Commission-v-mushroom Transportation Company, Inc., now assigned for hearing on April 14, 1980 at Philadelphia, PA, is postponed indefinitely.

MC 144630 (Sub-18F), Stoops Express, Inc., now being assigned for hearing on July 16, 1980 (1 Day), at Tampa, FL, in a hearing room to be designated later.

MC 146002 (Sub-2F), Brookridge Leasing, Inc., now being assigned for hearing on July 17, 1980 (2 Days), at Tampa, FL, in a hearing room to be designated later.

MC 147144-F, International Carriers, Inc., now being assigned for hearing on July 21, 1980 (5 Days), at Miami, FL, in a hearing room to be designated later.

MC 140094 (Sub-1F), Latin Express Service, Inc., now assigned for hearing on April 9, 1980 at Miami, FL, is postponed indefinitely.

MC 123048 (Sub-441F), Diamond Transportation System, Inc., now being assigned for hearing on June 3, 1980 (1 Day), at Chicago, IL, in a hearing room to be designated later.

MC 106647 (Sub-44F), Clark Transport Company, Inc., now being assigned for hearing on June 4, 1980 (3 Days), at Chicago, IL, in a hearing room to be designated later.

MC 119493 (Sub-297F), Monkem Company, Inc., now being assigned for hearing on June 9, 1980 (2 Days), at Chicago IL, in a hearing room to be designated later.

MC 120098 (Sub-31F), Uintah Freightways, A Corporation, Application Dismissed.

MC 116457 (Sub-43F), General Transportation Incorporated, now assigned for hearing on June 2, 1980 at Phoenix, AZ, is canceled and transferred to Modified Procedure.

MC 140829 (Sub-253F), Cargo, Inc., now being assigned for hearing on May 9, 1980 (1 Day), at Chicago, IL, in a hearing room to be designated later.

MC-C-10038, A&H Truck Line, Inc., Etal, -v-Overnite Transportation Company, Application Dismissed.

MC 16513 (Sub-15F), Reisch Trucking & Tranportation Company, Inc., transferred to Modified Procedure.

MC 69116 (Sub-238F), Spector Industries, Inc. d.b.a. Spector Freight Systems, transferred to Modified Procedure.

MC 125708 (Sub-167F), Thunderbird Motor Freight Lines, Inc., now assigned for hearing on April 15, 1980 at Ft. Worth, TX, is canceled and transferred to Modified Procedure.

MC 146965-F, Redding Lumber Transport, Inc., now assigned for hearing on May 5, 1980 at Sacramento, CA, is canceled and transferred to Modified Procedure.

MC 57239 (Sub-45F), Renner's Express, Inc., now being assigned for hearing on July 21, 1980 (5 Days), at Indianapolis, IN, in a hearing room to be designated later.

MC 106887 (Sub-10F), A. D. Ray Trucking, Inc., MC 145976 (Sub-2F), C & Y Leasing Corporation, now assigned for hearing on May 5, 1980 (1 week) at Casper, WY, in a hearing room to be designated later.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-11332 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

[Rule 19; Ex Parte No. 241; 41st Rev. Exemption No. 12]

Exemption Under Provision of Mandatory Car Service Rules

It appearing, That the railroads named herein own numerous plain boxcars; that under present conditions, there is virtually no demand for these cars on the lines of the car owners; that return of these cars to the car owners would result in their being stored idle on these lines; that such cars can be used by other carriers for transporting traffic offered for shipments to points remote from the car owners; and that compliance with Car Service Rules 1 and 2 prevents such use of plain boxcars owned by the railroads listed herein, resulting in unnecessary loss of utilization of such cars.

It is ordered, That, pursuant to the authority vested in me by Car Service Rule 19, plain boxcars described in the Official Railway Equipment Register, ICC RER 6410-D, issued by W. J. Trezise, or successive issues thereof, as having mechanical designation "XM" or "XMI," and bearing reporting marks assigned to the railroads named below, shall be exempt from provisions of Car Service Rules 1(a), 2(a) and 2(b).

Atlantic and Western Railway
Reporting Marks: ATW
Chicago & Illinois Midland Railway Company
Reporting Marks: CIM
*Consolidated Rail Corporation
Reporting Marks: BCK-CNJ-CR-DLW-EL-ERIE-LV-NH-NYC-P&E PAE-PC-PCA-PRR-RDG-TOC
Fonda, Johnstown and Gloversville Railroad Company
Reporting Marks: FJG
Hartford and Slocum Railroad Company
Reporting Marks: HS
Hillsdale County Railway Company Inc.
Reporting Marks: HCRC
Lackawaxen and Stourbridge Railroad Corporation
Reporting Marks: LASB
Maryland and Pennsylvania Railroad Company
Reporting Marks: MPA
Pickens Railroad Company
Reporting Marks: PICK

Effective April 1, 1980, and continuing in effect until further order of this Commission.

Issued at Washington, D.C., March 28, 1980.

Interstate Commerce Commission.

Joel E. Burns,

Agent.

[FR Doc. 80-11327 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

[Rule 19; Ex Parte No. 241; 82d Rev. Exemption No. 90]

Exemption Under Provision of Mandatory Car Service Rules

It appearing, That the railroads named below own numerous 50-ft. plain boxcars; that under present conditions there are substantial surpluses of these cars on their lines; that return of these cars to the owners would result in their being stored idle; that such cars can be used by other carriers for transporting traffic offered for shipments to points remote from the car owners; and that compliance with Car Service Rules 1 and 2 prevents such use of these cars, resulting in unnecessary loss of utilization of such cars.

It is ordered, That pursuant to the authority vested in me by Car Service Rule 19, 50-ft. plain boxcars described in the Official Railway Equipment Register, ICC RER 6410-D, issued by W. J. Trezise, or successive issues thereof, as having mechanical designation "XM," and bearing reporting marks assigned to the railroads named below, shall be exempt from provisions of Car Service Rules 1, 2(a), and 2(b).

*Addition.

Aberdeen and Rockfish Railroad Company
Reporting Marks: AR
The Ahnapee & Western Railway Company
Reporting Marks: AHW
Ann Arbor Railroad System, Michigan Interstate Railway Company, Operator
Reporting Marks: AA
Apalachicola Northern Railroad Company
Reporting Marks: AN
The Arcata and Mad River Railroad Company
Reporting Marks: AMR
The Atchison, Topeka and Santa Fe Railway Company
Reporting Marks: ATSF
Atlanta & Saint Andrews Bay Railway Company
Reporting Marks: ASAB
Bath and Hammondsport Railroad Company
Reporting Marks: BH
Berlin Mills Railway, Inc.
Reporting Marks: BMS
* * *
Cadiz Railroad Company
Reporting Marks: CAD
Camino, Placerville & Lake Tahoe Railroad Company
Reporting Marks: CPLT
Central Vermont Railway, Inc.
Reporting Marks: CV
Chesapeake Western Railway
Reporting Marks: CHW
City of Prineville
Reporting Marks: COP
The Claredon and Pittsford Railroad Company
Reporting Marks: CLP
Columbus and Greenville Railway Company
Reporting Marks: CAGY
Delaware and Hudson Railway Company
Reporting Marks: DH
Delta Valley & Southern Railway Company
Reporting Marks: DVS
Detroit and Mackinac Railway Company
Reporting Marks: D&M–DM
Detroit, Toledo and Ironton Railroad Company
Reporting Marks: DT&I–DTI
Duluth, Missabe and Iron Range Railway Company
Reporting Marks: DMIR
East Camden & Highland Railroad Company
Reporting Marks: EACH
East St. Louis Junction Railroad Company
Reporting Marks: ESLJ
Galveston Wharves
Reporting Marks: GWF
Genessee and Wyoming Railway Company
Reporting Marks: GNWR
Green Bay and Western Railway Company
Reporting Marks: GBW
Green Mountain Railroad Company
Reporting Marks: GMRC
Greenville and Northern Railway Company
Reporting Marks: GRN
The Hutchinson and Northern Railway Company
Reporting Marks: HN
Helena Southwestern Railroad Company
Reporting Marks: HSW
Illinois Terminal Railroad Company
Reporting Marks: ITC
Indiana Eastern Railroad and Transportation, Inc. d.b.a. The Hoosier Connection
Reporting Marks: HOSC
Lake Erie, Franklin & Clarion Railroad Company
Reporting Marks: LEF
Lake Superior & Ishpeming Railroad Company
Reporting Marks: LSI
Lamoille Valley Railroad Company
Reporting Marks: LVRC
Lancaster and Chester Railway Company
Reporting Marks: LC
Lenawee County Railroad Company, Inc.
Reporting Marks: LCRC
Longview, Portland & Northern Railway Company
Reporting Marks: LPN
Louisiana Midland Railway Company
Reporting Marks: LOAM
Louisville and Wadley Railway Company
Reporting Marks: LW
Louisville, New Albany & Corydon Railroad Company
Reporting Marks: LNAC
Manufacturers Railway Company
Reporting Marks: MRS
Maryland and Delaware Railroad Company
Reporting Marks: MDDE
McCloud River Railroad Company
Reporting Marks: MR
Middletown and New Jersey Railway Company, Inc.
Reporting Marks: MNJ
Mississippian Railway
Reporting Marks: MISS
Missouri-Kansas-Texas Railroad Company
Reporting Marks: MKT–BKTY
*Moscow, Camden & San Augustine Railroad
Reporting Marks: MCSA
New Hope and Ivyland Railroad Company
Reporting Marks: NHIR
New Jersey, Indiana & Illinois Railroad Company
Reporting Marks: NJII
New Orleans Public Belt Railroad
Reporting Marks: NOPB
New York, Susquehanna and Western Railroad Company
Reporting Marks: NYSW
Norfolk and Western Railway Company
Reporting Marks: ACY–N&W–NKP–WAB
Norfolk, Franklin and Danville Railway Company
Reporting Marks: NFD
North Louisiana & Gulf Railroad Company
Reporting Marks: NL&G
Octararo Railway, Inc.
Reporting Marks: OCTR
*Ontario Midland Railroad Corp.
Reporting Marks: OMID
*Oregon, California & Eastern Railway Company
Reporting Marks: OCE
*Oregon, Pacific and Eastern Railway Company
Reporting Marks: OPE
Pearl River Valley Railroad Company
Reporting Marks: PRV
Peninsula Terminal Company
Reporting Marks: PT
Pittsburgh, Allegheny & McKees Rocks Railroad Company
Reporting Marks: PA&M
*The Pittsburgh and Lake Erie Railroad Company
Reporting Marks: P&LE
Port Huron and Detroit Railroad Company
Reporting Marks: PHD
Port of Tillamook Bay Railroad
Reporting Marks: POTB
Prairie Trunk Railway
Reporting Marks: PARY
Raritan River Rail Road Company
Reporting Marks: RR
St. Lawrence Railroad
Reporting Marks: NSL
St. Louis Southwestern Railway Company
Reporting Marks: SSW
St. Marys Railroad Company
Reporting Marks: SM
Sandersville Railroad Company
Reporting Marks: SAN
Savannah State Docks Railroad Company
Reporting Marks: SSDK
Sierra Railroad Company
Reporting Marks: SERA
Southern Pacific Transportation Company
Reporting Marks: SP
Southern Railway Company
Reporting Marks: CG–NS–SA–SOU
Terminal Railway, Alabama State Docks
Reporting Marks: TASD
The Texas Mexican Railway Company
Reporting Marks: TM
Toledo, Peoria & Western Railroad Company
Reporting Marks: TPW
*Transkentucky Transportation Railroad, Inc.
Reporting Marks: TTIS
Union Railroad of Oregon
Reporting Marks: UO
Upper Merion and Plymouth Railroad Company
Reporting Marks: UMP
Vermont Railway, Inc.
Reporting Marks: VTR
The Virginia and Maryland Railroad Company
Reporting Marks: VAMD
Virginia Central Railway
Reporting Marks: VC
Warwick Railway Company
Reporting Marks: WRWK
Wabash Valley Railroad Company
Reporting Marks: WVRC
WCTU Railway Company
Reporting Marks: WCTR
Youngstown & Southern Railway Company
Reporting Marks: YS
Yreka Western Railroad Company
Reporting Marks: YW

Effective April 1, 1980, and continuing in effect until further order of this Commission.

Issued at Washington, D.C., March 28, 1980.

Interstate Commerce Commission.

Joel E. Burns,

Agent.

*Additions.
***Delete: Burlington Northern Inc.

[FR Doc. 80–11328 Filed 4–14–80; 8:45 am]
BILLING CODE 7035–01–M

[Ex Parte No. 311]

Expedited Procedures for Recovery of Fuel Costs

Decided: April 8, 1980.

In our decision of February 26, March 4, 11, 18, 25, and April 1, 1980, a 13-percent surcharge was authorized on all owner-operator traffice, and on all truckload traffic whether or not owner-operators were employed. We ordered that all owner-operators were to receive compensation at this level.

The weekly figures set forth in the appendix for transportation performed by owner-operators and for truckload traffic is 13.5-percent. Accordingly, we are authorizing a 13.5 percent surcharge for this traffic. All owner-operators are to receive compensation at the 13.5-percent-level. No change will be made in the existing authorization of a 2.3-percent surcharge on less-than-truckload (LTL) traffic performed by carriers not utlizing owner-operators, the 1.3-percent surcharge for United Parcel Service, nor in the 5.0-percent surcharge authorized for the bus carriers.

Notice shall be given to the general public by mailing a copy of this decision to the Governor of each State and to the Public Utilities Commission or Boards of each State having jurisdiction over transportation, by depositing a copy in the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., for public inspection and by delivering a copy to the Director, Office of the Federal Register for publication therein.

It is ordered:

This decision shall become effective Friday 12:01 a.m., April 11, 1980.

By the Commission: Chairman Gaskins, Vice Chairman Gresham Commissioners Stafford, Clapp, Trantum and Alexis. Commissioner Stafford dissenting with a separate expression.

Agatha L. Mergenovich,

Secretary.

Commissioner Stafford (Dissenting)

I would hold the owner-operator/truckload surcharge to 13 percent.

Appendix—Fuel Surcharge

Base date and price per gallon (including tax)

January 1, 1979 ..... 63.5¢

Date of current price measurement and price per gallon (including tax)

April 7, 1980 ..... 114.1¢

	(1) From transportation performed by owner-operators [1]	(2) Other [2]	(3) Bus carrier	(4) UPS
Average percent: Fuel expenses (including taxes) of total revenue	16.9	2.9	6.3	3.3
Percent surcharge developed	13.5	2.3	5.0	[3]2.1
Percent surcharged allowed	13.5	2.3	5.0	[4]1.3

[1] Apply to all truckload rated traffic.

[2] Including less-than-truckload traffic.

[3] The percentage surcharge developed for UPS is calculated by applying 81 percent of the percentage increase in the current price per gallon over the base price per gallon to the UPS average percent of fuel expense to revenue figure as of January 1, 1979 (3.3 percent).

[4] The developed surcharge figure is reduced 0.8 percent to reflect fuel-related increases already included in UPS rates.

[FR Doc. 80-11331 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

Long- and Short-Haul Application for Relief; Formerly Fourth Section Application

April 9, 1980.

This application for long-and-short-haul relief has been filed with the ICC.

Protests are due at the ICC on or before April 30, 1980.

No. 43812, Southwestern Freight Bureau, Agent No. B-59, on Clay from stations in South Dakota and Wyoming to Kirbyville TX, and stations taking same basis of rates as published in Supplement 12 to Southwestern Freight Bureau, Agent's Tariff ICC SWFB 4321-A, effective May 14, 1980. Grounds for relief-destination rate relationships.

By the Commission.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-11330 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

[ICC Order No. 64 under S.O. No. 1344]

Meridian & Bigbee Railroad Co.; Rerouting or Diversion of Traffic

In the opinion of Joel E. Burns, Agent, the Meridian & Bigbee Railroad Company is unable to transport promptly all traffic offered for movement between Meridian, Mississippi, and Myrtlewood, Alabama, because of flooding.

It is ordered,

(a) *Rerouting traffic.* The Meridian & Bigbee Railroad Company being unable to transport promptly all traffic offered for movement between Meridian, Mississippi, and Myrtlewood, Alabama, because of flooding, that line and its connections are authorized to divert or reroute such traffic via any available route to expedite the movement. Traffic necessarily diverted by authority of this order shall be rerouted so as to preserve as nearly as possible the participation and revenues of other carriers provided in the original routing. The billing covering all such cars rerouted shall carry a reference to the order as authority for the rerouting.

(b) *Acceptance of traffic in interchange.* In the event the Meridian & Bigbee Railroad Company cannot accept traffic in interchange from a connecting carrier, the delivering carrier, after establishing such condition, may reroute or divert the traffic via any available route.

(c) *Concurrence of receiving roads to be obtained.* The railroad rerouting cars in accordance with this order shall receive the concurrence of other railroads to which such traffic is to be diverted or rerouted, before the rerouting or diversion is ordered.

(d) *Notification to shippers.* Each carrier rerouting cars in accordance with this order, shall notify each shipper at the time each shipment is rerouted or diverted and shall furnish to such shipper the new routing provided for under this order.

(e) Inasmuch as the diversion or rerouting of traffic is deemed to be due to carrier disability, the rates applicable to traffic diverted or rerouted by said Agent shall be rates which were applicable at the time of shipment on the shipments as originally routed.

(f) In executing the directions of the Commission and of such Agent provided for in this order, the common carriers involved shall proceed even though no contracts, agreements or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to said traffic. Divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between said carriers; or upon failure of the carriers to so agree, said divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(g) *Effective date.* This order shall become effective at 10:00 a.m., March 28, 1980.

(h) *Expiration date.* This order shall expire at 9:00 a.m., April 1, 1980, unless otherwise modified, changed or suspended.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. A copy of this order shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., March 28, 1980.

Interstate Commerce Commission.

Joel E. Burns,

Agent.

[FR Doc. 80-11325 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

Transportation of "Waste" Products for Reuse or Recycling; Special Certificate Letter Notice(s)

The following letter notices request participation in a Special Certificate of Public Convenience and Necessity for the transportation of "waste" products

for reuse or recycling in furtherance of a recognized pollution control program under the Commission's regulations (49 CFR Part 1062) promulgated in *"Waste" Products,* Ex Parte No. MC–85, 124 M.C.C. 583 (1976). Requests are processed as seeking authority between all points in the United States.

An original and one copy of protests (including protestant's complete argument and evidence) against applicant's participation may be filed with the Interstate Commerce Commission or or before May 5, 1980. A copy must also be served upon applicant or its representative. Protests against the applicant's participation will not operate to stay commencement of the proposed operation.

If the applicant is not otherwise informed by the Commission, operations may commence *within 30 days* of the date of its notice in the **Federal Register,** subject to its tariff publication effective date.

P–5–80 (Special certificate—waste products), filed March 10, 1980. Applicant: North Pacific Lumber Co., 1505 SE Gideon, Portland, OR. Representative: Michael D. Crew, 1700 Standard Plaza, Portland, OR 97204. Sponsor: Publishers Paper Company of Oregon City, OR. Commodity: Waste Products (waste paper).

By the Commission.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80–11329 Filed 4–14–80; 8:45 am]

BILLING CODE 7035–01–M

Decision-Notice

The following applications seek approval to consolidate, purchase, merge, lease operting rights and properties, or acquire control of motor carriers pursuant to 49 U.S.C. 11343 or 11344. Also, applications directly related to these motor finance applications (such as conversions, gateway eliminations, and securities issuances) may be involved.

The applications are governed by Special Rule 240 of the Commission's rules of practice (49 CFR 1100.240). These rules provide, among other things, that opposition to the granting of an application must be filed with the Commission within 30 days after the date of notice of filing of the application is published in the**Federal Register.** Failure seasonably to oppose will be construed as a waiver of opposition and participation in the proceeding. Opposition under these rules should comply with Rule 240(c) of the rules of practice which requires that it set forth specifically the grounds upon which it is made, and specify with particularity the facts, matters and things relied upon, but shall not include issues or allegations phrased generally. Opposition not in reasonable compliance with the requirements of the rules may be rejected. The original and one copy of any protest shall be filed with the Commission, and a copy shall also be served upon applicant's representative or applicant if no representative is named. If the protest includes a request for oral hearing, the request shall meet the requirements of Rule 240(c)(4) of the special rules and shall include the certification required.

Section 240(e) further provides, in part, that an applicant who does not intend timely to prosecute its application shall promptly request its dismissal.

Further processing steps will be by Commission notice or order which will be served on each party of record. *Broadening amendments will not be accepted after April 15, 1980 except for good cause shown.*

Any authority granted may reflect administratively acceptable restrictive amendments to the transaction proposed. Some of the applications may have been modified to conform with Commission policy.

We find with the exception of those applications involving impediments (e.g., jurisdictional problems, unresolved fitness questions, questions involving possible unlawful control, or improper divisions of operating rights) that each applicant has demonstrated, in accordance with the applicable provisions of 49 U.S.C. 11301, 11302, 11343, 11344, and 11349, and with the Commission's rules and regulations, that the proposed transaction should be authorized as stated below. Except where specifically noted this decision is neither a major Federal action significantly affecting the quality of the human environment nor does it appear to qualify as 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 protestant, that the proposed dual operations are consistent with the public interest and the national transportation policy subject to the right of the Commission, which is expressly reserved, to impose such conditions as it finds necessary to insure that applicant's operations shall conform to the provisions of 49 U.S.C. 10930.

In the absence of legally sufficient protests as to the finance application *or* any application directly related thereto filed on or before May 15, 1980 (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with impediments) upon compliance with certain requirements which will be set forth in a notification of effectiveness of this decision-notice. To the extent that the authority sought below may duplicate an applicant's existing authority, the duplication shall not be construed as conferring more than a single operating right.

Applicant(s) must comply with all conditions set forth in the grant or grants of authority within the time period specified in the notice of effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

MC–F–14291F, filed January 9, 1980. NATIONAL FREIGHT, INC. (National) (57 West Park Avenue, Vineland, NJ 08360)—control—ALL FLORIDA FREIGHTWAYS, INC. (All) (57 West Park Avenue, Vineland, NJ 08360) and ALL FLORIDA FREIGHTWAYS, INC.—control and merger—CROWN MOTOR LINES, INC. (Crown) (2225 Broadway Avenue, Jacksonville, FL 32211). Representative: Peter J. Nickles, 888 16th Street NW., Washington, DC 20006. National seeks authority to control All, through the purchase of all of the capitol stock of All. By the same application All seeks authority to acquire control of Crown and to merge the operating rights and property of Crown into All for ownership, management, and operation. Bernard A. Brown who controls National through ownership of 58% of its common stock, and who controls All through ownership of its common stock, seeks to acquire control of All and Crown through this transaction.

The operating rights to be acquired by All are contained in Crown's certificates issued in No. MC–96925 and sub-numbers thereunder, which authorizes the transportation as follows: (1) Irregular route authority for *commodities generally,* except commodities in bulk or in tank trucks, commodities requiring special equipment or special handling, or commodities requiring mechanical refrigeration; between Callahan, Hilliard, Cecil Field, Jacksonville, Jacksonville Beach and Mayport, FL. (Service between Cecil Field, FL, on the one hand, and, Mayport and Jacksonville, Naval Air Station, FL, on the other, shall be restricted to shipments originating and terminating at those three points only); and (2) *Commodities generally,* except articles in bulk and articles requiring specialized

equipment and specialized handling, between Jacksonville and Palatka, FL, over U.S. Hwy 17, serving intermediate points of Orange Park, Green Cove Springs and Bostwick, FL, and off-route point of Penny Farms, FL; thence over FL Hwy 207 to Hastings and Spuds, FL; thence over FL Hwy 13 to Riverdale, Picolata, Orangedale, Switzerland, Mandarin, and Jacksonville, FL. *General commodities*, except those of unusual value, Classes A and B explosives, commodities in bulk, those requiring special equipment, and household goods as defined by the Commission, between Orlando, FL, and Ocala, FL, serving all intermediate points and the off-route points of Eustis and Altamonte Springs, FL: From Orlando over U.S. Hwy 441 to Ocala, and return over the same route; between DeLand, FL, and Eustis, FL, serving all intermediate points: from DeLand over FL Hwy 44 to Eustis, and return over the same route, between DeLand, FL, and Altoona, FL, serving all intermediate points: from FL Hwy 42 to Altoona, and return over the same route, between Eustis, FL, and Groveland, FL, serving all intermediate points: from Eustis over Hwy 19 to Groveland, and return over the same route, between Ocala, FL, and Barberville, FL, serving all intermediate points and the off-route points of Moss Bluff, Fort McCoy, Orange Springs, Starke's Landing and Connor, FL: from Ocala over FL Hwy 40 to Barberville and return over the same route, between Sanford, FL, and Mt. Dora, FL, serving all intermediate points: from Sanford over FL Hwy 46 to Mt. Dora, and return over the same route, between Astor Park, FL, and Clermont, FL, serving all intermediate points: from Astor Park over FL Hwy 445 to jct FL Hwy 19, thence over FL Hwy 19 to jct FL Hwy 561, and thence over FL Hwy 561 to Clermont, and return over the same route, between Jacksonville, FL, and New Smyrna Beach, FL, serving all intermediate points and the off-route point of Ormond Beach, FL: from Jacksonville over U.S. Hwy 1 to New Smyrna Beach, and return over the same route. *General commodities*, except those of unusual value, Classes A and B explosives, commodities in bulk, those requiring special equipment, and household goods as defined by the Commission, between Jacksonville, FL, and Greenland, FL, as an alternate route for operating convenience only, in connection with carrier's authorized regular-route operations, serving no intermediate points: from Jacksonville over Alternate U.S. Hwy 1 (via John E. Matthews Bridge) to jct U.S. Hwy 1, thence over U.S. Hwy 1 to Greenland, and return over the same route.

(Restriction: These operations are restricted to the transportation of shipments having an immediate prior or subsequent movement in pool car or pool truck service or to the transportation of shipments having an immediate prior or subsequent movement by water.) *General commodities*, except those of unusual value, Classes A and B explosives, commodities in bulk, those requiring special equipment, and household goods as defined by the Commission, between Hawthorne, FL, and Palatka, FL, serving all intermediate points and the off-route point of Edgar, FL: from Hawthorne over FL Hwy 20 to Palatka, and return over the same route, between St. Augustine, FL, and Bunnell, FL, serving all intermediate points: from St. Augustine over FL Hwy 207 to Palatka, FL, thence over FL Hwy 100 to jct FL Hwy 20, and thence over FL Hwy 20 to Bunnell, and return over the same route, between DeLand, FL, and New Smyrna Beach, FL, serving all intermediate points: from DeLand over FL Hwy 44 to New Smyrna Beach, and return over the same route, between DeLand, FL, and Daytona Beach, FL, serving all intermediate points: from DeLand over U.S. Hwy 17 to jct U.S. Hwy 92, thence over U.S. Hwy 92 to Daytona Beach, and return over the same route, between DeLand, FL, and Bunnell, FL, serving all intermediate points: from DeLand over U.S. Hwy 17 to FL Hwy 11, and thence over FL Hwy 11 to Bunnell, and return over the same route, between Bunnell, FL, and Flagler Beach, FL, serving all intermediate points: from Bunnell over FL Hwy 11 to Flagler Beach, and return over the same route, between Jacksonville, FL, and Ocala, FL, serving all intermediate points: from Jacksonville over FL Hwy 228 to Maxville, FL, thence over U.S. Hwy 301 to Waldo, FL, thence over FL Hwy 24 to Gainesville, FL, and thence over U.S. Hwy 441 to Ocala, and return over the same route. (Restriction: These operations are restricted to the transportation of shipments having an immediate prior or subsequent movement in pool car or pool truck service or to the transportation of shipments having an immediate prior or subsequent movement by water.) *General commodities* (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), between Orlando, FL, and Ocala, FL, serving all intermediate points and the off-route points of Eustis and Altamonte Springs, FL: from Orlando over U.S. Hwy 441 to Ocala, and return over the same route, between Orlando, FL, and Leesburg, FL, serving all intermediate points: from Orlando over FL Hwy 50 to jct FL Hwy 33, thence over FL Hwy 33 to jct U.S. Hwy 27, and thence over U.S. Hwy 27 to Leesburg, and return over the same route, between DeLand, FL, and Eustis, FL, serving all intermediate points: from DeLand over FL Hwy 44 to Eustis, and return over the same route, between DeLand, FL, and Altoona, FL, serving all intermediate points: from DeLand over FL Hwy 42 to Altoona, and return over the same route, between Eustis, FL, and Groveland, FL, serving all intermediate points: from Eustis over FL Hwy 19 to Groveland, and return over the same route, between Ocala, FL, and Barberville, FL, serving all intermediate points and the off-route points of Moss Bluff, Fort McCoy, Orange Springs, Starke's Landing and Conner, FL: from Ocala over FL Hwy 40 to Barberville, and return over the same route. *General commodities* (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), between Sanford, FL, and Mt. Dora, FL, serving all intermediate points, from Sanford over FL Hwy 46 to Mt. Dora, and return over the same route, between Astor Park, FL, and Clermont, FL, serving all intermediate points: from Astor Park over FL Hwy 445 to FL Hwy 19, thence over FL Hwy 19 to jct FL Hwy 561, and thence over FL Hwy 561 to Clermont, and return over the same route, between Jacksonville, FL, and New Smyrna Beach, FL, serving all intermediate points and the off-route point of Ormond Beach, FL; from Jacksonville over U.S. Hwy 1 to New Smyrna Beach, and return over the same route, between Palatka, FL, and Hawthorne, FL, serving all intermediate points and the off-route point of Edgar, FL: from Palatka over FL Hwy 20 to Hawthorne, and return over the same route. (Restriction: This operation is restricted against service to, from, or between points in Alachua Cy., FL), between St. Augustine, FL, and Bunnell, FL, serving all intermediate points: from St. Augustine over FL Hwy 207 to Palatka, FL, thence over FL Hwy 100 to jct FL Hwy 20 and thence over FL Hwy 20 to Hawthorne, and return over the same route. *General commodities* (except those of unusual value, Classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), between DeLand, FL, and New Smyrna Beach, FL, serving all intermediate points: from DeLand over FL Hwy 44 to New Smyrna Beach, and return over the same route,

between DeLand, FL, and Daytona Beach, FL, serving all intermediate points: from DeLand over U.S. Hwy 17 to jct U.S. Hwy 92, thence over U.S. Hwy 92 to Daytona Beach, and return over the same route, between DeLand, FL, and Bunnell, FL, serving all intermediate points: From DeLand over U.S. Hwy 17 to jct FL Hwy 11, and thence over FL Hwy 11 to Bunnell, and return over the same route, between Bunnell, FL, and Flagler Beach, FL, serving all intermediate points: from Bunnell over FL Hwy 100 to Flagler Beach, and return over the same route, between Jacksonville, FL, and Ocala, FL, serving all intermediate points: from Jacksonville over FL Hwy 228 to Maxville, FL, thence over U.S. Hwy 301 to Waldo, FL, thence over U.S. Hwy 24 to Gainesville, FL, thence over U.S. Hwy 441 to Ocala, and return over the same route. (Restriction: This operation is restricted against service to, from or between any points in Alachua Cy., FL), between Jacksonville, FL, and Lake City, FL, serving all intermediate points: from Jacksonville, and over U.S. Hwy 90 to Lake City, and return over the same route, (Restriction: This operation is restricted against service to, from or between points in Columbia Cy, FL), between New Smyrna Beach, FL, and Melbourne, FL, serving all intermediate points: from New Smyrna Beach over U.S. Hwy 1 to Melbourne, and return over the same route, between Melbourne, FL, and Orlando, FL, serving all intermediate points: from Melbourne over U.S. Hwy 192 to Ashton, FL, thence over FL State Road 15 to Orlando, and return over the same route, between Jacksonville, FL, and Greenland, FL, as an alternate route for operating convenience, only, in connection with carrier's authorized regular-route operations, serving no intermediate points: From Jacksonville over Alternate U.S. Hwy 1 (via John E. Matthews Bridge), to jct U.S. Hwy 1, thence over U.S. Hwy 1 to Greenland, and return over the same route. *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 and tractors), between Ocala, FL, and Tampa, FL, serving no intermediate points, but serving points in Pinellas Cy., FL, as off-route points: from Ocala over FL Hwy 200 to jct Interstate Hwy 75, thence over Interstate Hwy 75, thence over Interstate Hwy 75 to Tampa, and return over the same route. (Restriction: These operations are restricted against the transportation of building and construction materials originating at Tampa, FL.) *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), (1) between Melbourne and Florida City, FL, over U.S. Hwy 1, serving all intermediate points, (2) between Tampa and Miami, FL: from Tampa over FL Hwy 60 to jct U.S. Hwy 27, at or near Lake Wales, FL, then over U.S. Hwy 27 to Miami, and return over the same route, serving all intermediate points, serving those points in FL on and south of a line beginning at Clearwater, FL, and extending along FL along FL Hwy 60 to its jct with Interstate Hwy 4, then along Interstate Hwy 4 to its jct with FL Hwy 50, then along FL Hwy 50 to its jct with FL Hwy 405, then along FL Hwy 405 to its jct with FL Hwy 402, then along FL Hwy 402 to the Atlantic Ocean (except Monroe Cy.) as off-route points in connection with routes (1) and (2) above, (3) between Melbourne and Miami, FL, from Melbourne over Interstate Hwy 95 to jct with Florida Turnpike, then over Florida Turnpike to Miami, and return over the same route, serving no intermediate points, as an alternate route for operating convenience only, (4) between Orlando and Miami, FL, from Orlando over Interstate Hwy 4 to jct with Florida Turnpike, then over Florida Turnpike to Miami, and return over the same route, serving no intermediate points, as an alternate route for operating convenience only. *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), between Ocala and Tampa, FL, (1) From Ocala over U.S. Hwy 301 to jct U.S. Hwy 92, then over U.S. Hwy 92 to Tampa, and return over the same route, serving all intermediate points, (2) from Ocala over State Road 40 to jct U.S. Hwy 41, then over U.S. Hwy 41 to Tampa, and return over the same route, serving all intermediate points. Serving in connection with routes (1) and (2) above, off-route points in Citrus, Hernando, Pasco, Pinellas, Hillsborough and Sumter Cys., FL. Operating rights of All Florida Freightways sought to be controlled by National Freight: all of the foregoing rights of Crown Motor Lines if All Florida's control of those rights and merger with Crown is approved; and the operating rights of Overseas Transportation Co. (Docket No. MC–1388) and South Florida Transportation Co. (Docket No. MC–97850), as approved in MC–F–13892, served March 6, 1980, specifically: regular route authority for *explosives, articles of unusual value,* and *general commodities,* except household goods as defined by the Commission, commodities in bulk, commodities requiring special equipment, and those injurious or contaminating to other lading, between Miami, FL, and Key West, FL, serving all intermediate points, and the off-route points of Opa Locka, FL, and points within ten miles of U.S. Hwy 1 between Miami and Key West, FL, from Miami over U.S. Hwy 1 to Key West, and return over the same route, and *automobiles, trucks,* and *buses,* in secondary movements, in truckaway and driveaway service, between Miami, FL, and Key West, FL, serving no intermediate points, From Miami over U.S. Hwy 1 to Key West, and return over the same route; regular route authority for *general commodities,* except those of unusual value, Class A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment, between Miami, FL, and Homestead, FL, serving all intermediate points, and the off-route point of the plant site of Lehigh Portland Cement Company, near Sweetwater, FL, from Miami over U.S. Hwy 41 to junction FL Hwy 27, and thence south over FL Hwy 27 to Homestead, and return over the same route; and authority to transport *freight* in common carriage: to, from and between Ft. Lauderdale and Miami, FL, and intermediate points over State Road No. 5 and, as an alternate route, over State Road No. 84, from Ft. Lauderdale to State Road No. 7, thence over State Road No. 7 to Miami, FL, serving Coconut Grove, Dania Beach, Davie, Deerfield Beach, Golden Beach, Gulfstream, Hialeah, Hollywood Beach, Miami Beach, Miami Springs, North Miami Beach, Opa-Locka, Pompano Beach, Port Everglades, and Wilton Manor, as off-route points, and between Ft. Lauderdale and Riviera Beach, FL, serving all intermediate points, over the following routes, from Ft. Lauderdale, FL, north over U.S. Hwy No. 1 (State Road No. 5) and/or State Road No. A1A to Riviera Beach, FL, and return over the same routes, with authority to use the Sunshine State Parkway for operating conveniences only, and including all lateral east-west highways and/or streets connecting the three routes above named; and a Certificate of Registration issued in Docket No. MC–97850 (Sub 2) issued on June 26, 1968, to operate and transport general commodities over regular and alternate routes as follows: (a) Between Riviera Beach and Orlando, FL, serving all intermediate points: from Riviera Beach

over U.S. Hwy 1 to Titusville, thence over State Road 405 to its junction with State Road 50, thence over State Road 50 to Orlando, and return over the same route, (b) between Miami and Orlando, FL, serving all intermediate points, from Miami over U.S. Hwy 27 to South Bay, thence over State Road 80 to Belle Glade, thence over U.S. Hwy 441 to Orlando, and return over the same route, (c) between South Bay and Orlando, FL, serving all intermediate points: from South Bay over U.S. Hwy 27 and 27A to Haines City, thence over U.S. Hwy 17 to Orlando and return over the same route, (d) between Miami and Tampa, FL, serving all intermediate points, from Miami over U.S. Hwy 41 to Punta Gorda, thence over U.S. Hwy 17 to Bartow, thence over U.S. Hwy 92 to Tampa and return over the same route, (e) Between Punta Gorda and Tampa, FL, over U.S. Hwy 41 serving all intermediate points, (f) Between the junction of U.S. Hwy 41 and State Road 29 near Everglades, FL, and Fort Myers, FL, serving all intermediate points: from said junction of U.S. Hwy 41 with State Road 29 to its junction with State Road 82, thence over State Road 82 to Fort Myers and return over the same route, (g) Between Orlando and Tampa, FL, over Interstate Hwy 4 serving no intermediate points, (h) Between the West Palm Beach interchange on the Sunshine State Parkway and the junction of said parkway with U.S. Hwy 17, over the Sunshine State Parkway, as an alternate route for operating convenience only, subject to the restriction that no authority is granted hereby to engage in heavy hauling, as construed by orders of the Commission, or to transport commodities in bulk, liquid or dry, and over the following off-route areas: (i) All other points in FL on or south of a line beginning at the western terminus of FL Hwy 60, thence easterly along FL Hwy 60 to its junction with Interstate Hwy 4, thence easterly along Interstate Hwy 4 to its junction with FL Hwy 50, thence easterly along FL Hwy 50 to its junction with FL Hwy 405, thence northeasterly along FL Hwy 405 to its junction with FL Hwy 402, thence easterly along FL Hwy 402 to its eastern terminus (except those points in Dade and Monroe Counties on U.S. Hwy 1 and FL Hwy 27, south of Miami will be served as off-route points). National is a *common carrier* pursuant to certificates No. MC–2860 and sub-numbers thereunder. These authorities include general commodity regular-routes extending between CT and DC, and general commodity irregular route authority in the New England and Middle-Atlantic states, and special commodity irregular route authority in the eastern half of the country. (Hearing site: Washington, DC.)

Note.—An application for temporary authority has been filed.

MC–F–14300F, Filed January 21, 1980. STAFFORD TRUCKING, INC. (2155 Hollyhock Lane, Elm Grove, Wisconsin 53122)—purchase—Wunnicke Transfer Lines, Inc. (101 South Buchanan Street, Boscobel, Wisconsin 53805.) Representatives: Richard A. Westley, 4506 Regent Street, suite 100, Madison, WI 53705 and Rolfe E. Hanson, 121 West Doty Street, Madison, WI 53703. Stafford Trucking, Inc. (Stafford) purchasing the operating rights of Wunnicke Transfer Lines, Inc. (Wunnicke). Jack P. Stafford and Grace Stafford, both of 2155 Hollyhock Lane, Elm Grove, WI 53122, and Wilcy Stafford, of 836 River Street, Portage, WI 53901, seeks to acquire control of the rights of Wunnicke through the transaction. The interstate operating rights that the transferee is purchasing are contained in Wunnicke's permits which authorize operations as a *contract carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, as follows: MC–13095 transporting *Malt Beverages*, from St. Paul, MN, to points in Crawford, Grant, Richland, and Iowa Counties, WI. *Empty malt beverage containers*, from points in Crawford, Grant, Richland, and Iowa Counties, WI to St. Paul, MN. *Canned goods*, from points in Brown, Calumet, Manitowoc, Sheboygan, Fond du Lac, Dodge, Columbia and Green Lake Counties, WI, to Dubuque, IA and East Dubuque, IL. *Apples*, from Gays Mills, WI, and points within six miles thereof, to points in ND, SD, MN, IA, and IL. *Grain, feed, salt, seed, and agricultural commodities*, between points in WI south and west of a line beginning at La Crosse, WI, and extending along U.S. Highway 16 to junction WI Highway 13, thence along WI Highway 13 to Beloit, WI, those points in IL north of U.S. Highway 6, and those points in IA north and east of a line beginning at Davenport, IA, and extending along U.S. Highway 6 to Des Moines, IA, thence along U.S. Highway 69 to the IA-MN state line, including points on the indicated portions of the highways specified. And under such contracts or agreements with persons (as defined in section 203(a) of the Interstate Commerce Act) who operate retail grocery and food business houses, the business of which is the sale of food, for the transportation of the commodities indicated and in the manner specified below: *Such merchandise* as is dealt by retail grocery and food business houses, and in connection therewith, *equipment, materials, and supplies* used in the conduct of such business, from Clinton, Davenport, and Dubuque, IA, and Freeport and Chicago, IL, to Boscobel, Soldiers Grove, Dodgeville, Fennimore, and Spring Green, WI. And under such contracts or agreements with persons (as defined in section 203(a) of the Interstate Commerce Act) who operate wholesale houses or retail stores, the business of which is the sale of food, for the transportation of the commodities indicated and in the manner specified below: *Such merchandise* as is dealt in by wholesale, retail, and chain grocery and food business houses, and in connection therewith, *equipment, materials, and supplies* used in the conduct of such business, (a) from Dubuque, IA and Milwaukee, WI, to points in WI south and west of a line beginning at La Crosse, WI, and extending along U.S. Highway 16 to Wisconsin Dells, WI, thence along WI Highway 13 to Beloit, WI including points on the indicated portions of the highways specified, and (b) Between points in Wisconsin territory described immediately above. And under such contracts or agreements with persons (as defined in section 203(a) of the Interstate Commerce Act) who operate wholesale houses, the business of which is the sale of cheese, for the transportation of the commodities indicated and in the manner specified below: *Creamery and cheese factory supplies and cheese*, (a) between Boscobel, WI, and points in WI within 35 miles of Boscobel, on the one hand, and, on the other, Sterling, Freeport, Dixon, and Chicago, IL, and Beaver Dam, Green Bay, Merrill, Sheboygan, Wisconsin Rapids, DePere, Loyal, Milwaukee, Superior, Fond du Lac, Marshfield, Plymouth, and Monroe, WI, (b) Between Sterling, Freeport, Dixon, and Chicago, IL, and points on that portion of U.S. Highway 18 between Clear Lake, IA, and the IA-WI state line, including Clear Lake, on the one hand, and, on the other, Beaver Dam, Green Bay, Merrill, Sheboygan, Wisconsin Rapids, DePere, Loyal, Milwaukee, Superior, Fond du Lac, Marshfield, Plymouth, and Monroe, WI, and (c) From points on that portion of U.S. Highway 18 between Clear Lake, IA, and the IA-WI state line, including Clear Lake, to Sterling, Freeport, Dixon, and Chicago, IL, and Boscobel, WI, and points in WI within 35 miles of Boscobel; MC–13095 (Sub-No. 8), transporting *Dried whey mixed with animal fat*, from Boscobel, WI, to Dundee, Gibson City, Peoria, Pittsfield, Union, and Waukegan, IL, Cedar Rapids, Davenport, Marshalltown, and Sioux

City, IA, and Mankato and Minneapolis, MN. *Lactose*, from Boscobel, WI, to Milwaukee, WI, Restriction: The operations authorized above are limited to a transportation service to be performed under a continuing contract, or contracts, with Milk Specialties, Inc., of Dundee, IL. *Butter*, from Richland Center, WI, to Dubuque, IA, Restriction: The operations authorized next above are limited to a transportation service to be performed, under a continuing contract, or contracts, with Breakstone Sugar Creek Foods Division of Kraftco Corporation, of Chicago, IL. *Cheese and creamery and cheese factory supplies*, (a) from points in WI, to Van Hert, OH, and (b) From Monticello and Luana, IA, Houston, MN, and Van Wert, OH, to points in WI, Restriction: The operations authorized immediately above are limited to a transportation service to be performed, under a continuing contract, or contracts, with Borden Foods, Cheese Division, Division of Borden, Inc., of Plymouth, WI.; MC–13095 (Sub-No. 10), transporting *Whey, whey by-products, lactose, feeds and feed ingredients*, from Boscobel, WI, and Dundee, IL, to points in the United States (except AK and HI); and *Materials, supplies, and equipment* used or useful in the manufacture and distribution of the commodities in (1) above, from points in the United States (except AK and HI), to Boscobel, WI, and Dundee, IL. Restriction: The service authorized herein is subject to the following conditions: The authority granted herein is limited to the transportation of service to be performed, under a continuing contract, or contracts, with Milk Specialists Co., Division of Cudahy Company, of Dundee, IL. The authority granted herein is restricted against the transportation of commodities in bulk; and MC–13095 (Sub-No. 12) transporting *Materials and supplies* used or useful in the manufacture and distribution of cheese, from points in WI to Mission, SD; and *Cheese*, from Mission, SD, to points in WI. Restriction: The operations authorized herein are limited to a transportation service to be performed, under a continuing contract, or contracts, with Borden, Inc. Stafford Trucking, Inc., holds motor common carrier authority pursuant to certificates issued in MC–117370 and sub-numbers thereunder. Dahlman Truck Lines, Inc., a motor common carrier controlled by Jack P. Stafford, holds authority pursuant to certificates issued in MC–123907 and sub-numbers thereunder. (Hearing site: Madison, WI, or Chicago, IL.)

Notes.—(1) Dual operations may be involved. (2) Application for temporary authority has been filed.

MC–F–14318F, filed February 15, 1980. ELEVELD CHICAGO FURNITURE SERVICE, INC. (Eleveld) (4020 West 24th Street, Chicago, IL 60623)—purchase (portion)—ALLIED VAN LINES, INC. (Allied) (25th Avenue and Roosevelt Road, Broadview, IL 60153). Representative: Terry G. Fewell, P.O. Box 4403, Chicago, IL 60680. Eleveld seeks authority to purchase a portion of the interstate operating rights of Allied. Allied, the sole stockholder of Eleveld, seeks authority to continue in control of said rights through the transaction. The operating rights to be purchased by Eleveld are contained in Allied's certificate No. MC–15735 (Sub-No. 27), which authorize operations, as a motor common carrier, over irregular routes, transporting *furniture, furnishings, appliances, store and office fixtures, kitchen fixtures and equipment, and institutional fixtures and equipment*, all new and uncrated, between points in CA, OK, and WA, on the one hand, and, on the other, points in the United States (except AK and HI). Eleveld holds authority from the Commission pursuant to a certificate issued in MC–87966, which authorizes the transportation of *household goods*, as defined by the Commission, between specified points in NJ, on the one hand, and, on the other, points in NJ, NY, PA, CT, and MA. Allied holds authority as a motor *common carrier* pursuant to certificates issued in MC–15735 and sub-numbers thereunder. Allied also controls Transportation Equity Corporation, a noncarrier which controls Blodgett Furniture Service, Inc., a motor *common carrier* pursuant to certificates issued in MC–35890 and sub-numbers thereunder. (Hearing site: Chicago, IL.)

MC–F–14325F, filed March 3, 1980. PENINSULA TRUCK LINES, INC. (Peninsula) (6314, Seventh Avenue South, P.O. Box 80038, Seattle, WA 98108)—purchase—OLYMPIC TRANSPORTATION CO. (Olympic) (306 East State Street, Aberdeen, WA 98520). Representative: Michael A. Jonson, 300 Central Building, Seattle, WA 98104. Peninsula seeks authority to purchase the interstate operating rights and property of Olympic. Stanley Vander Pol, Merwyn Haveman, and Paul Vander Pol, who combined control Peninsula through the majority stock ownership, seek to acquire control of said rights and property through the transaction. Peninsula is purchasing the interstate operating rights contained in Olympic's Certificates in MC–65773 and MC–65723 (Sub-No. 2), which authorize the transportation, as a motor common carrier, over regular routes, of *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), (1) between Aberdeen and Forks, WA, over U.S. Hwy 101, with service authorized to and from the intermediate and off-route points of Hoquiam, Humptulips, Neilton, Quinault, Queets, Kalaloch, Ewell Ranch, and Clearwater, WA; (2) between Aberdeen and Taholah, WA, from Aberdeen over U.S. Hwy 101 to junction WA Hwy 9C, then over WA Hwy 9C to Taholah, and return over the same route, serving all intermediate points; and (3) between Copalis Beach and Aberdeen, WA, from Copalis Beach over WA Hwy 90 to junction U.S. Hwy 101, then over U.S. Hwy 101 to Aberdeen, and return over the same route, with service authorized to and from the intermediate and off-route points of Hoquiam, Tulips, Copalis, Copalis Crossing and Ocean City, WA. Peninsula is authorized to operate as a motor common carrier, transporting general and specified commodities, over regular and irregular routes, in the State of WA, pursuant to certificates issued in MC–113165 and sub-numbers thereunder. (Hearing site: Seattle or Tacoma, WA.)

Note.—Application for temporary authority has been filed in MC–FC–78243F.

MC–F–14326F, filed February 29, 1980. DONALD H. BAUGHMAN, INC. (Baughman) (986 Oliver Street, North Tonawanda, NY 14120)—purchase (portion)—JOHN SCHUTT, JR., INC. (Schutt) (665 River Road, North Tonawanda, NY 14120). Representative: William J. Hirsch, 43 Court Street, Buffalo, NY 14202, and Frank J. Weiner, 15 Court Square, Boston, MA 02108. Baughman seeks authority to purchase a portion of the interstate operating rights and property of Schutt. Donald H. Baughman, the sole stockholder of Baughman, seeks authority to acquire control of said rights through the transaction. Baughman is purchasing the interstate operating rights contained in Schutt's Certificates in MC–104123 (Sub-Nos. 60, 66, 69, 71, 73, 75, and 77), which authorize the transportation, as a motor common carrier, over irregular routes, of the following: (1) *Malt*, in bulk, from Buffalo, NY to points in CT, DE, MD, MA, NH, NJ, NY, PA, and RI; (2) *aluminum chloride anhydrous*, in bulk, in tank vehicles, equipped with pneumatic unloading devices, from Lockport, NY to Institute, WV; (3) *aluminum chloride*, in bulk, in tank vehicles, from Elberta, NY to Institute,

WV; (4) *aluminum chloride,* in bulk, in tank vehicles, from the port of entry on the U.S.-Canada Boundary line at Buffalo, NY to points in that part of WV on and west of U.S. Hwy 19; (5) *aluminum chloride,* in bulk, from Elberta and Lockport, NY and ports of entry on the U.S.-Canada Boundary line located on the Niagara River to points in AL, CT, DE, FL, GA, IL (except points in St. Louis, MO—East St. Louis, IL Commercial Zone as defined by the Commission), IN KY, ME, MD, MA, MI, MS, NH, NJ, NY, NC, OH, PA, RI, SC, TN, VT, VA, WV, and WI; (6) *dry aluminum chloride,* in bulk, in tank vehicles, (a) from Elberta and Lockport, NY to points in TX and LA, (b) from Brainards, NJ to Ashtabula, OH, Baltimore, MD, Institute, WV, West Elizabeth, PA, and Staten Island, NY; (c) from Elton, MD to Ashtabula, OH, Institute, WV, West Elizabeth, PA, and Staten Island, NY and (d) from LaPorte, TX, to Ashtabula, OH, Baltimore, MD, Institute, WV, West Elizabeth, PA and Staten Island, NY; (7) *anhydrous aluminum chloride,* dry, in bulk, in tank vehicles, from ports of entry on the U.S.-Canada Boundary line located in MI and NY to points in LA, MD, and TX restricted to traffic originating at the facilities of Welland Chemical, Ltd., at Sarnia, Ontario, Canada. Vendee is authorized to operate as a common carrier in the transportation of anhydrous aluminum chloride, in bulk, from the facilities of Ascension Chemical of Texas, Inc., at or near Huntsville, TX, to points in the United States (except AK, CA, and HI), under Certificae No. MC–144335F. (Hearing site: Buffalo, NY.)

MC–F–14327F, filed March 3, 1980. Applicant: WILLIAM A. NEELY (2055 North River Road, St. Clair, MI 48079), PAUL L. COSPER (28473 Westerleigh Road, Farmington Hills, MI 48018), CHARLES H. RACHES, JR. (2686 Birch Harbor Lane, West Bloomfield, MI 48033), FREDERICK G. SCHRIEVER (64 Clairview, Gross Pte. Shores, MI 8236), and G. WILLIAM COBLE (3618 Chalmette Court, Nashville, TN 37215)—Control—AURELIA TRUCKING CO. (Aurelia) (2121 Petit Avenue, Port Huron, MI 48060). Representative: Robert D. Schuler, 100 West Long Lake Road, suite 102, Bloomfield Hills, MI 48013. The individual vendees seek to acquire control of Aurelia through the purchase of 1,889 shares of the issued and outstanding shares of the capital stock of Aurelia. Vendees Neely, Cosper, Raches, and Schriever control W. H. Froh, Inc., a motor *contract carrier* pursuant to Permits in MC 117910 and sub-numbers thereunder, which authorize the transportation, over irregular routes, of *specified commodities,* in AR, IL, IN, IA, LA, MI, MN, MO, NY, OH, and WI. Vendee Coble controls Coble Systems, Inc., a non-carrier and sole stockholder of Liberty Contract Carrier, Inc., a motor *contract carrier* pursuant to authority authorized in MC 142181 and sub-numbers thereunder. The interstate operating rights of Aurelia sought to be controlled are contained in Certificates in MC 117820 and sub-numbers thereunder, which authorize the transportation, as a motor *common carrier,* over irregular routes, of *specified commodities,* in AL, AR, CT, DE, FL, GA, IL, IN, IA, KS, KY, LA, ME, MD, MA, MI, MN, MO, MS, NE, NH, NJ, NY, NC, OH, OK, PA, RI, SC, TN, VT, VA, WV, WI, and DC. (Hearing site: Lansing, MI.)

Notes.—(1) Dual operations may be involved. (2) Application for temporary authority has been filed.

MC–F–14304F, filed January 21, 1980. Applicant: ECKLEY TRUCKING, INC. (Eckley) (P.O. Box 201, Mead, NE 68041)—purchase (portion)—ERNEST McRAE, trustee in bankruptcy, and the FIRST NATIONAL BANK & TRUST CO. OF SALINA, KS, a secured creditor, for DALKE TRANSPORT, INC. (Dalke) (606 Douglas Building, Wichita, KS 67202). Representatives: A. J. Swanson, P.O. Box 1103, 226 North Phillips Avenue, Sioux Falls, SD 57101, and John E. Jandera, 641 North Harrison, Topeka, KS 66603. Eckley seeks authority to purchase a portion of the interstate operating rights of Dalke. Gerald Eckley, Gladys Eckley, James Eckley, Connie Eckley, Monty Walker, and Chris Walker, the stockholders of Eckley, also seek authority to acquire control of said rights through the transaction. Eckley is purchasing the interstate operating rights contained in Dalke's certificates in MC 140241 (Sub-Nos. 10, 19, and 25), which authorize the transportation, as a motor *common carrier,* over irregular routes, of (1)(a) *metal forming equipment and rolled formed steel articles,* from Moundridge, KS, to points in the United States (except AK, HI, and KS), and (b) *materials and supplies* used in the manufacture of metal forming equipment and rolled formed steel articles (except commodities in bulk), from points in the United States (except AK, HI, and KS), to Moundridge, KS, restricted to the transportation of traffic originating at or destined to the facilities of The Bradbury Co., Inc., at or near Moundridge, KS; (2)(a) *iron and steel articles,* and (b) *grain handling equipment,* from the facilities of Grain Spouting and Elevator of Kansas, Inc., at or near Hutchinson, KS, to points in the United States (except AK and HI), restricted to the transportation of traffic originating at the above-named origin facilities; and (3) *plastic pipe and plastic pipe fittings* (except commodities in bulk), from Broken Arrow, OK, to points in the United States (except AK and HI), restricted to the transportation of traffic originating at the facilities of Continental Industries, Inc., at or near Broken Arrow, OK. Eckley holds motor *common carrier,* authority pursuant to certificates issued in MC 5227 and sub-numbers thereunder. (Hearing site: Omaha, NE, or Wichita, KS.)

Notes.—(1) Application for temporary authority has been filed. (2) Eckley also seeks to purchase authority granted to Dalke in Mc 140241 (Sub-No. 8). This authority has not been certificated. Eckley should file a Petition for Substitution of Applicant in this sub-number.

Decided: April 3, 1980.

By the Commission, Review Board Number 5, Members Krock, Taylor, and Williams. (In MC–F–14300F, Board member Taylor dissents. He would condition the notice to show that applicant has failed to establish the amount of the purchase price. He is unwilling to approve an indefinite purchase price such as here proposed.)

Agatha Mergenovich,

Secretary.

[FR Doc. 80-11323 Filed 4-14-80; 8:45 am]

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[Vol. No. 7]

Petitions, Applications, Finance Matters (Including Temporary Authorities), Alternate Route Deviations, Intrastate Applications, Gateways, and Pack and Crate

Petitions for Modification, Interpretation or Reinstatement of Motor Carrier Operating Rights Authority; Notice

The following petitions seek modification or interpretation of existing motor carrier operating rights authority, or reinstatement of terminated motor carrier operating rights authority.

All Pleadings and documents must clearly specify the suffix numbers (e.g., M1 F, M2 F) where the docket is so identified in this notice.

The following petitions, filed on or after March 1, 1979, are governed by Special Rule 247 of the Commission's general rules of practice (49 CFR 1100.247). These rules provide, among other things, that a *petition to intervene either with or without leave* must be filed with the Commission on or before May 15, 1980, with a copy being furnished the applicant. Protests to these applications will be *rejected.*

A petition for intervention without leave must comply with Rule 247(k) which requires petitioner to demonstrate that if (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). In deciding whether to grant leave to intervene, the Commission considers, among other things, whether petitioner has (a) solicited the traffic or business of those persons 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. Another factor considered is the effects of any decision on petitioner's interests.

Samples of petitions and the text and explanation of the intervention rules can be found at 43 FR 50908, as modified at 43 FR 60277.

Petitioner not in reasonable compliance with these rules may be rejected. Note that Rule 247(e), where not inconsistent with the intervention rules, still applies. Especially refer to Rule 247(e) for requirements as to supplying a copy of conflicting authority, serving the petition on applicant's representative, and oral hearing requests.

MC 8973 (Sub-52M2F and Sub-44M1F), (notice of filing of petition to modify certificates), filed August 8, 1979. Petitioner: METROPOLITAN TRUCKING, INC., 2424 95th Street, North Bergen, NJ 07047. Representative: Morton E. Kiel, Suite 1832, 2 World Trade Center, New York, NY 10048. Petitioner holds a motor *common carrier* certificate in MC 8973 Sub-52 issued September 27, 1979, and MC 8973 Sub-44G issued July 14, 1978, respectively. MC 8973 Sub-52 authorizes transportation, over irregular routes (1) *Plastic articles* and *materials, equipment, and supplies* used in the manufacture or distribution of plastic articles (except commodities in bulk), between points in CT, NY, and those in NY located on or east of U.S. Hwy 11 and on or south of U.S. Hwy 20, on the one hand, and, on the other, points in the United States (except AK and HI). (2) *Aluminum articles, aluminum products, building materials,* and *materials, equipment, and supplies* used in the manufacture, sale, processing, distribution, and installation of the commodities listed in (2) above (except commodities in bulk), between New York, NY, on the one hand, and, on the other, points in the United States (except AK and HI). (3) *Chemicals and coal tar products,* in containers, between points in Bergen, Middlesex, and Morris Counties, NJ, on the one hand, and, on the other, points in CT and NJ, and those in NY on or east or U.S. Hwy 11 and on or south of U.S. Hwy 20. (4) *Such building materials* and *materials, equipment and supplies* used in the manufacture, sale, processing, distribution, or installation of building materials, as are chemicals or coal tar products in containers, between points in CT, NJ, and those points in NY, located on or east of U.S. Hwy 11 and on or south of U.S. Hwy 20, on the one hand, and, on the other, points in the United States (except AK and HI). (5) *Such asphalt, composition roofing products, urethane and urethane products,* as are chemicals or coal tar products, in containers, from points in CT, NJ and those points in NY on or east of U.S. Hwy 11 and on or south of U.S. Hwy 20, to points in AL, AR, IL, IN, KY, LA, MI, MS, OH, TN, and WV. (6) *Resins,* in containers, from points in CT and NJ and those points in NY on or east of U.S. Hwy 11 and on or south of U.S. Hwy 20 to points in OH, VA, MD, DE, PA, NJ, NY, MA, CT, ME, RI, NH, VT, and DC, restricted in (6) above to the transportation of shipments having a prior movement by water and destined to the points named above. MC 8973 Sub-44G authorizes transportation, over irregular routes, (1) *Materials, equipment, and supplies* (except commodities in bulk and commodities requiring special equipment) used in the manufacture and sale of plastic articles (except commodities in bulk), between those points in the United States in and east of ND, SD, NE, CO, NM, and TX (except points in NJ, NH, and ME), on the one hand, and, on the other New York, NY, and those points in Bergen, Middlesex, Morris, Passaic, and Somerset Counties, NJ, which are located more than 20 miles from the corporate limits of New York, NY. (2) *Such plastic articles and hardware used in the manufacture and sale of plastic articles* (except commodities in bulk and those requiring special equipment) and (commodities in bulk), from those points in the United States in and east of ND, SD, NE, CO, NM, and TX (except points in NJ, NH, and ME), to points in NJ, NY, ME, NH, VT, MA, RI, CT, PA, OH, DE, MD, VA, and DC. Restriction: The service authorized herein is restricted against the transportation of traffic from the facilities of the Celotex Corporation and Wicto Chemical Co., at or near Perth Amboy, NJ. This certificate may not be joined or tacked with the carrier's other irregular-route authority. By the instant petition, petitioner seeks to modify the above certificates by adding "chemicals (except in bulk)" to the commodity description in Sub-52, part (1), and in Sub-44G, part (1) and (2).

MC 29934 (M2F), MC 29934 (Sub-3 M1F), MC 29934 (Sub-14 M1F), and MC 29934 (Sub-15 M1F), notice of filing of petition to modify certificates, filed November 29, 1979. Petitioner: LO BIONDO BROTHERS MOTOR EXPRESS, INC., P.O. Box 160, Bridgeton, NJ 08302. Representative: Michael R. Werner, 167 Fairfield Rd., P.O. Box 1409, Fairfield, NJ 07006. Petitioner holds *common carrier* authority in MC 29934, MC 29934 Sub-3, MC 29934 Sub-14, and MC 29934 Sub-15, issued January 10, 1941, March 21, 1949, January 16, 1967, and April 24, 1969, respectively. MC 29934 authorizes, as pertinent, over irregular routes, the transportation of *groceries,* between Philadelphia, PA, on the one hand, and, on the other, New York, NY, Newark, NJ, Baltimore, MD, and Wilmington, DE. MC 29934 Sub-3 authorizes, as pertinent, over irregular routes, the transportation of *canned, preserved, or frozen foodstuffs,* from Camden and Winslow, NJ, and points in Cumberland County, NJ, to points in VA, and *frozen foods,* from Camden, NJ, and points in Cumberland County, NJ, to Washington, DC, and points in CT, DE, MA, MD, NY (except New York City), PA (except Philadelphia), and RI. MC 29934 Sub-14 authorizes over irregular routes, the transportation of *canned goods,* from points in Union County, NJ, to points in CT, and Columbia, Greene, Ulster, Dutchess, Sullivan, Orange, Putnam, Westchester, and Rockland Counties, NY. MC 29934 Sub-15 authorizes over irregular routes, the transportation of *food* and *food products,* (except commodities in bulk), from points in Cumberland, Salem, and Gloucester Counties, NJ, to points in CT, DE, MD, MA, NY, PA, RI, and DC, restricted to the transportation of traffic originating at points in Cumberland, Salem, and Gloucester Counties, NJ. By the instant petition, petitioner seeks to consolidate the above authority and modify it to read: "*such commodities* as are used in and dealt by chain grocery and food business houses, and materials, supplies, and equipment used

in the distribution and sale of such commodities (except in bulk), between points in CT, DE, MD, NJ, MA, NY, PA, RI, VA, and DC."

MC 35045 M1F notice of filing of petition to modify certificate, filed October 22, 1979. Petitioner: HORNE HEAVY HAULING, INC., P.O. Drawer L, Madisonville, KY 42431. Representative: Carl U. Hurst (same address as petitioner). Petitioner holds a motor *common carrier* certificate in MC 35045, issued December 9, 1974, authorizing transportation over irregular routes, as pertinent, of (1) *commodities*, the transportation of which, because of size or weight, requires the use of special equipment, and of *related machinery parts* and *related contractors' materials* and *supplies*, when their transportation is incidental to the transportation by carrier of commodities which by reason of size or weight require special equipment, and (2) *self-propelled articles*, each weighing 15,000 pounds or more, and *related machinery, tools, parts* and *supplies* moving in connection therewith (restricted to commodities which are transported on trailers), between points within 175 miles of Chattanooga, TN, including Chattanooga. By the instant petition, petitioner seeks to modify the above territory to read, "Between points in TN, MS, AL, GA, SC, NC, VA, and those points in KY within 175 miles of Chattanooga, TN.

MC 51146 (Sub-204 M1F), notice of filing of petition to modify a certificate, filed January 22, 1980. Petitioner: SCHNEIDER TRANSPORT, INC., P.O. Box 2298, Green Bay, WI 54306. Representative: John R. Patterson, 2480 E. Commercial Blvd., 2nd Floor, Ft. Lauderdale, FL 33308. Petitioner holds motor common carrier authority in MC 51146 Sub-204, issued August 23, 1974, authorizing transportation over regular routes, of *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), between Chicago, IL and Green Bay, WI, serving the intermediate points of Fond du Lac, Oshkosh, and Appleton, WI, and the off-route points of West Bend, Waupun, Neenah, and Menasha, WI, over specified routes. By the instant petition, petitioner seeks to modify the above authority so as to read: "general commodities (except those of unusual value, classes A and B explosives, and commodities requiring special equipment), between Chicago, IL and Green Bay, WI, serving all intermediate points, and the off-route points of Waukegan and Zion, IL, and Kenosha, Racine, West Bend, Sheboygan, Waupun, Manitowac, Neenah, and Menash, WI, over the same specified routes".

MC 55896 (Sub-79 M1F), notice of filing of petition to modify certificate, filed February 19, 1980. Petitioner: R–W SERVICE SYSTEM, INC., 20225 Goddard Rd., Taylor, MI 48180. Representative: George E. Batty (same address as applicant). Petitioner holds motor *common carrier* authority in certificate MC 55896 Sub-79, issued October 1, 1979, authorizing transportation over irregular routes, of *glass containers* and *container accessories*, from the facilities of Kerr Glass Manufacturing Corporation, at or near Dunkirk, IN, to points in IL, MI, MO, OH, PA, and WI. By the instant petition, petitioner seeks to modify the above authority so as to read: "*glassware, glass containers*, and *container accessories*, from Dunkirk, IN, to points in IL, MI, MO, OH, PA, and WI."

MC 59655(M1F), notice of filing of petition to modify the terrritorial description, filed November 9, 1979. Petitioner: SHEEHAN CARRIERS, INC., 62 Lime Kiln Rd., Suffern, NY 10901. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. Petitioner holds *common carrier* authority in MC–59655, served October 15, 1962, MC 59655 authorizes, as pertinent, over irregular routes, the transportation of *general commodities* (except those of unusual value, liquor, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), between points in Passaic, Bergen, Hudson, Essex, and Union Counties, NJ, on the one hand, and, on the other, New York, NY, and points in Westchester, Rockland, and Orange Counties, NY. By the instant petition, petitioner seeks to modify the territorial description, so that it may read: "between points in NJ, on the one hand, and, on the other, New York, NY, and points in Westchester, Rockland, and Orange Counties, NY."

MC 100666 (Sub-222M1F) notice of filing of petition to delete a restriction, filed December 26, 1979. Petitioner: MELTON TRUCK LINES, INC., 1129 Grimmett Dr., Box 7666, Shreveport, LA 71107. Representative: Wilburn L. Willimson, Suite 615-East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. Petitioner holds motor *common carrier authority* in Certificate MC–100666 Sub 222, issued March 27, 1974, over irregular routes, authorizing the transportation of *building and construction materials* (except commodities in bulk), between points in AR, KS, LA, OK, TN, and TX. RESTRICTION: The authority granted herein is restricted to the transportation of shipments originating at and destined to points in such states. By instant petition, petitioner seeks to modify the authority herein by deleting the restriction.

MC 109736 (Sub-8M1F), notice of filing of petition to delete a restriction, filed December 27, 1979. Petitioner: CAPITOL BUS COMPANY, P.O. Box 3343, Harrisburg, PA 17105. Representative: S. Berne Smith, P.O. Box 1166, Harrisburg, PA 17108. Petitioner holds motor *common carrier* authority in Certificate MC–109736 Sub 8, issued December 9, 1958, over regular routes, authorizing transportation of *passengers and their baggage, and express and newspapers* in the same vehicle with passengers, between Gettysburg, PA, and Washington, DC, serving intermediate points between Gettysburg, PA, and Frederick, MD, including Frederick, restricted (1) against the pick-up of passengers at Frederick on southbound trips, and (2) against the discharge of passengers at Frederick on northbound trips: From Gettysburg over U.S. Hwy 15 to Frederick, thence over U.S. Hwy 240 to Washington, and return over the same route. By instant petition, petitioner seeks to delete the restriction which reads "restricted (1) against the pick-up of passengers at Frederick on southbound trips, and (2) against the discharge of passengers at Frederick on northbound trips".

MC 109736 (Sub—24M1F), notice of filing of petition to delete a restriction, filed December 27, 1979. Petitioner: CAPITOL BUS COMPANY, P.O. Box 3343, Harrisburg, PA 17105. Representative: S. Berne Smith, P.O. Box 1166, Harrisburg, PA 17108. Petitioner holds motor *common carrier* authority in Certificate MC–109736 Sub 24, issued February 16, 1968, over alternate routes, authorizing transportation of *passengers and their baggage, and express and newspapers*, in the same vehicle with passengers, between Binghamton, NY, and Scranton, PA, serving no intermediate points: From Binghamton over New York Hwy 17 to junction Interstate Hwy 81, and thence over Interstate Hwy 81 to Scranton, and return over the same route, restricted against the transportation of passengers and their baggage and of shipments of express and newspapers (1) originating or interchanged at Binghamton on southbound trips, and (2) destined to or interchanged at Binghamton on northbound trips. By instant petition, petitioner seeks to delete the restriction

which reads "restricted against the transportation of passengers and their baggage and of shipments of express and newspapers (1) originating or interchanged at Binghamton on southbound trips, and (2) destined to or interchanged at Binghamton on northbound trips".

MC 109736 (Sub-39M1F), notice of filing of petition to delete a restriction, filed December 27, 1979. Petitioner: CAPITOL BUS COMPANY, P.O. Box 3343, Harrisburg, PA 17105. Representative: S. Berne Smith, P.O. Box 1166, Harrisburg, PA 17108. Petitioner holds motor *common carrier* authority in Certificate MC–109736 Sub 39, issued November 19, 1979, over irregular routes, authorizing the transportation of *passengers and their baggage, and express and newspapers,* in the same vehicle with passengers, between Baltimore, MD, and Washington, DC: From Baltimore over the Baltimore-Washington Parkway to junction U.S. Hwy 50, then over U.S. Hwy 50 to Washington, and return over the same route, serving Baltimore for purposes of joinder only, serving no intermediate points, and serving Baltimore-Washington International Airport as an off-route point, restricted to the transportation of traffic moving to or from points north of Baltimore, MD. By instant petition, petitioner seeks to delete the restriction which reads "serving Baltimore for purposes of joinder only and to the transportation of traffic moving to or from points north of Baltimore, MD".

MC 112304 (Sub-91 MlF) (notice of filing of petition to modify the commodity description), filed November 30, 1979. Petitioner: ACE DORAN HAULING & RIGGING CO., 1601 Blue Rock St., Cincinnati, OH 45223. Representative: A. Charles Tell, 100 East Broad St., Columbus, OH 43215. Petitioner was authorized in MC–F–12116 and MC 112304 (Sub-91), by the Initial Decision served February 8, 1979, which became effective on March 19, 1979, *common carrier* authority, over irregular routes. MC 112304 (Sub-91), when certificated, would authorize the transportation of *machinery,* the transportation of which by reason of size or weight requires the use of special equipment, between points in IL, IN, KY, MD, MI, NY, OH, PA, VA, WV, WI, and DC, on the one hand, and, on the other, points in CT, MD, MA, NJ, NY, RI, and DC. By the instant petition, petitioner seeks to modify the commodity description to read: "*commodities* which by reason of their size or weight require special handling or the use of special equipment, self-propelled articles, each weighting 15,000 pounds or more, and related machinery, tools, parts, and supplies moving in connection therewith".

MC 114004 (Sub-124 MlF) (notice of filing of petition to modify the commodity description), filed October 29, 1979. Petitioner: CHANDLER TRAILER CONVOY, INC., 8828 New Benton Hwy, Little Rock, AR 72209. Representative: Winston G. Chandler (same address as petitioner). Petitioner holds *common carrier* authority in MC 114004 (Sub-124), served September 29, 1976. MC 114004 (Sub-124) authorizes over irregular routes, the transportation of *motor homes,* in secondary movements, in driveaway service, between Dublin, Edgemont, Ontario, Perris, Riverside, San Fernando, San Marcos, and Sun Valley, CA, Colorado Springs and Lafayette, CO, Boise, ID, Macomb, IL, Decatur, Elkhart, and Nappanee, IN, Southbridge, MA, Benton Harbor, MI, Winona, MN, Carbondale and Paxinos, PA, New Taxewell, TN, McKinney and Sulphur Springs, TX, Sunnyside, WA, and the facilities of Recreational Enterprises, Inc., at or near Gainesville, FL, the facilities of Georgie Boy Manufacturing Company, Inc. at or near Edwardsburg, MI, and the facilities of Travel Equipment Corporation, at or near Howe, In, on the one hand, and, on the other, points in the United States (including AK, but excluding HI). By the instant petition, petitioner seeks to modify he commodity description, by adding "automobiles".

MC 116044 (MlF) (notice of filing of petition to modify the territorial description), filed November 5, 1979. Petitioner: MORTON DELIVER SERVICE, INC., 260 W. 35th St., New York, NY 10001. Representative: George A. Olsen, P.O. Box 357, Gladston, NJ 07934. Petitioner holds *common carrier* authority in MC 116044, served July 20, 1956. MC 116044 authorizes over irregular routes, the transportation of *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), between points in Bergen, Passaic, Hudson, Essex, Union, Middlesex, Monmouth, and Somerset Counties, NJ, on the one hand, and, on the other, New York, NY. By the instant petition, petitioner seeks to modify the territorial description so that it may read: "between points in NJ, on the one hand, and, on the other, New York, NY".

MC 117257 (Sub-3M lF) (notice of filing of petition to modify a permit), filed January 28, 1980. Petitioner: D-S TRANSPORT, INC., 324 16th St., North Moorhead, MN 56560. Representative: Gene P. Johnson, P.O. Box 2471 Fargo, ND 58108. Petitioner holds motor contract carrier authority in Permit MC 117257 (Sub-3), issued December 26, 1979, authorizing transportation, over irregular routes, of *malt beverages,* (1) from St. Louis, MO, and LaCrosse, WI, to Detroit Lakes and Perham, MN, under continuing contract(s) with D-S Beverages, Inc., of Moorhead, MN (2) from Milwaukee, WI, to Moorhead, MN, under continuing contract(s) with Valley Distributing Company, and Hansen Distributing, Inc., both of Moorhead, MN, (3) Milwaukee, WI, to Fargo, ND, under continuing contract(s) with Beverage Wholesalers, Inc., of Fargo, ND, and (4) from St. Paul, MN, and St. Louis, MO, to Wahpeton, ND, under continuing contract(s) with Red River Jobbing, of Wahpeton, ND. By the instant petition, petitioner seeks to modify (3) above so as to read: "from Milwaukee, WI, to Fargo, ND, under continuing contract(s) with Beverage Wholesalers, Inc., of Fargo, ND, and D-S Beverages, Inc., of Moorhead, MN"; and further seeks to modify (4) above so as to read: "from St. Paul, MN, and St. Louis, MO, to Fargo, Grand Forks, and Wahpeton, ND, under continuing contract(s) with D-S Beverages, Inc., of Moorhead, MN, Dakota Sales Company, Inc., of Grand Forks, ND, and Red River Jobbing, of Wahpeton, ND".

MC 117852 (Sub-2 MlF) (notice of filing of petition to modify certificate), filed September 17, 1979. Petitioner: HAROLD'S GARAGE, INC., 19 Holyoke Street, Northampton, MA 01060. Representative: Harold F. Willard (same address as applicant). Petitioner holds a motor *common carrier* certificate in MC 117852 (Sub-2) issued January 25, 1978, to operate in interstate or foreign commerce, over irregular routes, transporting *Motor vehicles, dollies, trailers, and semi-trailers* (except house trailers designed to be drawn by passenger automobiles), by use of wrecker equipment only, between Enfield, Suffield, Windsor Locks, and Warehouse Point, CT, and points in MA, on the one hand, and, on the other, points in that part of the United States on and east of ND, SD, NE, KS, OK, and TX. This certificate is issued pursuant to an application filed after November 23, 1973, and in accordance with 49 CFR 1065 may not be tacked or joined with the carrier's other irregular-route authority unless specifically authorized herein. By the instant petition, petitioner seeks to modify the authority as follows: remove the restriction "by the use of wrecker equipment only".

MC 121567 (Sub-1M1F) (notice of filing of petition to modify certificate), filed August 16, 1979. Petitioner: WICHITA AIR CARGO DELIVERY, INC., Cargo Building, Municipal Airport, Wichita, Kansas 67209. Representative: George Schneller (same adress as above). Petitioner holds a motor common carrier certificate in MC 121567 (Sub-1), authorzing transportation over irregular routes of 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), between Wichita, municipal Airport, Wichita, KS, on the one hand, and, on the other, points in Butler, Cowley, Harvey, Kingman, Reno, Sedgwick Counties, KS and Kay County, OK, (except points within 25 miles of the Wichita Municipal Airport). Restriction: The operations authorized herein are restricted to traffic having an immediately prior or immediately subsequent movement by air. By the instant petition, Petitioner seeks to eliminate the territorial restriction "except points within 25 miles of the Wichita Municipal Airport" and to add the counties of Barton, Ellsworth, Rice, McPherson, Saline, and Stafford Counties, KS.

MC 121335 (Sub-2M1F) (notice of filing petition to modify the commodity description), filed November 30, 1979. Petitioner: FILM TRANSPORT CO. OF CAL., INC., 1525 W. 23 St., Los Angeles, CA 90007. Representative: R. Y. Schureman, 1545 Wilshire Blvd., Los Angeles, CA 90017. Petitioner holds a motor *common carrier* certificate in MC 121335, (Sub-2), issued November 30, 1978, authorizing in part transportation over irregular routes of: *General commodities* (except classes A and B explosives, commodities of unusual value, households goods as defined by the Commission, commodities in bulk, commodities requiring special equipment, and motor vehicles), between desert Hot Springs, Yucaipa, Joshua Tree, Yucca Valley and Twenty-Nine Palms, CA, and those points in that part of CA on and within a boundary line beginning at the junction of CA Hwy. 1 and CA Hwy. 27 at the shoreline of the Pacific Ocean, then north along CA Hwy. 27 to its junction with the northern boundary of Los Angeles, CA, then north and east along the Los Angeles city limits to its junction with the Angeles National Forest boundary, then east along the southern boundaries of the Angeles and San Bernardino National Forests' boundaries to the San Bernardino-Riverside Counties boundary near Beaumont, CA, then east along said county Boundary to CA Hwy. 62, then south along CA Hwy. 62 to junction I-10, then east along I-10 to junction CA Hwy. 111 at or near Coachella, CA, then south along CA Hwy. 111 to juncton CA Hwy 115 at or near Calipatria, CA, then south along CA Hwy 115 to junction Interstate Hwy 8 at or near Holtville, CA, then east along Interstate Hwy 8 to junction CA Hwy 98, then south approximately 2 miles along an imaginary line to its junction with the international boundary line between the U.S. and Mexico, then west along the international boundary line between the U.S. and Mexico to the shoreline of the Pacific Ocean, then northwest along the shoreline of the Pacific Ocean to the point of beginning. Petitioner seeks deletion of "classes A and B explosives" from the exceptions to the commodity description. The certificate, otherwise, would remain the same.

MC 123407 (Sub-134M1F) (notice of filing of petition for modification and interpretation), filed December 6, 1979. Petitioner: SAWYER TRANSPORT, INC., Sawyer Center, Route #1, Chesterton, IN 46304. Representative: H. E. Miller Jr. (same address as applicant). Petitioner holds motor common carrier authority in Certificate MC 123407 (Sub-134), issued May 26, 1978, authorizing, as pertinent, transportation of *empty containers*, between points in the United States (except AK and HI). By the instant petition, petitioner seeks an interpretation of the term "empty containers", and further seeks to add an additional commodity description to its present authority which would read as follows: "such commodities as are dealt in and used by manufacturers and distributors of containers (except commodities in bulk)".

MC 124174 (M1F) (notice of filing of petition to modify the commodity description), filed November 26, 1979. Petitioner: MOMSEN TRUCKING CO., P.O. Box 37490, Omaha, NE 68137. Representative: Marshall D. Becker, Suite 610, 7171 Mercy Road, Omaha, NE 68106. Petitioner holds *common carrier* authority in MC 124174, served March 17, 1972. MC 124174 authorizes, as pertinent, over regular routes, the transportation of "*General commodities*, (except those of unusual value, classes A and B explosives, groceries, dry goods, drugs, liquor, household goods as defined by the Commission, emigrant moveables, commodities in bulk, commodities requiring special equipment, and those injurious or contaminating to other lading)." Between Oskaloosa, IA, and Omaha, NE serving the intermediate and off-route points of Knoxville, Ackworth, Indianola, Adel, Dexter, Casey, Anita, Atlantic, Oakland, Pleasantville, Beech, and Menlo, Iowa, without restriction; and the off-route point of Grinnell, Iowa, restricted to the transportation of feed (animal and poultry), and agricultural implements and parts, from Omaha, Nebraska, to Grinnell; and points within 35 miles of Oskaloosa, and those within 5 miles of Gilman, Iowa, including Gilman, restricted to livestock to or from Omaha: From Oskaloosa over IA Highway 92 to junction U.S. Highway 65, then over U.S. Highway 65 to Des Moines, Iowa, then over Iowa Highway 90 to junction U.S. Highway 6 (portion formerly Iowa Highway 90), and then over U.S. Highway 6 to Omaha, and return over the same route. Between Oskaloosa, IA, and Chicago, IL, serving the intermediate and off-route points Rock Island, Moline, Rock Falls, East Moline, and Sandwich, IL, without restriction; and points within 35 miles of Oskaloosa, and those within 5 miles of Gilman, IA, including Gilman, restricted to livestock only, as follows: From Oskaloosa over Iowa Highway 92 to junction U.S. Highway 61, then over U.S. Highway 61 to junction Iowa Highway 22, then over Iowa Highway 22 to Davenport, Iowa, then over U.S. Highway 6 to junction IL Highway 92, then over IL Highway 92 to junction U.S. Highway 34, then over U.S. Highway 34 to Chicago, and return over the same route; and also Return from Chicago over U.S. Highway 20 to Rockford, IL, then over U.S. Highway 51 to junction U.S. Highway 34, and then over the above-specified route to Oskaloosa." This Petition seeks to remove the restriction against the transportation of groceries, dry goods, drugs and liquors. Removal of the restriction would allow Petitioner to transport "general commodities, except those of unusual value, classes A and B explosives, household goods as defined by the Commission, emigrant moveables, commodities in bulk, commodities requiring special equipment and those injurious or contaminating to other lading."

MC 128972 (Sub-1M1F) (notice of filing of petition to modify permit), filed March 1, 1979. Petitioner: JOHN LOUIE GIBSON, P.O. Box 22, Walnut Cove, NC 27052. Representative: John E. Gehring, P.O. Box 575, Walnut Cove, NC 27052. Petitioner holds a motor *contract carrier* permit in MC 128972 (Sub-1), issued June 6, 1968, to operate over irregular routes, in interstate or foreign commerce, transporting *Lime* and *fertilizer* in bags, From Austinville, Chatham, Danville, Norfolk, and Roanoke, VA, to Walnut

Cove, NC, with no transportation for compensation on return except as otherwise authorized. *Lime*, in bags, From Austinville, Chatham, Danville, Norfolk, and Roanoke, VA, to Greensboro, NC, with no transportation for compensation on return except as otherwise authorized. Restriction: The operations authorized herein are limited to a transportation service to be performed, under a continuing contract, or contracts, with Agrico Chemical Company, Division of Continental Oil Company, of Greensboro, NC. By the instant petition, petitioner seeks to modify the permit by changing the name of the shipper from John G. Fulton, to the new dealership of Smith-Douglas, a division of Borden Chemical, Borden, Incorporated, and to haul fertilizer and lime from the facilities of Smith-Douglas at Danville, VA, to Walnut Cove, NC. Also add another contract with Monitor Roller Mill, Incorporated, Walnut Grove, NC, transporting fertilizer and lime from the facilities of Monitor Roller Mill, Incorporated at Roanoke and Norfolk, VA, to Walnut Cove, NC.

MC 136786(M1) (notice of filing of petition for modification), filed December 27, 1979. Petitioner: ROBCO TRANSPORTATION, INC., 4333 Park Ave., Des Moines, IA 50321. Representative: Stanley C. Olsen, 7400 Metro Blvd., Suite 411, Edina, MN 55435. Petitioner holds motor common carrier authority in Certificate MC 136786 issued November 5, 1973, authorizing, as pertinent, transportation of (1) *cheese and cheese products*, and (2) *pizza toppings*, from Denver, CO, Superior, NE, and Hutchinson and Wichita, KS, to points in AL, FL, GA, MS, NC, SC, and TN, restricted to the transportation of shipments originating at the facilities of Leprino Cheese Company at the above-named origin points. By instant petition, petitioner seeks to modify the certificate in MC 136786 as follows: (1) cheese and cheese products, and (2) pizza toppings, from the facilities of Leprino Cheese Company at Denver, CO, and Hutchinson and Wichita, KS and the facilities of Mid-America Dairymen, Inc. and/or Mid-America Farms, Inc. at Superior, NE, to points in AL, FL, GA, MS, NC, SC, and TN, restricted to the transportation of traffic originating at the facilities named above.

MC 138225(M1F) and MC 138225 (Sub-2M1F) (notice of filing of petition to modify the territorial descriptions), filed October 23, 1979. Petitioner: HEDRICK ASSOCIATES, INC., R.R. No. 2, Box 10A2, Douglas Rd., Far Hills, NJ 07931. Representative: William P. Jackson, Jr., 3426 N. Washington Blvd., P.O. Box 1240, Arlington, VA 22210. Petitioner holds *contract carrier* authorities in MC 138225, served July 12, 1974, and MC 138225 (Sub-2), served October 17, 1974. MC 138225 authorizes over irregular routes, the transportation of (1) *swimming pools*, (2) *swimming pool parts* and (3) *materials, supplies, and equipment* used in connection with swimming pools (except commodities in bulk), from Garfield and East Paterson, NJ, to points in the United States (except AK and HI), under continuing contract(s) with Heldor Associates, Inc., of Hamden, CT. MC 138225 (Sub-2), authorizes, over irregular routes, the transportation of *materials, equipment, and supplies* (except commodities in bulk, the transportation of which because of size or weight require the use of special equipment) used in the manufacture or installation of swimming pools, from points in the United States (except AK and HI), to the facilities of Heldor Associates, Inc., at or near Garfield, and East Paterson, NJ, restricted to the transportation of traffic destined to the facilities of Heldor Associates, Inc., at or near Garfield and East Paterson, NJ, under a continuing contract(s) with Heldor Associates, Inc., of Hamden, CT. By the instant petition, petitioner seeks to modify (1) MC 138225, by adding the origin point of Morristown, NJ, and (2) MC 138225 (Sub-2), by adding the destination point of Morristown, NJ and modify the restriction to read: "restricted to the transportation of traffic destined to the facilities of Heldor Associates, Inc., at or near Garfield, East Paterson and Morristown, NJ."

MC 140024 (Subs- 56 and 81M1F) (notice of filing of petition to modify certificates), filed November 8, 1979. Petitioner: J. B. MONTGOMERY, INC., 5565 East 52nd Ave., Commerce City, CO 80022. Representative: Jeffrey A. Knoll (same address as petitioner). Petitioner holds *common carrier* authority in MC 140024 (Subs- 56 and 81), served August 19, 1976, and June 27, 1978 respectively. MC 140024 (Sub-56) authorizes over irregular routes, the transportation of *iron and steel articles*, from the facilities of Nucor Steel Division of Nucor Corporation, at or near Norfolk, NE, to points in IL, IN, MI, OH, and WI, restricted to the transportation of shipments originating at the above-named facilities and destined to the destinations. This certificate is issued pursuant to an application filed after November 23, 1973, and in accordance with 49 CFR 1065 may not be tacked or joined with the carrier's other irregular-route authority unless specifically authorized therein. MC 140024 (Sub-81) authorizes over irregular routes, the transportation of *iron and steel articles*, from the facilities of Nucor Steel Division of Nucor Corporation, at or near Norfolk, NE, to points in AL, AR, KY, LA, MS, NY, PA, TN, and WV, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. MC 140024 (Sub-81) may not be tacked or joined with the carrier's other irregular-route authority. By the instant petition, petitioner seeks to modify and embrace both certificates so that the authority would read: *iron and steel articles*, from the facilities of the Nucor Corporation, at or near Norfolk, NE, to points in AL, AR, IL, IN, KY, LA, MI, MS, OH, NY, PA, TN, WV, and WI. This modification not only removes the restrictions, but also provides service to all three divisions of the Nucor Corporation.

MC 142205 (Sub-7 M1F) (notice of filing of petition to modify the territorial description), filed October 12, 1979. Applicant: LOUDOUN TRANSFER, INC., P.O. Box 703, Leesburg, VA 22073. Representative: James E. Savitz, Suite 145, 4 Professional Dr., Gaithersburg, MD 20760. Petitioner holds a motor *contract carrier* Permit in MC 142205 (Sub-7), served August 18, 1978, authorizing transportation, over irregular routes of: (1) *Custom upholstered furniture*, from Sterling, VA, to points in the United States in an east of MN, IA, NE, KS, OK, and TX (except VA); and (2) *Equipment, materials, and supplies* (except lumber) *used in the manufacture of custom upholstered furniture*, from the destination states listed in (1) above, to Sterling, VA, under a continuing contract(s) with Metro Manufacturing Co., of Herndon, VA. Restriction: The Commission reserves the right to impose such terms, conditions, or limitations in the future as it may find necessary to insure that carrier's operations conform to the provisions of Section 210 of the Act. By the instant petition, petitioner seeks to modify the authority by changing the origin point in Part (1) from Sterling, VA to Culpeper, VA, and by changing the termination point of Part (2) from Sterling, VA to Culpeper, VA.

MC 145216 (Sub-1M1F) (notice of filing of petition to modify a certificate), filed December 27, 1979. Applicant: SUNSHINE EXPRESS OF WILSON, INC., P.O. Box 4812, Rocky Mount, NC 27801. Representative: Robert B. Walker, 915 Pennsylvania Bldg., 425 13th Street, N.W., Washington, DC 20004. Petitioner holds motor *common carrier* certificate in MC 145216 (Sub-1F) issued December 5, 1979, authorizing transportation, over irregular routes, transporting *general*

commodities, between railroad ramps located at or near Rocky Mount, Smithfield, Goldsboro, Greenville, and Wilmington, NC, on the one hand, and, on the other, points in North Carolina, restricted to the transportation of shipments having a prior or subsequent movement by rail or water. By the instant petition, petitioner seeks to modify the authority so as to add the railroad ramps at Raleigh, Fayetteville and Morehead City, NC to the base area and to authorize ex-water shipments.

Republications of Grants of Operating Rights Authority Prior to Certification

The following grants of operating rights authorities are republished by order of the Commission to indicate a broadened grant of authority over that previously noticed in the **Federal Register.**

An original and one copy of a petition for leave to intervene in the proceeding must be filed with the Commission on or before May 15, 1980. Such pleading shall comply with Special Rule 247(e) of the Commission's *General Rules of Practice* (49 CFR 1100.247) addressing specifically the issue(s) indicated as the purpose for republication, and including copies of intervenor's conflicting authorities and a concise statement of intervenor's interest in the proceeding setting forth in detail the precise manner in which it has been prejudiced by lack of notice of the authority granted. A copy of the pleading shall be served concurrently upon the carrier's representative, or carrier if no representative is named.

MC 116004 (Sub-51F) (republication), filed October 24, 1978, published in the **Federal Register** issue of January 18, 1979, and republished this issue. Applicant: TEXAS OKLAHOMA EXPRESS, INC., P.O. Box 47112, Dallas, TX 75247. Representative: Doris Hughes (same address as applicant). An Initial Decision, of the Commission, Administrative Law Judge, decided July 3, 1979, served July 17, 1979 and a Decision, of the Commission, Division 1, decided November 13, 1979, and served November 28, 1979, finds that the present and future convenience and necessity require operation by applicant, in interstate or foreign commerce, as a common carrier by motor vehicle, over regular routes, 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), between Liberal, KS, and St. Louis, MO, from Liberal over U.S. Hwy 54 to junction Kansas Turnpike, then over Kansas Turnpike to junction Interstate Hwy 70, and then over Interstate Hwy 70 to St. Louis, and return over the same route, serving all intermediate points in Kansas which applicant is authorized to serve under its presently existing authority, restricted against the transportation of traffic moving between Kansas City and St. Louis, MO; that applicant is fit, willing and able properly to perform the granted service and to conform to the requirements of the Interstate Commerce Act and the Commission's regulations. The purpose of this republication is to reflect applicant's actual grant of authority.

MC 126305 (Sub-96F) (republication), filed September 7, 1978, published in the **Federal Register** issue of November 2, 1978, and republished this issue. Applicant: BOYD BROTHERS TRANSPORTATION CO., INC., R.D. 1, Clayton, AL 36016. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. A Decision of the Commission, Review Board Number 4, decided July 30, 1979, and served August 31, 1979 and a Decision of the Commission, Division 2, Acting as an Appellate Division, decided January 21, 1980 and served January 29, 1980, on further consideration find that the present and future public convenience and necessity require operations by applicant to operate as a *common carrier*, by motor vehicle, interstate or foreign commerce, over irregular routes, transporting *iron and steel articles, machinery, and equipment*, between Birmingham, AL, on the one hand, and, on the other, points in the United States (except AK and HI); that applicant is fit, willing, and able properly to perform the granted service and to conform to statutory and administrative requirements, The purpose of this republication is to delete the plantsite restriction.

MC 135810 (Sub-10F) (republication), filed September 28, 1978, published in the **Federal Register** issue of November 28, 1979, and republished this issue. Applicant: RICCI TRANSPORTATION CO., INC., Odessa Avenue, Pomona, NJ 18240. Representative: J. Raymond Clark, Suite 1150, 600 New Hampshire Avenue, NW., Washington, D.C. 20037. A Decision of the Commission, Review Board Number 2, decided October 23, 1979, and served November 14, 1979, finds that the present and future public convenience and necessity require operation by applicant as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *malt beverages*, in containers, from Rochester, NY, to Pleasantville, NJ; that applicant is fit, willing, and able properly to perform the granted service and to conform to the requirements of Title 49, Subtitle IV, U.S. Code and the Commission regulations. The purpose of this republication is to reflect service as a *common carrier* authority in lieu of contract as previously published, and assigned MC 127955 (Sub-5F).

Motor Carrier Operating Rights Applications

The following applications, filed on or after March 1, 1979, are governed by Special Rule 247 of the Commission's general rules of practice (49 CFR 1100.247). These rules provide, among other things, that a *petition to intervene either with or without leave* must be filed with the Commission within 30 days after the date of publication in the **Federal Register** with a copy being furnished the applicant. Protests to these applications *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). In deciding whether to grant leave to intervene, the Commission considers, among other things, whether petitioner has (a) solicited the traffic or business of those persons 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. Another factor considered is the effects of any decision on petitioner's interests.

Samples of petitions and the text and explanation of the intervention rules can be found at 43 FR 50908, as modified at 43 FR 60277. Petitions not in reasonable compliance with these rules may be rejected. Note that Rule 247(e), where not inconsistent with the intervention rules, still applies. Especially refer to Rule 247(e) for requirements as to supplying a copy of conflicting authority, serving the petition on applicant's representative, and oral hearing requests.

Permanent Ex-Water Authority Decision-Notices

Decided: March 25, 1980.

The following applications are governed by 49 CFR 1062.3. Applicants seek to obtain motor common carrier authority to perform service within the commercial zone of port cities where the shipment has a prior or subsequent movement by maritime carrier. The full text and explanation of the rules are contained at 44 FR 7965, as corrected at 44 FR 37230.

The sole issue upon which these applications can be protested is the applicant's fitness to perform the service. Protests (an original and one copy) must be filed with the Commission on or before May 15, 1980. The protest must contain she *specific facts* being relied upon to challenge fitness, and must contain a certification that it has been served concurrently upon applicant's representative, or, if none is listed, upon the applicant. Applicant may file a reply statement to any protext. The filing of these statements will complete the record, unless it is later determined that more evidence must be supplied.

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 April 15, 1980.*

Any authority granted may reflect administratively 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.

Each applicant is fit, willing, and able to properly perform the service proposed and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulations. 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 protestant, 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 protests, filed within 30 days of publication of this decision-notice (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 grant or grants of authority within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

By the Commission, Review Board Number 1, Members Carleton, Joyce, and Jones.

MC 147694 (Sub-2F), filed October 19, 1979. Applicant: H E K, INCORPORATED, d.b.a. ELLIOTT BAY SERVICE TRANSFER, 1701 First Ave. S., Seattle, WA 98134. Representative: Jack R. Davis, 1100 IBM Bldg., Seattle, WA 9801. Transporting *general commodities* (except classes A and B explosives), between points in the commercial zones of (a) Seattle, WA and (b) Tacoma, WA, restricted to traffic having a prior or subsequent movement by water. (Hearing site: Seattle, WA.)

MC 148295F, filed September 25, 1979. Applicant: CAROLINA SHIPPING COMPANY, INC., P.O. Box 873, Charleston, SC 29402. Representative: Roy A. Powell, Jr. (same address as applicant). Transporting *general commodities* (except classes A and B explosives), between points in the commercial zone of Charleston, SC, restricted to traffic having a prior or subsequent movement by water. (Hearing site: Charleston or Columbia, SC.)

MC 150119 (Sub-1F), filed February 25, 1980. Applicant: WILLETT OF TEXAS, INC., 711 Louisiana, Suite 1150, S. Tower, Houston, TX 77002. Representative: Joe G. Fender (same address as applicant). Transporting *general commodities* (except classes A and B explosives), between points in the commercial zone of Houston, TX, restricted to traffic having a prior or subsequent movement by water.

Note.—The person or persons who appear to be engaged in common control must either file an application under 49 U.S.C. 11343(a) (formerly Section 5(2) of the Interstate Commerce Act), or submit an affidavit indicating why such approval is unnecessary.

Permanent Authority Decisions Volume, Decision-Notice

Decided: March 25, 1980.

The following broker, freight forwarder or water carrier applications 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 protest 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.** Failure to file a protest within 30 days will be considered as a waiver of opposition to the application. A protest under these rules shall comply with Rule 247(e)(3) of the rules of practice which requires that it set forth specifically the grounds upon which it is made, contain a detailed statement of protestant's interest in the proceeding, as specifically noted below), and specify with particularity the facts, matters and things relied upon. The protest shall not include issues or allegations phrased generally. A protestant shall include a copy of the specific portion of its authority which it believes to be in conflict with that sought in the application, and describe in detail the method whether by joinder, interline, or other means—by which protestant would use this authority to provide all or part of the service proposed. Protests not in reasonable compliance with the requirements of the rules may be rejected. The original and one copy of the protest shall be filed with the Commission. A copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named. If the protest includes a request for oral hearing, the request shall meet the requirements of section 247(e)(4) of the special rules and shall include the certification required in that section.

Section 247(f) provides, in part, that an applicant which does not intend timely to 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.

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 April 15, 1980.*

Any authority granted may reflect administratively 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 exceptions of those applications involving duly noted problems (e.g., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each applicant has demonstrated that its proposed service is either (a) required by the public convenience and necessity, or, (b) 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 regulations. 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 the absence of legally sufficient protests, filed within 30 days of publication of this decision-notice (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 this decision-notice. To the extent that the authority sought below may duplicate an applicant's existing authority, such duplication shall not be construed as conferring more than a single operating right.

Applicants must comply with all specific conditions set forth in the grant or grants of authority within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

By the Commission, Review Board Number 1, Members Carleton, Joyce, and Jones.

Brokers

MC 130785F, filed December 24, 1979. Applicant: AUTOMOBILE CLUB OF SOUTHERN CALIFORNIA, d.b.a. WORLD TRAVEL SERVICE, 2601 South Figueroa St., Los Angeles, CA 90007. Representative: George L. Hayford, c/o Automobile Club of Southern California, 605 West Olympice Blvd., Los Angeles, CA 90015. To engage in operation, in interstate or foreign commerce, as a *broker*, at Los Angeles, CA, in arranging for the transportation, by motor vehicle, of *passengers and their baggage*, between points in the United States (including AK and HI). (Hearing site: Los Angeles, CA.)

MC 130794F, filed January 24, 1980. Applicant: INTERNATIONAL TOURS, INC., 5001 East 68th St., Suite 530, Tulsa, OK 74136. Representative: David Forbes (same address as applicant). To engage in operations, in interstate or foreign commerce, as a *broker*, at Tulsa, OK, in arranging for the transportation, by motor vehicle, of *passengers and their baggage*, in special and charter operations, between points in the United States (except AK and HI). (Hearing site: Tulsa or Oklahoma City, OK.)

Permanent Authority Decisions, Decision-Notice, Substitution Applications: Single-Line Service for Existing Joint-Line Service

Decided: March 26, 1980.

The following applications, filed on or after April 1, 1979, are governed by the special procedures set forth in Part 1062.2 of Title 49 of the Code of Federal Regulations (49 CFR 1062.2).

The rules provide, in part, that carriers may file petitions with this Commission for the purpose of seeking intervention in these proceedings. Such petitions may seek intervention either with or without leave as discussed below. However, all such petitions must be filed in the form of verified statements, and contain all of the information offered by the submitting party in opposition. Petitions must be filed with the Commission within 30 days of publication of this decision-notice.

Petitions for intervention without leave (i.e. automatic intervention), may be filed only by carriers which are, or have been, participating in the joint-line service sought to be replaced by applicant's single-line proposal, and then only if such participation has occurred within the one-year period immediately proceeding the application's filing. Only carriers which fall within this filing category can base their opposition upon the issue of the public need for the proposed service.

Petitions for intervention with leave may be filed by any carrier. The nature of the opposition; however, must be limited to issues other than the public need for the proposed service. The appropriate basis for opposition, i.e. applicant's fitness, may include challenges concerning the veracity of the applicant's supporting information, and the bona-fides of the joint-line service sought to be replaced (including the issue of its substantiality). Petitions containing only unsupported and undocumented allegations will be rejected.

Petitions not in reasonable compliance with the requirements of the rules may be rejected. An original and one copy of the petition to intervene shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named.

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 April 15, 1980.*

Any authority granted may reflect administratively 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 applicant has demonstrated that its proposed service is required by the present and future public convenience and necessity. 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 regulations. 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, preliminary 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, filed on or

before May 15, 1980 (or, if the application later become 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 grant or grants of authority within 90 days after the service of the notification of the effectiveness of this decision-notice, or the application of a non-complying applicant shall stand denied.

By the Commission, Review Board Number 4, Members Fitzpatrick, Fisher, and Felder. Member Felder not participating.

MC 110325 (Sub-122F), filed November 8, 1979. Applicant: TRANSCON LINES, a corporation, P.O. Box 92220, Los Angeles, CA 90009. Representative: Wentworth E. Griffin, Midland Bldg., 1221 Baltimore Ave., Kansas City, MO 64105. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), serving Muskegon, MI as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Grand Rapids, MI)

Note.—The sole purpose of this application is to substitute single-line for joint-line operations.

MC 111231 (Sub-291F), filed November 7, 1979. Applicant: JONES TRUCK LINES, INC., 610 East Emma Ave., Springdale, AR 72764. Representative: Kim D. Mann, Suite 1010, 7101 Wisconsin Ave., Washington, DC 20014. To operate as a common carrier, by motor vehicle, over regular routes transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commisison, commodities in bulk, and commodities which require the use of special equipment) (1) between Atlanta GA and Jacksonville, FL, from Atlanta over Interstate Hwy 75 to junction Interstate Hwy 10, then over Interstate Hwy 10 to Jacksonville, and return over the same route, (2) between Mobile, AL and Jacksonville, FL, over Interstate Hwy 10, and (3) between Birmingham, AL and Jacksonville, FL, from Birmingham over Interstate Hwy 65 to Montgomery, AL, then over U.S. Hwy 231 to Dothan, AL, then over U.S. Hwy 82 to junction U.S. Hwy 27, then over U.S. Hwy 27 to junction Interstate Hwy 10, then over Interstate Hwy 10 to Jacksonville, and return over the same route, serving no intermediate points in (1) through (3) above. (Hearing site: Little Rock, AR or Washington, DC.)

Note.—Applicant intends to tack the authority sought at Mobile, Birmingham, and Atlanta with existing regular-route authority. The sole purpose of this application is to substitute single-line for joint-line operations.

MC 138104 (Sub-87F), filed October 19, 1979. Applicant: MOORE TRANSPORTATION CO., INC., 3509 N. Grove St., Fort Worth, TX 76106. Representative: Bernard H. English, 6270 Firth Rd., Fort Worth, TX 76116. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *iron and steel articles and pipe*, between points in CO, KS, NM, OK, and TX. (Hearing site: Fort Worth or Dallas, TX.)

Note.—The sole purpose of this application is to substitute single-line for joint-line operations.

Motor Carrier Alternate Route Deviations

The following letter-notices to operate over deviation routes for operating convenience only have been filed with the Commission under the Deviation Rules—Motor Carrier of Property (49 CFR 1042.4(c)(11)).

Protests against the use of any proposed deviation route herein described may be filed with the Commission in the manner and form provided in such rules at any time, but will not operate to stay commencement of the proposed operations unless filed on or before May 15, 1980.

Each applicant states that there will be no significant effect on either the quality of the human environment or energy policy and conservation.

Motor Carriers of Property

MC 29555 (Deviation 38), BRIGGS TRANSPORTATION CO., North 400, Griggs-Midway Bldg., St. Paul, MN 55104, filed March 18, 1980. Carrier proposes to operate as a *common carrier*, by motor vehicle, of *general commodities*, with certain exceptions, over a deviation route as follows: From Kansas City, MO, over Interstate Hwy 70 to Indianapolis, IN and return over the same route for operating convenience only. The notice indicates that the carrier is presently authorized to transport the same commodities over a pertinent service route as follows: From Kansas City, MO, over U.S. Hwy 71 to Clarinda, IA, then over Iowa Hwy 2 to Sidney, IA, then over U.S. Hwy 275 to Omaha, NE, then over U.S. Hwy 6 to junction Iowa Hwy 149, then over Iowa Hwy 149 to Cedar Rapids, IA, then over U.S. Hwy 30 to junction alternate U.S. Hwy 30, then over alternate U.S. Hwy 30 to Chicago, IL, then over U.S. Hwy 41 to junction US. Hwy 52, then over U.S. Hwy 52, to Lafayette, IN, then over Indiana Hwy 43 (also U.S. Hwy 231) to Crawfordsville, IN, then over Indiana Hwy 32 to Lebanon, IN, then over Interstate Hwy 65 to junction Indiana Hwy 100, then over Indiana Hwy 100 to junction Interstate Hwy 65, then over Interstate Hwy 65 to Indianapolis, IN.

MC 29555 (Deviation 39), BRIGGS TRANSPORTATION CO., North 400, Griggs-Midway Bldg., St. Paul, MN 55104, filed March 18, 1980. Carrier proposes to operate as a *common carrier*, by motor vehicle, of *general commodities*, with certain exceptions, over a deviation route as follows: From Kansas City, MO, over Interstate Hwy 70 to St. Louis, MO, then over Interstate Hwy 64 to junction U.S. Hwy 41, then over U.S. Hwy 41 to Evansville, IN, and return over the same route for operating convenience only. The notice indicates that the carrier is presently authorized to transport the same commodities over a pertinent service route as follows: From Kansas City, MO, over U.S. Hwy 71 to Clarinda, IA, then over Iowa Hwy 2 to Sidney, IA, then over U.S. Hwy 275 to Omaha, NE, then over U.S Hwy 6 to junction Iowa Hwy 149, the over Iowa Hwy 149 to Cedar Rapids, IA, then over U.S. Hwy 30 to junction alternate U.S. Hwy 30, then over alternate U.S. Hwy 30 to Chicago, IL, then over U.S. Hwy 41 to junction U.S. Hwy 52, then over U.S. Hwy 52, to Lafayette, IN, then over Indiana Hwy 43 (also U.S. Hwy 231) to Crawfordsville, IN, then over Indiana Hwy 47 to junction U.S. Hwy 41, then over U.S. Hwy 41 to Terre Haute, IN, then over U.S. Hwy 41 to Evansville, IN.

MC 29555 (Deviation 40), BRIGGS TRANSPORTATION CO., North 400, Griggs-Midway Bldg., St. Paul, MN 55104, filed March 18, 1980. Carrier proposes to operate as a *common carrier* by motor vehicle, of *general commodities*, with certain exceptions, over a deviation route as follows: From Kansas City, MO, over Interstate Hwy 70 to Indianapolis, IN, then over Interstate Hwy 74 to Cincinnati, OH and return over the same for operating convenience only. The notice indicates that the carrier is presently authorized to transport the same commodities over a pertinent service route as follows: From Kansas City, MO, over U.S. Hwy 71 to Clarinda, IA, then over Iowa Hwy 2 to Sidney, IA, then over U.S. Hwy 275

to Omaha, NE, then over U.S. Hwy 6 to junction Iowa Hwy 149, then over Iowa Hwy 149 to Cedar Rapids, IA, then over U.S. Hwy 30 to junction alternate U.S. Hwy 30, then over alternate U.S. Hwy 30 to Chicago, IL, then over U.S. Hwy 41 to junction U.S. Hwy 52, then over U.S. Hwy 52, to Lafayette, IN, then over Indiana Hwy 43 (also U.S. Hwy 231) to Crawfordsville, IN, then over Indiana Hwy 32 to Lebanon, IN, then over Interstate Hwy 65 to junction Indiana Hwy 100, then over Indiana Hwy 100 to junction Interstate Hwy 65, then over Interstate Hwy 65 to Indianapolis, IN, then over Indiana Hwy 37 to Bedford, IN, then over U.S. Hwy 50 to Cincinnati, OH.

MC 29555 (Deviation 41), BRIGGS TRANSPORTATION CO., North 400, Griggs-Midway Bldg., St. Paul, MN 55104, filed March 18, 1980. Carrier proposes to operate as a *common carrier* by motor vehicle, of *general commodities,* with certain exceptions, over a deviation route as follows: From Kansas City, MO, over Interstate Hwy 70 to St. Louis, MO, then over Interstate Hwy 64 to Louisville, KY and return over the same route for operating convenience only. The notice indicates that the carrier is presently authorized to transport the same commodities over a pertinent service route as follows: From Kansas City, MO, over U.S. Hwy 71 to Clarinda, IA, then over Iowa Hwy 2 to Sidney, IA, then over U.S. Hwy 275 to Omaha, NE, then over U.S. Hwy 6 to junction Iowa Hwy 149, then over Iowa Hwy 149 to Cedar Rapids, IA, then over U.S. Hwy 30 to junction alternate U.S. Hwy 30, then over alternate U.S. Hwy 30 to Chicago, IL, then over U.S. Hwy 41 to junction U.S. Hwy 52, then over U.S. Hwy 52, to Lafayette, IN, then over Indiana Hwy 43 (also U.S. Hwy 231) to Crawfordsville, IN, then over Indiana Hwy 32 to Lebanon, IN, then over Interstate Hwy 65 to junction Indiana Hwy 100, then over Indiana Hwy 100 to junction Interstate Hwy 65, then over Interstate Hwy 65 to Indianapolis, IN, then over Indiana Hwy 37 to English, IN, then over Indiana Hwy 64 to Edwardsville, IN, then over Indiana Hwy 62 to New Albany, IN, then over U.S. Hwy 31W to Louisville, KY.

MC 112713 (Deviation 64), YELLOW FREIGHT SYSTEM, INC., P.O. Box 7270, 10990 Row Avenue, Overland Park, KS 66207, filed March 14, 1980. Carrier proposes to operate as a **common** carrier, by motor vehicle, of *general commodities,* with certain exceptions, over a deviation route as follows: (1) From Winston-Salem, NC, over Interstate Hwy 40 to Nashville, TN, and (2) From Kings Mountain, NC, over U.S. Hwy 74 to junction Interstate Hwy 40, then over Interstate Hwy 40 to Nashville, TN, and return over the same routes for operating convenience only. The notice indicates that the carrier is presently authorized to transport the same commodities over a pertinent service route as follows: From Winston-Salem, NC, over U.S. Hwy 52 to junction U.S. Hwy 29, then over U.S. Hwy 29 to Atlanta, GA, then over U.S. Hwy 41 to Nashville, TN.

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, any 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.

California Docket 59440, filed February 8, 1980. Applicant: GROSKOPF-WEIDER TRUCKING CO., INC., 1761 Denmark Street, Sonoma, CA. Representative: Daniel W. Baker, 100 Pine Street, Suite 2550, San Francisco, CA 94111. Certificate of Public Convenience and Necessity sought to operate a freight service, as follows: Transportation of: General commodities, except the following: (a) Used household goods and personal effects not packed in accordance with the crated property requirements; (b) Livestock; (c) Liquids, compressed gases, commodities in semi-plastic form and commodities in suspension in liquids, in bulk, in tank trucks, tank trailers, tank semi-trailers or a combination of such highway vehicles; (d) Commodities when transported in bulk, in dump trucks or in hopper-type trucks; (e) Commodities when transported in motor vehicles equipped for mechanical mixing in transit; (f) Logs; (g) Fresh fruits and vegetables; (h) Articles of extraordinary value; (i) Automobiles, trucks, buses, and trailer coaches and campers. Between all points and places in the San Francisco Territory, as described in Note A, attached hereto, on the one hand, and all points and places in Napa, Sonoma and Mendocino Counties, on the other hand. In performing the service herein authorized, applicant may make use of any and all streets, roads, highways and bridges necessary or convenient for the performance of said service.

San Francisco Territory

San Francisco Territory includes all the City of San Jose and that area embraced by the following boundary: Beginning at the point the San Francisco-San Mateo County Line meets the Pacific Ocean; thence easterly along said County Line to a point one mile west of State Highway 82; southerly along an imaginary line one mile west of and paralleling State Highway 82 to its intersection with Southern Pacific Company right-of-way at Arastradero Road; southeasterly along the Southern Pacific Company right-of-way to Pollard Road, including industries served by the Southern Pacific Company spur line extending approximately two miles southwest from Simla to Permanente; easterly along Pollard Road to W. Parr Avenue; easterly along W. Parr Avenue to Capri Drive; southerly along Capri Drive to Division Street; easterly along Division Street to the Southern Pacific Company right-of-way; southerly along the Southern Pacific right-of-way to the Campbell-Los Gatos City Limits; easterly along said limits and the prolongation thereof to South Bascom Avenue (formerly San Jose-Los Gatos Road); northeasterly along South Bascom Avenue to Foxworthy Avenue; easterly along Foxworthy Avenue to Almaden Road; southerly along Almaden Road to Hillsdale Avenue; easterly along Hillsdale Avenue to State Highway 82; northwesterly along State Highway 82 to Tully Road; northeasterly along Tully Road and the prolongation thereof to White Road; northwesterly along White Road to McKee Road; southwesterly along McKee Road to Capitol Avenue; northwesterly along Capitol Avenue to State Highway 238 (Oakland Road); northerly along State Highway 238 to Warm Springs; northerly along State Highway 238 (Mission Blvd.) via Mission San Jose and Niles to Hayward; northerly along Foothill Blvd. and MacArthur Blvd. to Seminary Avenue; easterly along Seminary Avenue to Mountain Blvd.; northerly along Mountain Blvd. to Warren Blvd. (State Highway 13); northerly along Warren Blvd. to Broadway Terrace; westerly along Broadway Terrace to College Avenue; northerly along College Avenue to Dwight Way; easterly along Dwight Way to the Berkeley-Oakland Boundary Line; northerly along said boundary line to the Campus Boundary

of the University of California; westerly, northerly and easterly along the campus boundary to Euclid Avenue; northerly along Euclid Avenue to Marin Avenue; westerly along Marin Avenue to Arlington Avenue; northerly along Arlington Avenue to San Pablo Avenue (State Highway 123); northerly along San Pablo Avenue to and including the City of Richmond to Point Richmond; southerly along an imaginary line from Point Richmond to the San Francisco waterfront at the foot of Market Street; westerly along said waterfront and shoreline to the Pacific Ocean; southerly along the shoreline of the Pacific Ocean to point of beginning. Intrastate, interstate and foreign commerce authority sought. Hearing: Date, time and place not yet fixed. Requests for procedural information should be addressed to California Public Utilities Commission, State Building, Civic Center, San Francisco, CA 94102, and should not be directed to the Interstate Commerce Commission.

New York Docket T-9729, filed January 24, 1980. Applicant: ROBERT O. ALLEN, JR., 57 Kattelville Road, Box 86, Chenango Bridge, NY 13745. Certificate of Public Convenience and Necessity sought to operate a freight service, as follows: Transportation of: *Concrete pipe and concrete products and materials and accessories* for the installation thereof: From the Town of Chenango (Broome County) and the Cities of Syracuse and Rochester to all points in the State. *Paper and paper products and waste paper:* Between Broome County on the one hand, and, on the other, the Counties of Clinton, Erie, Essex, Franklin, Hamilton, Herkimer, Jefferson, Lewis, Niagara, Rensselaer, St. Lawrence, Warren and Washington. Intrastate, interstate and foreign commerce authority sought. Hearing: Date, time, and place not yet fixed. Requests for procedural information should be addressed to New York State Department of Transportation, 1220 Washington Ave., State Campus Bldg. No. 4, Room G-21, Albany, NY 12232, and should not be directed to the Interstate Commerce Commission.

South Carolina Docket No. 77-473-T, filed March 4, 1980. Applicant: SMITH & WATERS, INC., Nation Road, Ware Shoals, SC 29692. Representative: William B. Patrick, Jr., P.O. Drawer 1207, Greenwood, SC 29646. Certificate of Public Convenience and Necessity sought to operate a freight service, as follows: Transportation of: Over irregular routes: Commodities in general (usual exceptions): Between points and places in Abbeville, Aiken, Allendale, Anderson, Bamberg, Barnwell, Colleton, Dorchester, Edgefield, Greenwood, Hampton, Laurens, McCormick, Newberry, Oconee, Orangeburg, Pickens and Saluda Counties, South Carolina, and between points and places in these counties and points and places in South Carolina and between points and places in Greenville County for the purpose of interchange only, and between points and places in Greenville County for the purpose of interchange only and points and places in South Carolina (except that no commodities in bulk in dump vehicles may be transported between points and places in Laurens, Newberry, Oconee and Pickens counties, and between points and places in these counties and points and places in South Carolina, not including that area within a five-mile radius of the post office at Ware Shoals); cotton in bales, cotton waste, cotton bagging and cotton ties; and, fertilizer and fertilizer materials: Between points and places in South Carolina; fruits and vegetables: Between points and places in Edgefield and Saluda Counties, South Carolina, and between points and places in Edgefield and Saluda Counties and points and places in South Carolina; brick, tile, terra cotta pipe, concrete blocks, pipe and slabs: Between points and places in Aiken, Fairfield, Greenwood, Lexington and Richland Counties, South Carolina, and from points and places in these counties to points and places in South Carolina; grain: Between points and places in Aiken, Edgefield and Saluda Counties, South Carolina, and between points and places in these counties and points and places in South Carolina; petroleum products in drums and packages: from Charleston, South Carolina, to points and places in Edgefield County, South Carolina. Intrastate, interstate and foreign commerce authority sought. Hearing: Date, time and place not yet fixed. Requests for procedural information should be addressed to The Public Service Commission Transportation Division, P.O. Drawer 11649, Columbia, SC 29211, and should not be direct to the Interstate Commerce Commission.

Permanent Authority Notices
Substitution Applications: Single-Line Service for Existing Joint-Line Service

The following applications, filed on or after April 1, 1979, are governed by the special procedures set forth in Part 1062.2 of Title 49 of the Code of Federal Regulations (49 CFR 1062.2). These proposals are published as "service sought", (as opposed to decision-notices), because in each case it appears questionable as to whether all or part of the authority sought should be issued, weighing applicant's evidence under 49 CFR 1062.2. (For example, questions may be raised relating to applicant's contentions concerning why the involved joint-line service has been cancelled or is in a state of deterioration which warrant a decision on the merits, regardless of whether the applicaiton is opposed.)

The rules provide, in part, that carriers may file petitions with this Commission for the purpose of seeking intervention in these proceedings. Such petitions may seek intervention either with or without leave as discussed below. However, all such petitions must be filed in the form of verified statements, and contain all of the information offered by the submitting party in opposition. Petitions must be filed with the Commission on or before May 15, 1980.

Petitions for intervention without leave (i.e., automatic intervention), may be filed only by carriers which are, or have been, participating in the joint-line service sought to be replaced by applicant's single-line proposal, and then only if such participation has occurred within the one-year period immediately preceding the applications's filing. Only carriers which fall within this filing category can base their opposition upon the issue of the public need for the proposed service.

Petitions for intervention with leave may be filed by any carrier. The nature of the opposition, however, must be limited to issues other than the public need for the proposed service. The appropriate basis for opposition, i.e., applicant's fitness, may include challenges concerning the veracity of the applicant's supporting information, and the bona-fides of the joint-line service sought to be replaced (including the issue of its substantiality). Petitions containing only unsupported and undocumented allegations will be rejected.

Petitions not in reasonable compliance with the requirements of the rules may be rejected. An original and one copy of the petition to intervene shall be filed with the Commission, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named.

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 April 15, 1980.*

MC 123907 (Sub-3F), filed September 4, 1979. Applicant: DAHLMAN TRUCK LINES, INC., 2041 Madison St., Stevens Point, WI 54481. Representative: Nancy J. Johnson, P.O. Box 218, 103 East Washington St., Crandon, WI 54520.

Authority sought to operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *such commodities* as are dealt in by wholesale, food business houses, and in connection therewith, equipment, materials, and supplies, when moving from, to or between warehouses, plants or other facilities of food manufacturing plants or wholesale food business houses, between those points in WI, on, south and west of U.S. Hwy 12 and those in IL on and north of a line extending from the IL–IN border, then west along U.S. Hwy 36 to junction IL Hwy 78, then north along IL Hwy 78 to the IL–WI border, and (2) *paper and paper products*, from those points in WI on, north and east of U.S. Hwy 12 to points in IL on and north of a line extending from the IL–IN border, then west along U.S. Hwy 36 to junction IL Hwy 78, then north along IL Hwy 78 to the IL–WI border. (Hearing site: Madison, or Milwaukee, WI.)

Note.—Applicant proposes to serve points between the described area of IL sought to be served herein and points in WI on, north and east of U.S. Hwy 12 which it is presently authorized to serve.

MC 135082 (Sub-86F), filed May 23, 1979. Applicant: ROADRUNNER TRUCKING, INC., P.O. Box 26748, 4100 Edith Blvd., NE, Albuquerque, NM 87125. Representative: Randall R. Sain (same address as applicant). Authority sought to operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *lumber, lumber products, wood products, and millwork*, (except commodities in bulk, in tank vehicles), between points in AR, AZ, CA, CO, ID, KS, KA, MO, OK, MI, NM, NV, OR, TX, UT, WA, and WY. (Hearing site: Albuquerque, NM.)

Note.—The sole purpose of this application is to substitute single-line for joint-line operations.

Irregular-Route Motor Common Carriers of Property Elimination of Gateway Applications

The following applications to eliminate gateways for the purpose of reducing highway congestion, alleviating air and noise pollution, minimizing safety hazards, and conserving fuel have been filed with the Interstate Commerce Commission under the Commission's Gateway Elimination Rules (49 CFR 1065(d)(2)), and notice thereof to all interested persons is hereby given as provided in such rules.

Carriers having a genuine interest in an application may file an original and three copies of verified statements in opposition with the Interstate Commerce Commission on or before May 15, 1980. (This procedure is outlined in the Commission's report and order in Gateway Elimination, 119 M.C.C. 530). A copy of the verified statement in opposition must also be served upon applicant or its named representative. The verified statement should contain all the evidence upon which protestant relies in the application proceeding including a detailed statement of protestant's interest in the proposal. No rebuttal statements will be accepted.

MC 113666 (Sub-97G), filed December 31, 1979. Applicant: FREEPORT TRANSPORT, INC., 1200 Butler Rd., Freeport, PA 16229. Representative: William H. Shawn, 1730 M St., NW., Suite 501, Washington, DC 20036. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting *refractory products* (except in bulk), (1) from points in PA, to points in NY, MI, IL, IN, OH, MD, NJ, and WV, (2) from points in OH, to points in IN, IL, OH, NY, NJ, MI, PA, and MD, (3) from points in PA, IL, IN, OH, MD, WV, NJ, MI, and NY, (4) from points in MO, to points in MI, WV, OH, IL, and IN, and (5) from points in WV, to points in NY, MI, NJ, IL, IN, OH, MD, and PA. The purpose of this filing is to eliminate the gateways of Detroit, MI and Buffalo, NY. (Hearing site: Washington, DC.)

MC 119777 (Sub-388G), filed June 19, 1979. Applicant: LIGON SPECIALIZED HAULER, INC., Hwy 85 East, Madisonville, KY 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY 42431. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *iron and steel annealing, charging and journal boxes, structural bases, and nails*, between (a) points in IL, on the one hand, and, on the other, points in FL, GA, and SC, (b) points in IN, on the one hand, and, on the other, points in AL, FL, LA, and MS, (c) New York, NY, on the one hand, and, on the other, points in AR, CO, KS, LA, MS, MO, OK, and TX, (d) points in OH, on the one hand, and, on the other, points in AL, AR, LA, MS, OK, and TX, (e) points in PA, on the one hand, and, on the other, points in AR, LA, MS, OK, and TX, and (f) points in WV, on the one hand, and, on the other, points in AR, CO, KS, OK, and TX, (2) *iron and steel mine roof bolts*, from Gadsden, AL, to points in IL, IN, and OH. The purpose of this filing is to eliminate the gateway of Hopkinsville or Bowling Green, KY. (3) *coated corrugated pipe and corrugated alloy pipe*, from points in IL to points in VA, on, south and west of a line beginning at the VA–WV state line and extending east along U.S. Hwy 60 through Covington, VA, to Clifton Forge, VA, and then south along U.S. Hwy 220 through Roanoke, VA to the VA–NC state line. The purpose of this filing is to eliminate the gateway of Jeffersonville, IN. (4) *iron and steel mine roof bolts*, from Birmingham, AL, to points in IL, IN, OH, and PA. (5) *iron and steel wire fencing, and fencing stays, fixtures, gates and rods*, (a) from Ft. Worth and Dallas, TX, and Oklahoma City, OK to New York, NY and points in IN, OH, PA, and WV, and (b) from Mobile and Birmingham, AL and New Orleans, LA, to New York, NY and points in IL, IN, OH, PA, and WV. The purpose of this filing is to eliminate the gateways of Mayfield, Paducah or Middlesboro, KY. (6) *iron and steel articles*, as described in Appendix V to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, the transportation of which, because of their size and weight, require the use of special equipment (except prefabricated buildings and oilfield commodities as described in 61 M.C.C. 209, 299), (a) from points in TN, IL, IN, and KY to points in NY and NJ within that part of the New York, NY, commercial zone as defined in the fifth supplemental report in *Commercial Zones and Terminal Areas*, 53 M.C.C. 451. The purpose of this filing is to eliminate the gateway of Louisville, KY and (b) from points in TN to points in ME, NH, VT, MI on and north of MI Hwy 21, MN, OH, PA, and WV. The purpose of this filing is to eliminate to gateways of Adolphus, KY and Wayne County, WV. (7) *iron and steel articles*, as described in Appendix V to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209, (a) between points in IL and IN, on the one hand, and, on the other, points in OH, PA, WV, TN, and New York, NY. The purpose of this filing is to eliminate the gateway of KY. (b) from New York, NY and points in IL, IN, KY, OH, WV, PA, and TN, to points in AL, AR, GA, IA, KS, LA, MS, MO, NE, OK, TN, TX, and WI. The purpose of this filing is to eliminate the gateways of Kokomo, IN, Hopkins County, KY, and Boyd County, KY. (c) from points in IL, IN and KY, to points in ME, NH, VT, MI on and north of MI Hwy 21, and MN. The purpose of this filing is to eliminate the gateway of KY and Wayne County, WV. and (d) from points in AR, LA, MS, and TX (except Houston), to points in KY, IL, IN, WI, IA, TN, MO, MN, points in MI on and north of MI Hwy 21, NH, VT, ME, OH, PA, WV, NY, and NJ within that part of the New York, NY commercial zone as defined in the fifth supplemental report

in *Commercial Zones and Terminal Areas*, 53 M.C.C. 451. The purpose of this filing is to eliminate the gateways of Parkersburg, WV, Boyd County, and Louisville, KY and Wayne County, WV. (8) *coated pipe, alloy pipe, steel sheets, iron and steel couplings, mine roof washers, crop ends, angles, channels, plates, pipe, casing and tubing*, (except commodities which because of size or weight require the use of special equipment), from New York, NY and points in KY, OH, WV, PA, TN, and AR to points in AZ, NM, NC, SC, and FL. The purpose of this filing is to eliminate the gateways of KY, Sparta, IL, and Parkersburg, WV. (9) *iron and steel guard rails*, from (a) points in IL to points in SC, (b) points in IN to points in LA, MS, NM, and TX, (c) points in OH to points in AR, LA, MS, NM, OK, and TX, (d) points in PA, to points in AR, CO, KS, LA, NM, OK, and TX, (e) points in TN, to MN and WI, and (f) points in WV, to points in AR, CO, KS, NM, OK, and TX. The purpose of this filing is to eliminate the gateway of Evansville, IN and its commercial zone. (Hearing site: not specified.)

MC 119777 (Sub-462G), filed June 6, 1979. Applicant: LIGON SPECIALIZED HAULER, INC., Hwy 85-East, Madisonville, KY 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY 42431. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *iron and steel annealing, charging and journal boxes, structural bases, and nails*, between (a) points in IL, on the one hand, and, on the other, points in FL, GA, and SC, (b) points in IN, on the one hand, and, on the other, points in AL, FL, LA and MS, (c) New York, NY, on the one hand, and, on the other, points in AR, CO, KS, LA, MS, MO, OK, and TX, (d) points in OH, on the one hand, and, on the other, points in AL, AR, LA, MS, OK and TX, (e) points in PA, on the one hand, and, on the other, points in AR, LA, MS, OK, and TX, and (f) points in WV, on the one hand, and, on the other, points in AR, CO, KS, OK, and TX. The purpose of this filing is to eliminate the gateway of Muhlenberg County, KY. (2) *Iron and steel mine roof bolts*, from Gadsden, AL, to points in IL, IN and OH. The purpose of this filing is to eliminate the gateway of Hopkinsville or Bowling Green, KY. (3) *Coated corrugated pipe and corrugated alloy pipe*, from points in IL, to points in VA, on, south and west of a line beginning at the VA–WV State line and extending east along U.S. Hwy 60 through Covington, VA to Clifton Forge, VA and thence south along U.S. Hwy 220 through Roanoke, VA to the VA–NC State line. The purpose of this filing is to eliminate the gateway of Jeffersonville, IN. (4) *Iron and steel mine roof bolts*, from Birmingham, AL to IL, IN, OH, and PA. The purpose of this filing is to eliminate the gateway of Hopkinsville, or Bowling Green, KY. (5) *Iron and steel wire fencing, and fencing stays, fixtures, gates and rods*, (a) from Ft. Worth and Dallas, TX and Oklahoma City, OK to New York, NY and points in IN, OH, PA, and WV, and (b) from Mobile and Birmingham, AL and New Orleans, LA to New York, NY and points in IL, IN, OH, PA, and WV. The purpose of this filing is to eliminate the gateways of Mayfield, Paducah or Middlesboro, KY. (6) *Iron and steel articles*, as described in Appendix V of the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, the transportation of which, because of their size and weight, require the use of special equipment (except prefabricated buildings and oilfield commodities as described in 61 M.C.C 209 and 299), (1) from points in TN, IL, IN, and KY, to points in NY and NJ within part of the New York, NY commercial zone as defined in the fifth supplemental report in *Commercial Zones and Terminal Areas*, 53 M.C.C. 451. The purpose of this filing is to eliminate the gateway of Louisville, KY, (b) from points in TN, to points in ME, NH, VT, MI on and north of MI Hwy 21, MN, OH, PA, and WV. The purpose of this filing is to eliminate the gateways of Adolphus, KY and Wayne County, WV. (7) *Iron and steel articles*, as described in Appendix V to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209, (a) between points in IL and IN, on the one hand, and, on the other, points in OH, PA, WV, TN and New York, NY. The purpose of this filing is to eliminate the gateways at points in KY. (b) From New York, NY and points in IL, IN, KY, OH, WV, PA and TN, to points in AL, AR, GA, IA, KS, LA, MS, MO, NE, OK, TN, TX, and WI. The purpose of this filing is to eliminate the gateways of Kokomo, IN, Hopkins County, KY and/or Boyd County, KY. (c) From points in IL, IN, and KY, to points in ME, NH, VT, MI on and north or MI Hwy 21, and MN. The purpose of this filing is to eliminate the gateway of Wayne County, WV and points in KY. (d) From points in AR, LA, MS, and TX (except Houston, TX) to points in KY, IL, IN, WI, IA, TN, MO, MN, points in MI on and north of MI Hwy 21, NH, VT, ME, OH, PA, WV, NY and NJ within that part of the New York, NY commercial zone as defined in the fifth supplemental report in *Commercial Zones and Terminal Areas*, 53 M.C.C. 451. The purpose of this filing is to eliminate the gateways of Parkersburg and Wayne County, WV and Louisville and Boyd County, KY. (8) *Coated pipe, alloy pipe, steel sheets, iron and steel couplings, mine roof washers, crop ends, angles, channels, plates, pipe, casing and tubing* (except commodities which because of size or weight the use of special equipment), from New York, NY and points in KY, OH, WV, PA, TN and AR, to points in AZ, NM, NC, SC, and FL. The purpose of this filing is to eliminate the gateways of Sparta, IL, Parkersburg, WV and points in KY. (9) *Iron and steel guard rails*, from points in (a) IL, to points in SC, (b) IN to points in LA, MS, NM, and TX, (c) OH, to points in AR, LA, MS, NM, OK and TX, (d) PA, to points in AR, CO, KS, LA, NM, OK and TX, (e) TN, to points in MN and WI, and (f) WV, to points in AR, CO, KS, NM, OK, and TX. The purpose of this filing is to eliminate the gateway of Evansville, IN and its commercial zone.

Irregular-Route Motor Common Carriers of Property-Elimination of Gateway Letter Notices

The following letter-notices of proposals to eliminate gateways for the purpose of reducing highway congestion, alleviating air and noise pollution, minimizing safety hazards, and conserving fuel have been filed with the Interstate Commerce Commission under the Commission's *Gateway Elimination Rules* (49 CFR Part 1065), and notice thereof to all interested persons is hereby given as provided in such rules.

An original and two copies of protests against the proposed elimination of any gateway herein described may be filed with the Interstate Commerce Commission on or before April 25, 1980. A copy must also be served upon applicant or its representative. Protests against the elimination of a gateway will *not* operate to stay commencement of the proposed operation.

Successively filed letter-notices of the same carrier under these rules will be numbered consecutively for convenience in identification. Protests, if any, must refer to such letter-notices by number.

The following applicants seek to operate as a *common carrier*, by motor vehicles, over irregular routes.

MC 107012 (Sub-E262), filed July 7, 1977. Applicant: NORTH AMERICAN VAN LINES, INC., P.O. Box 988, Fort Wayne, IN 46801. Representatives: David D. Bishop and Gary M. Crist (same as above). *New Household Furnishings, crated* (1) From points in NM, to points in CT, DE, DC, MD, MA, MI, NJ, NY, OH, PA, and RI. (2) From points in Bernalillo, Guadalupe, Los

Alamos, Sandoval, San Miguel, Santa Fe, Torrance, Valencia, Colfax, Harding, Mora, Taos, Union Counties, NM, to points in Adams, Allen, Blackford, De Kalb, Delaware, Elkhart, Grant, Huntington, Jay, Kosciusko, Lagrance, Noble, Randolph, Steuben, Wabash, Wells, Whitley, Boone, Clinton, Hamilton, Hancock, Hendricks, Johnson, Madison, Marion, Morgan, Shelby, Tipton, Bartholomew, Brown, Clark, Dearborn, Decatur, Fayette, Floyd, Franklin, Harrison, Henry, Jackson, Jefferson, Jennings, Ohio, Ripley, Rush, Scott, Switzerland, Union, Washington, Wayne, Benton, Carroll, Cass, Fountain, Fulton, Howard, Jasper, Lake, La Porte, Marshall, Miami, Montgomery, Newton, Porter, Pulaski, Saint Joseph, Starke, Tippecanoe, Warren, White Counties, IN; Bath, Boone, Bourbon, Boyd, Bracken, Campbell, Carroll, Carter, Clark, Elliott, Fleming, Franklin, Gallatin, Grant, Greenup, Harrison, Johnson, Kenton, Lawrence, Lewis, Magoffin, Martin, Mason, Menifee, Montgomery, Morgan, Nicholas, Owen, Pendleton, Powell, Robertson, Rowan, Scott, Wolfe Counties, KY; and points in WV. (3) From points in McKinley, Rio Arriba, San Juan Counties, NM, to points in Adams, Allen, Blackford, De Kalb, Delaware, Elkhart, Grant, Huntington, Jay, Kosciusko, Lagrange, Noble, Randolph, Steuben, Wabash, Wells, Whitley, Boone, Clinton, Hamilton, Hancock, Hendericks, Johnson, Madison, Marion, Morgan, Shelby, Tipton, Bartholomew, Brown, Clark, Dearborn, Decatur, Fayette, Floyd, Franklin, Harrison, Henry, Jackson, Jefferson, Jennings, Ohio, Ripley, Rush, Scott, Switzerland, Union, Washington, Wayne, Benton, Carroll, Cass, Fountain, Fulton, Howard, Jasper, Lake, La Porte, Marshall, Miami, Montgomery, Newton, Porter, Pulaski, Saint Joseph, Starke, Tippecanoe, Warren, White Counties, IN; Adair, Anderson, Boyle, Casey, Clinton, Cumberland, Fayette, Gerrard, Green Jessamine, Lincoln, Madison, Marion, Mercer, Metcalfe, Monroe, Pulaski, Rockcastle, Russell, Taylor, Washington, Wayne, Woodford, Allen Barren, Breckinridge, Bullitt, Butler, Christian, Edmonson, Grayson, Hardin, Hart, Henry, Jefferson, La Rue, Logan, Meade, Muhlenberg, Nelson, Ohio, Oldham, Shelby, Simpson, Spencer, Todd, Trimble, Warren, Bath, Boone, Bourbon, Boyd, Bracken, Campbell, Carroll, Carter, Clark, Elliott, Fleming, Franklin, Gallatin, Grant, Greenup, Harrison, Johnson, Kenton, Lawrence, Lewis, Magoffin, Martin, Mason, Menifee, Montgomery, Morgan, Nicholas, Owen, Pendleton, Powell, Robertson, Rowan, Scott, Wolfe, Bell, Breathitt, Clay, Estill, Floyd, Harlan, Jackson, Knott, Knox, Laurel, Lee, Leslie, Letcher, McCreary, Owsley, Perry, Pike, Whitley Counties, KY; and points in WV. (4) From points in Chaves, Curry, De Baca, Eddy, Lea, Lincoln, Quay, Roosevelt Counties, NM, to points in Adams, Allen, Blackford, De Kalb, Delaware, Elkhart, Grant, Huntington, Jay, Kosciusko, Lagrange, Noble, Randolph, Steuben, Wabash, Wells, Whitley, Boone, Clinton, Hamilton, Hancock, Hendricks, Johnson, Madison, Marion, Morgan, Shelby, Tipton, Benton, Carroll, Cass, Fountain, Fulton, Howard, Jasper, Lake, La Porte, Marshall, Miami, Montgomery, Newton, Porter, Pulaski, Saint Joseph, Starke, Tippecanoe, Warren, White Counties, IN; Braxton, Clay, Fayette, Kanawha, Nicholas, Webster, Barbour, Berkeley, Doddridge, Grant, Hampshire, Hardy, Harrison, Jefferson, Lewis, Marion, Mineral, Monongalia, Morgan, Pendleton, Preston, Randolph, Taylor, Tucker, Tyler, Upshur, Wetzel, Calhoun, Gilmer, Jackson, Mason, Pleasants, Ritchie, Roane, Wirt, Wood, Brooke, Hancock, Marshall, Ohio Counties, WV. (5) From points in Catron, Dona Ana, Grant, Hidalgo, Luna, Otero, Sierra, Socorro Counties, NM, to points in Adams, Allen Blackford, De Kalb, Delaware, Elkhart, Grant, Huntington, Jay, Kosciusko, Lagrange, Noble, Randolph, Steuben, Wabash, Wells, Whitley, Boone, Clinton, Hamilton, Hancock, Hendricks, Johnson, Madison, Marion, Morgan, Shelby, Tipton, Bartholomew, Brown, Clark, Dearborn, Decatur, Fayette, Floyd, Franklin, Harrison, Henry, Jackson, Jefferson, Jennings, Ohio, Ripley, Rush, Scott, Switzerland, Union, Washington, Wayne, Benton, Carroll, Cass, Fountain, Fulton, Howard, Jasper, Lake, La Porte, Marshall, Miami, Montgomery, Newton, Porter, Pulaski, Saint Joseph, Starke, Tippecanoe, Warren, White Counties, IN; points in KY, and WV. (Eliminate the gateway of Chicago, IL)

By the Commission.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-11324 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

[Service Order No. 1344; ICC. Order No. 58; Amdt. No. 1]

Louisiana Midland Railway Co.; Rerouting Traffic

To: Louisiana Midland Railway Company.

Upon further consideration of I.C.C. Order No. 58, and good cause appearing therefor:

It is ordered, I.C.C. Order No. 58 is amended by substituting the following paragraph (h) for paragraph (h) thereof:

(h) *Expiration date.* This order shall expire at 11:59 p.m., May 31, 1980, unless otherwise modified, changed or suspended.

Effective date. This amendment shall become effective at 11:59 p.m., March 31, 1980.

This amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. A copy of this amendment shall be filed with the Director, Office of the Federal Register.

Issued at Washington, D.C., March 31, 1980.

Interstate Commerce Commission.

Joel E. Burns,

Agent.

[FR Doc. 80-11326 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

[Directed Service Order No. 1462; Supplemental Order No. 2]

Various Railroads—Directed Service—Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

Decided: April 7, 1980.

On March 28, 1980, we authorized various railroads to provide service as "directed rail carriers" (DRCs)—without federal subsidization under 49 U.S.C. § 11125(b)(5)—over described lines of the Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee) ("Rock Island" or "RI") until May 31, 1980. *See* Directed Service Order No. 1462, *Various Railroads—Directed Service—Chicago, R.I. & P.* I.C.C. ———(1980), 45 FR 22945 (April 4, 1980).

This decision is being issued to modify the appendix to DSO No. 1462 by extending the line authorized to be served by the Fort Worth and Denver Railroad Company (FW&D).

The FW&D has requested the extension of the line authorized to be served under the terms and conditions of DSO No. 1462, so that it may serve a shipper at Bushland, TX. The shipper along the extended line requires immediate rail service. Accordingly, we will amend paragraph 8 to the appendix to DSO No. 1462 [45 FR 22947] ("RI Lines Authorized To Be Operated by DRCS") to read as follows:

8. *Fort Worth and Denver Railroad Company (FW&D):*

A. Terminal trackage at Amarillo and Bushland, Texas (milepost 754.1 to milepost 776.0) including all yard trackage within these points and including the spur tracks (old Liberal line) to the Asarco Plant.

B. Bowie, Texas (milepost 543.2) to North Fort Worth, Texas (milepost 609.6).

We find: (1) This action will not significantly affect either the quality of the human environment or the conservation of energy resources. *See* 49 CFR Parts 1106, 1108 (1978).

It is ordered: (1) Directed Service Order No. 1462 (served March 28, 1980) is amended as indicated in this decision.

(2) This decision shall be effective on its service date.

By the Commission, Chairman Gaskins, Vice Chairman Gresham, Commissioners Stafford, Clapp, Trantum, and Alexis.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-11389 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

[Directed Service Order No. 1462; Supplemental Order No. 5]

Various Railroads—Directed Service—Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

Decided: April 8, 1980.

On March 28, 1980, we authorized various railroads to provide service as "directed rail carriers" (DRCs)—without federal subsidization under 49 U.S.C. § 11125(b)(5)—over described lines of the Chicago, Rock Island & Pacific Railroad Company, Debtor (William M. Gibbons, Trustee) ("Rock Island" or "RI") until May 31, 1980. *See* Directed Service Order No. 1462, *Various Railroads—Directed Service—Chicago, R.I. & P.*, ——— I.C.C. ——— (1980), 45 FR 22945 (April 4, 1980).

This decision is being issued to modify the appendix to DSO No. 1462 by including an additional DRC and specifying the RI lines over which it will be authorized to operate.

The Atchison, Topeka, and Sante Fe Railway Company (Sante Fe) has requested to be authorized to operate as a DRC under terms and conditions similar to those set forth in DSO No. 1462, with certain exceptions discussed below.

The Santa Fe is not a party to the negotiated labor protection agreement signed March 4, 1980 (entitled *Labor Protective Agreement Between Railroads Parties Hereto Involved in Midwest Rails Restructuring and Employees of Such Railroads Represented by the Rail Labor Organizations Operating Through the Railway Labor Executives Association*), referred to hereafter as the March 4 agreement. In its request for authority to operate as a DRC, Santa Fe states that it is willing to provide labor protection in accordance with the terms of the March 4 agreement, subject to specified exceptions.

We have interpreted the March 4 agreement as satisfying the employee protection requirements of the Interstate Commerce Act—including the provisions of 49 U.S.C. § 11125(b)(4)—for purposes of interim operations over the Rock Island. We do not believe that Santa Fe has shown that the March 4 agreement, modified as it proposes, would satisfy the relevant statutory labor protective requirements. Therefore, if the Santa Fe commences operations as authorized in this decision, it must either become a party to the March 4 agreement or comply with the requirements of 49 U.S.C. § 11125(b)(4) in the manner specified in Directed Service Order No. 1398, *Kansas City Term. Ry. Co.—Operate—Chicago, R.I. & P.*, 360 I.C.C. 289, at 300–303 (1979), or in any other manner negotiated with affected RI employees.

The shippers along the involved line require significant rail service. Accordingly, we will amend the appendix to DSO No. 1462 [45 FR 22948] ("RI Lines Authorized To Be Operated by DRCs") by adding the following provision:

19. *Atchison, Topeka, and Santa Fe Railway Company (Santa Fe):* From Etter to Morse Junction, TX, including the branch line to Sheerin, TX, and from Morse, TX, to Liberal, KS. In performing the operations specified in this paragraph, Santa Fe shall comply with the employee protection requirements of 49 U.S.C. § 11125(b)(4) in the manner specified in Directed Service Order No. 1398, *Kansas City Term. Ry. Co.—Operate—Chicago, R.I. & P.*, 360 I.C.C. 289, at 300–303 (1979), or in any other manner negotiated with the affected RI employees, unless it becomes a party to the negotiated labor protection agreement signed March 4, 1980 (entitled *Labor Protective Agreement Between Railroads Parties Hereto Involved in Midwest Rail Restructuring and Employees of Such Railroads Represented by the Rail Labor Organizations Operating Through the Railway Association*), in which case the latter agreement shall govern Santa Fe's obligations to RI employees under DSO No. 1462.

We find: (1) This action will not significantly affect either the quality of the human environment or the conservation of energy resources. *See* 49 CFR Parts 1106, 1108 (1978).

It is ordered: (1) Directed Service Order No. 1462 (served March 28, 1980) is amended as indicated in this decision.

(2) This decision shall be effective on its service date.

By the Commission, Chairman Gaskins, Vice Chairman Gresham, Commissioners Stafford, Clapp, Trantum, and Alexis.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-11390 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 29305; Service Order No. 1451]

St. Louis-San Francisco Railway Co.—Compensation for Use of Terminal Tracks—Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee); and St. Louis-San Francisco Railway Co.—Authority To Use Terminal Tracks—Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

Decided: April 7, 1980.

In Service Order No. 1451, (45 FR 20883, March 31, 1980) as revised, we authorized the St. Louis-San Francisco Railway Company (Frisco) to operate over designated terminal tracks of the Chicago, Rock Island & Pacific Railroad Company (Rock Island or RI). The service order was issued in order to authorize the performance of essential railroad service for shippers located on lines embargoed by the bankrupt Rock Island. Under the provisions of the service order, the trustee of the RI estate and the Frisco were to establish terms of compensation to be paid to the estate for the use of Rock Island Properties. If the parties failed to agree upon compensation, the service order provided that compensation would be fixed by the Commission, as authorized by 40 U.S.C. 11123(b)(2).

Frisco has filed a petition asserting that it has been unable to reach agreement with the RI trustee regarding compensation. Frisco requests, therefore, that the Commission fix reasonable terms of compensation. It states that it believes reasonable compensation should be based upon a monthly rental charge equal to one-twelvth of 10 percent of "ledger value of the Rock Island road property account for the track segments involved".

The trustee has replied to the petition. The trustee takes the position that reasonable compensation should equal

1.2 percent of gross salvage value of the involved property or 1.2 percent of going concern value of the property, whichever is greater. Going concern value, for this purpose, would be considered to be equal to the annual gross revenues attributable to the property.

Discussion and Conclusions

Under the provisions of 49 U.S.C. 11123, the Commission is not required to fix compensation in every decision authorizing use of one carrier's facilities by another. Our authority to fix compensation is limited to instances where the carriers do not agree on terms of compensation. The Commission's role, therefore, is to arbitrate an unresolved dispute between two negotiating parties. When the Commission performs this function, its duty is to make a rational accommodation of the opposing interests on review. The Court will limit its consideration to determining whether the Commission has done so. See *National R. R. Passenger Corp.* v. *I.C.C.*, 610 F.2d 865, 875 (D.C. Cir. 1979) (remanded to the Commission, in part, on other grounds), and *National R. R. Passenger Corp.* v. *I.C.C.*, 610 F.2d 881, 886 (D.C. Cir., 1979).

Frisco has offered to pay compensation to the trustee that would yield a return of 10 percent per year on the depreciated book value of the involved property. We believe this would be unreasonably low. The depreciated book value of the property does not reflect the current fair value of the property. Further, an annual rate of return of 10 percent would be well below currently prevailing rates on conservative investments, such as government notes and bank certificates.

The trustee seeks compensation that would yield 14.4 percent per year on the greater of either gross salvage value of the property or on the going concern value of the property (measured by 1978 Rock Island gross station revenues adjusted for rate increases since 1978). We believe that the trustee's proposed rate of return of 14.4 percent is reasonable in view of current returns on conservative investments. The method of determining going concern value of the property proposed by the trustee, however, would greatly overstate the fair rental value of the property. Fair rental value of the property should be determined on the basis of net revenues produced by the property, not gross revenues.

We believe that the trustee should be compensated for the use of RI properties in accordance with a two-part formula. The first part of the formula will be a base rental assessed on route miles, payable on a monthly basis, in advance. The second part of the formula will be a share of net revenues, if any, derived by Frisco from its operations over the involved tracks. The base rental payment will assure the trustee of some payment for the use of the property, even if the involved lines do not produce net revenues when operated as rail property. The second part of the formula will provide the trustee with a return on the going concern value of the property, if the involved lines generate net revenues from rail operations.

We conclude that the rental under the first part of our compensation formula should be fixed at $1,250.00 per route mile per year, payable on a monthly basis, in advance. We are aware of former track rental agreements where compensation has been $2,475 per route mile per year and other agreements where no compensation has been paid. The facts involved in those cases show that they are extreme situations involving high and low compensation.

In the high compensation case, the involved lines were used solely to provide service on an interim basis and would not be acquired by the carrier providing such service under subsidy. In the case involving no compensation in return for undertaking to provide security and maintenance of the involved lines, an agreement regarding sale of the line to the lessee had already been reached. The instant proceeding involves a situation between those two extremes. The RI will be liquidated and many of its lines will be purchased by other railroads. No purchase agreements have been reached as yet, however. Because an intermediate situation is involved here, we believe a reasonable base rental would be one-half the amount set in the previous high-compensation case, that is $1,237.50 per route mile per year. In addition, Frisco will be required to provide for the security and maintenance of rail properties actually utilized by it in providing interim service pursuant to Service Order No. 1451 as revised.

If the Frisco's operations over the involved lines yield a profit, the trustee will receive additional compensation under the second part of our formula. Because the share of profits would be passive income to the trustee, we believe that 14.4 percent of net revenues would yield a fair return. Net revenues should be calculated in accordance with the Commission's regulations applicable in abandonment proceedings (49 CFR 1121.41–1121.43), subject only to the following exceptions: (1) the casualty reserve account is eliminated; (2) rehabilitation expenses are reported under maintenance of way and structures costs; and (3) bridge traffic revenues and costs are eliminated.

In determining the share of traffic attributable to RI at former RI-Frisco reciprocal switching points, RI's share shall be considered to be the same as the share handled by Kansas City Terminal Railway Company in its operations under Directed Service Order No. 1398.

We are arriving at this interim resolution based on the best information available to us because of the need to establish some level of compensation so that service will be commenced. We will entertain any additional information submitted by the parties if they wish us to reconsider this decision.

The parties are advised that our conclusions here are not etched in stone. We will entertain petitions and are ready to reconsider this matter if anyone offers a better idea.

We find:

1. The Frisco and the Rock Island Trustee have been unable to agree upon terms for compensation of the RI estate for the use of RI property by Frisco under Service Order No. 1451, as revised.

2. The terms of compensation set forth in this decision will be reasonable within the meaning of 49 U.S.C. 11123.

3. This action will not significantly affect either the quality of the human environment or the conservation of energy resources. *See* 49 CFR Parts 1106, 1108 (1978).

It is ordered:

1. If the Frisco commences operations over the Rock Island's lines as authorized in Service Order No. 1451, as revised, it shall compensate the Rock Island estate for the use of RI properties in accordance with the terms of this decision.

2. This decision shall be effective on the date it is served.

By the Commission. Chairman Gaskins, Vice Chairman Gresham, Commissioners Stafford, Clapp, Trantum, and Alexis. Commissioner Clapp concurring with a separate expression. Commissioner Alexis was absent and did not participate.

Agatha L. Mergenovich,

Secretary.

Commissioner Clapp, concurring:

I am disappointed that a majority is unwilling to make a firm commitment on the compensation formula in this proceeding. While our conclusions should never be "etched in stone," it is important at this juncture to give railroads contemplating temporary service a definite statement on

which they can rely. The action taken here continues the uncertainty.

[FR Doc. 80-11391 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

[Directed Service Order No. 1462; Supplemental Order No. 3]

Various Railroads—Directed Service—Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

Decided: April 7, 1980.

On March 28, 1980, we authorized various railroads to provide service as "directed rail carriers" (DRCs)—without federal subsidization under 49 U.S.C. 11125(b)(5)—over described lines of the Chicago, Rock Island & Pacific Railroad Company, Debtor (William M. Gibbons, Trustee) ("Rock Island" or "RI") until May 31, 1980. See Directed Service Order No. 1462, *Various Railroads—Directed Service—Chicago, R.I. & P.* ——— I.C.C. ——— (1980.) 45 FR 22945 (1980).

This decision is being issued to modify the appendix to DSO No. 1462 by including two additional RI lines over which the Chicago and North Western Transportation Company (C&NW) will be authorized to operate.

The C&NW has requested authority to operate from Altoona to Pella, IA, and from Carlisle to Indianola, IA under the terms and conditions of DSO No. 1462. The shippers along these lines require significant rail service. Accordingly, we will amend the appendix to DSO No. 1462 [45 FR 22948] ("RI Lines Authorized To Be Operated by DRCS") by adding the following provisions under paragraph 9. *Chicago and North Western Transportation Company (C&NW):*

R. from Altoona to Pella, IA.
S. from Carlisle to Indianola, IA.

We find:

(1) This action will not significantly affect either the quality of the human environment or the conservation of energy resources. *See* 49 CFR Parts 1106, 1108 (1978).

It is ordered:

(1) Directed Service Order No. 1462 (served March 28, 1980) is amended as indicated in this decision.

(2) This decision shall be effective on its service date.

By the Commission, Chairman Gaskins, Vice Chairman Gresham, Commissioners Stafford, Clapp, Trantum, and Alexis. Commissioner Trantum absent and not participating.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-11393 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

[Directed S.O. No. 1462, Supplemental Order No. 4]

Various Railroads—Directed Service—Chicago, Rock Island & Pacific Railroad Co., Debtor (William M. Gibbons, Trustee)

Decided: April 7, 1980.

On March 28, 1980, we authorized various railroads to provide service as "directed rail carriers" (DRCs)—without federal subsidization under 49 U.S.C. 11125(b)(5)—over described lines of the Chicago, Rock Island & Pacific Railroad Company, Debtor (William M. Gibbons, Trustee) ("Rock Island" or "RI") until May 31, 1980. *See* Directed Service Order No. 1462, Various Railroads—Directed Service—Chicago, R.I. & P. —— I.C.C. — — (1980), 45 FR 22945 (April 4, 1980).

This decision is being issued to modify the terms and conditions of DSO No. 1462 by including operations by DRCs under continuation of RI trackage rights agreements.

Operation under continuation of RI trackage rights agreements is necessary in order for some DRCs to provide service over RI lines. We will, therefore, authorize continuation of trackage rights to the extent necessary for DRCs to provide the services authorized in DSO No. 1462. We will amend the "Operations" section of DSO No. 1462 to read as follows:

Operations—The DRC's are authorized to operate over the RI tracks designated in the appendix to this decision. The DRCs further, may operate under continuation of trackage rights agreements between the RI and other carriers to the extent necessary in order to perform the services authorized in this decision. Operation over the designated tracks includes use of facilities and appurtenances thereto that are necessary or reasonably related to train operations, including but not limited to: Yards; yard facilities; maintenance facilities; communication, electrical, and signal facilities; locomotive and car repair facilities; scales; etc.; subject, however, to the following notification requirements. The DRC's shall, within one week of commencing operations, notify the RI Trustee of those facilities they believe are necessary or reasonably related to the authorized operations. Any facilities or appurtenances not so identified in the notification shall not be deemed to be part of the operations authorized by this decision, unless contested. Disagreements concerning the scope of operations and use of facilities shall be resolved by appropriate Commission orders.

Operation over the designated RI tracks includes entry and exit to those tracks, for the purpose of handling traffic to or from stations on the lines, as well as for the purpose of handling traffic that neither originates nor terminates at any station on any such line.

We find:

(1) This action will not significantly affect either the quality of the human environment or the conservation of energy resources. See 49 CFR Parts 1106, 1108 (1978).

It is ordered:

(1) Directed Service Order No. 1462 (served March 28, 1980) is amended as indicated in this decision.

(2) This decision shall be effective on its service date.

By the Commission, Chairman Gaskins, Vice Chairman Gresham, Commissioners Stafford, Clapp, Trantum, and Alexis. Commissioner Trantum absent and not participating.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-11333 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

Permanent Authority Decision; Decision-Notice

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, filed within 30 days of publication of this decision-notice (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. 70

Decided: March 24, 1980.

By the Commission, Review Board Number 3, Members Parker, Fortier, and Hill.

MC 8515 (Sub-36F), filed December 21, 1979. Applicant: TOBLER TRANSFER, INC., Junction Interstate 80 and Illinois 89, Spring Valley, IL 61362. Representative: Leonard R. Kofkin, 39 South La Salle St., Chicago, IL 60603. Transporting (1) *alcoholic liquors* in bulk or in containers and (2) *materials and supplies* used in the production of the commodities in (1), between points in IL, on the one hand, and, on the other, Bardstown, Cox's Creek, Frankfort, and Louisiville, KY. (Hearing site: Chicago, IL.)

MC 8535 (Sub-109F), filed December 27, 1979. Applicant: GEORGE TRANSFER AND RIGGING COMPANY, INC., P.O. Box 500, Parkton, MD 21120. Representative: John Guandolo, 1000 Sixteenth St., NW., Washington, DC 20036. Transporting *iron and steel articles* (except in dump vehicles), from the facilities of Raritan River Steel Company, at Perth Amboy, NJ, to those points in the United States in and east of AR, IA, LA, MS, and MO (except points in DE, KY, MD, NJ, NY, OH, PA, VA, WV, and DC). (Hearing site: Newark, NJ, or Washington, DC.)

MC 14215 (Sub-79F), filed December 21, 1979. Applicant: SMITH TRUCK SERVICE, INC., 1118 Commercial, Mingo Junction, OH 43938. Representive: A. Charles Tell, 100 East Broad St., Columbus, OH 43215. Transporting *alloys and silicon metal*, from the facilities of Ohio Ferro-Alloys Corp., at Philo and Powhattan, OH, to points in VA. (Hearing site: Columbus, OH.)

MC 41635 (Sub-52F), filed December 26, 1979. Applicant: DEALERS TRANSPORT COMPANY, A CORPORATION, 1368 Riverside Blvd., Memphis, TN 38101. Representative: John A. Crawford, 17th Floor, Deposit Guaranty Plaza, P.O. Box 22567, Jackson, MS 39205. Transporting *automobiles and trucks*, in secondary movements in truck-away service, between points in TN, and KY. (Hearing site: Memphis, TN.)

Note.—Applicant intends to tack the requested authority with its present authority in MC 41635 at points in KY and TN.

MC 67234 (Sub-27F), filed December 26, 1979. Applicant: UNITED VAN LINES, INC., One United Drive, Fenton, MO 63026. Representative: B. W. LaTourette, Jr., 11 S. Meramec, Suite 1400, St. Louis, MO 63105. Transporting (1) *games and toys* and (2) *toy and game*

parts used in the manufacture of toys, from Seattle, WA, to Toledo, OH, and Mt. Clemens, MI. (Hearing site: Minneapolis, MN, or Washington, DC.)

MC 73165 (Sub-499F), filed December 11, 1979. Applicant: EAGLE MOTOR LINES, INC., 830 33rd St., North, Birmingham, AL 35202. Representative: R. Cameron Rollins, P.O. Box 11086, Birmingham, AL 35202. Transporting (1) *machinery*, and (2) *equipment and supplies, materials, accessories and parts* for machinery, between points in the United States (except AK and HI), restricted to movements originating at or destined to the facilities used by Gandy Equipment Corporation. Condition: The person or persons who appear to be engaged in common control of applicant and another regulated carrier must either file an application under 49 U.S.C. 11343(a) (1978) or submit an affidavit indicating why such approval is unnecessary. (Hearing site: Philadelphia, PA.)

MC 73165 (Sub-500F), filed December 27, 1979. Applicant: EAGLE MOTOR LINES, INC., 830 33rd St., North, Birmingham, AL 35202. Representative: R. Cameron Rollins, P.O. Box 11086, Birmingham, AL 35202. Transporting (1) *buildings, building panels, building parts*, and (2) *materials, accessories and supplies* used in the installation and construction of commodities in (1) (except commodities in bulk), between the facilities of Butler Manufacturing Company, at or near San Marcos, TX, on the one hand, and, on the other, points in the U.S. (except AK and HI), restricted to transportation of traffic originating at or destined to the named facilities. (Hearing site: Dallas or Houston, TX.)

MC 94265 (Sub-338F), filed December 26, 1979. Applicant: BONNEY MOTOR EXPRESS, INC., P.O. Box 305, Windsor, VA 23487. Representative: John J. Capo, P.O. Box 720434, Atlanta, GA 30328. Transporting *meats, meat products and meat byproducts* as described in Section A of Appendix I to the Report in *Description in Motor Carrier Certificates* 61 M.C.C. 209 and 766 (1) from Norfolk, VA, to points in FL and WI; (2) from Philadelphia, PA, to points in DE, IA, IL, IN, KS, KY, MD, MN, MO, NE, NC, OH, PA, TN, and WI, and (3) from Charleston, SC, to points in AL, AR, DE, FL, GA, IA, IL, IN, KS, KY, LA, MD, MI, MN, MO, MS, NC, NE, OH, OK, SC, TN, TX, VA, WV, and DC. (Hearing site: Richmond, VA, or Washington, DC.)

MC 99234 (Sub-19F), filed December 26, 1979. Applicant: WESTWAY MOTOR FREIGHT, INC., 5231 Monroe St., Denver, CO 80216. Representative: Leslie R. Kehl, 1600 Lincoln Center, 1660 Lincoln St., Denver, CO 80264. Transporting *building materials, equipment and supplies and iron and steel articles*, between points in AZ, CA, CO, ID, MT, NV, NM, OR, UT, WA, and WY. (Hearing site: Denver, CO.)

MC 105045 (Sub-138F), filed December 26, 1979. Applicant: R. L. JEFFRIES TRUCKING CO., INC., 1020 Pennsylvania St., Evansville, IN 47701. Representative: Paul F. Sullivan, 711 Washington Building, Washington, DC 20005. Transporting *architectural stone, mortar (in bags) and metal lathes*, between the facilities of Architectural Cast Stone, of Indiana, at Indianapolis, IN, on the one hand, and, on the other, points in the US (except AK and HI). (Hearing site: Indianapolis, IN.)

MC 106074 (Sub-140F), filed December 26, 1979. Applicant: B AND P MOTOR LINES, INC., Shiloh Road and U.S. Hwy. 221 South, Forest City, NC 28043. Representative: Clyde W. Carver, P.O. Box 720434, Atlanta, GA 30328. Transporting *synthetic staple fiber*, from the facilities of American Cyanamid Company, at or near Pace, FL, to points in NC, SC, TN on and east of Interstate Hwy 65, and VA on and south of Interstate Hwy 64. (Hearing site: New York, NY, or Washington, DC.)

Note.—Dual operations are involved.

MC 106674 (Sub-452F), filed December 26, 1979. Applicant: SCHILL MOTOR LINES, INC., P.O. Box 123, Remington, IN 47977. Representative: Jerry L. Johnson (same address as applicant). Transporting *cornstarch*, in bags, from Morrisville, PA, to points in IL, IN, MI, MN, OH, and WI. (Hearing site: Chicago, IL, or Indianapolis, IN.)

MC 106674 (Sub-453F), filed December 26, 1979. Applicant: SCHILL MOTOR LINES, INC., P.O. Box 123, Remington, IN 47977. Representative: Jerry L. Johnson (same address as applicant). Transporting *unfinished cross-ties, wooden* from points in TN to Indianapolis, IN and Madison, IL. (Hearing site: Chicago, IL, or Indianapolis, IN.)

MC 106674 (Sub-455F), filed December 26, 1979. Applicant: SCHILL MOTOR LINES, INC., P.O. Box 123, Remington, IN 47977. Representative: Jerry L. Johnson (same address as applicant). Transporting *building materials* (except commodities in bulk), from facilities of Bird & Son, Inc., at or near Shreveport, LA, to points in AL, AR, IL, IN, KY, MS, MO, TN, and TX. (Hearing site: Chicago, IL, or Indianapolis, IN.)

MC 107295 (Sub-957F), filed December 26, 1979. Applicant: PRE-FAB TRANSIT CO., a corporation, P.O. Box 146, Farmer City, IL 61842. Representative: Todd A. Peterman (same address as applicant). Transporting *composition board*, from Marinette, WI, to points in the US (except AK and HI). (Hearing site: Chicago, IL.)

MC 107295 (Sub-958F), filed December 26, 1979. Applicant: PRE-FAB TRANSIT CO., a corporation, P.O. Box 146, Farmer City, IL 61842. Representative: Todd A. Peterman (same address as applicant). Transporting (1) *fabricated metal articles*, from Eufaula, AL, to points in the US (except AK and HI), and (2) *materials, equipment, and supplies* (except commodities in bulk), used in the manufacture and distribution of the commodities in (1), in the reverse direction. (Hearing site: Atlanta, GA.)

MC 107295 (Sub-959F), filed December 26, 1979. Applicant: PRE-FAB TRANSIT CO., a corporation, P.O. Box 146, Farmer City, IL 61842. Representative: Todd A. Peterman (same address as applicant). Transporting *aluminum scrap metal and aluminum products*, between Chandler, AZ, and Russellville, AR, and from Russelville, AR, to Seattle, WA, Dallas, TX, and San Diego and Los Angeles, CA. (Hearing site: Phoenix, AZ.)

MC 111214 (Sub-19F), filed December 27, 1979. Applicant: GREENWOOD STORAGE & TRUCKING CO., INC., P.O. Box 943, Greenwood, MS 38930. Representative: Harold H. Mitchell, Jr., P.O. Box 1295, Greenville, MS 38701. *Contract carrier* transporting (1) *pipe, pipe fittings, castings, and assessories and (2) material, equipment, and supplies* (except in bulk) used in the manufacture and distribution of the commodities in (1), between the facilities of The Central Foundry Company, at or near Holt, AL, on the one hand, and, on the other points in AL, AR, FL, GA, LA, MS, NC, SC, TN and TX, under continuing contract(s) with Central Foundry Company, of Holt, AL. (Hearing site: Tuscaloosa, AL.)

MC 111375 (Sub-110F), filed May 16, 1979, previously noticed in **Federal Register** on March 27, 1980. Applicant: PIRKLE REFRIGERATED FREIGHT LINES, INC., P.O. Box 3358, Madison, WI 53704. Representative: Elaine M. Conway, 10 South LaSalle St., Suite 1600, Chicago, IL 60603. Transporting *such commodities* as are dealt in or used by manufacturers, converters, processors, distributors, and printers of paper and paper products (except commodities in bulk), from points in WI, to points in AZ, CA, CO, ID, MT, NM, NV, OR, UT, WA, and WY. (Hearing site: Milwaukee, WI, or Chicago, IL.)

Note.—This republication corrects the docket number adding the sub number, to read MC 111375 Sub-110F.

MC 114604 (Sub-103F), filed December 27, 1979. Applicant: CAUDELL TRANSPORT, INC., P.O. Drawer I, Forest Park, GA 30050. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Road, NE, Atlanta, GA 30326. Transporting *glass containers, container accessories, and empty cartons* (except in bulk), from the facilities of Kerr Glass Manufacturing Corp., at or near Huntington, WV, to points in AL, MS, LA, AR, TX, FL, GA, NC, SC, TN, VA, KY, IL, IN, and OH. (Hearing site: Atlanta, GA.)

MC 114604 (Sub-104F), filed December 27, 1979. Applicant: CAUDELL TRANSPORT, INC., P.O. Drawer I, Forest Park, GA 30050. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Road, NE, Atlanta, GA 30326. 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 Certificate,* MCC 209 and 766 (except hides and commodities in bulk), and foodstuffs (frozen or chilled), from the facilities of New Orleans, Cold Storage and Warehouse Co., LTD, at or near New Orleans, LA, to those points in the US in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: Atlanta, GA.)

MC 114604 (Sub-105F), filed December 27, 1979. Applicant: CAUDELL TRANSPORT, INC., P.O. Drawer I, Forest Park, GA 30050. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Road, NE., Atlanta, GA 30326. Transporting *foodstuffs* (except frozen foods or commodities in bulk), between the facilities of Stokely-Van Camp, Inc., at or near Gibson City, Hoopston, and Rochelle, IL, Indianapolis and Tipton, IN, Hart and Scottville, MI, Norwalk and Paulding, OH, Appleton, Cumberland, Frederic, and Plymount, WI, and, Newport and Tellico Plains, TN, on the one hand, and, on the other, those points in the US in and east of ND, SD, NE, KS, OR, and TX, restricted to transportation of traffic originating at or destined to the facilities of Stokely-Van Camp, Inc. (Hearing site: Atlanta, GA.)

MC 125335 (Sub-95F), filed December 26, 1979. Applicant: GOODWAY TRANSPORT, INC., P.O. Box 2283, York, PA 17405. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. Transporting (1) *paper, paper forms, and paper products, and (2) such commodities* as are used in the manufacture and distribution of commodities in (1) between points in Rutherford County, TN, on the one hand, and on the other, points in AL, FL, GA, IL, IN, KS, LA, ME, MI, MN, MO, NC, OH, PA, TX, and WI. (Hearing site: Dayton, OH, or Harrisburg, PA.)

MC 128555 (Sub-42F), filed December 21, 1979. Applicant: MEAT DISPATCH, INC., P.O. Box 1058, Palmetto, FL 33561. Representative: Raymond P. Keigher, 1400 Gerard St., Rockville, MD 20850. *Contract carrier,* transporting *canned goods,* from the facilities of Woldert Canning, Inc., at or near Lindale, TX, to points in the US (except points in AK, HI, ID, ME, MT, ND, NH, NV, OR, SD, UT, VT, WA, and WV), under continuing contract(s) with Woldert Canning, Inc., of Tyler, TX. (Hearing site: Tampa, FL.)

MC 128555 (Sub-43F), filed December 26, 1979. Applicant: MEAT DISPATCH, INC., P.O. Box 1058, Palmetto, FL 33561. Representative: Robert D. Gunderman, 710 Statler Building, Buffalo, NY 14202. *Contract carrier,* transporting *foodstuffs,* (except in bulk in tank vehicles) and *materials, supplies and equipment* used in the manufacture and distribution of foodstuffs, between points in the US (except AK and HI), under continuing contract(s) with Ragu' Foods Inc., of Greenwich, CT. (Hearing site: Miami, FL, or Washington, DC.)

MC 129455 (Sub-40F), filed December 21, 1979. Applicant: GARRETTA TRUCKING, INC., S 160 Route 17, Paramus, NJ 07652. Representative: Joseph Garetta (same address as applicant). *Contract carrier,* transporting (1) *drugs and toilet preparations* (except in bulk), from Decatur, IL, to points in the U.S. (except AK and HI) and (2) *materials, equipment and supplies* used in the manufacture and distribution of commodities in (1), in the reverse direction, under continuing contract(s) with Carter Wallace, Inc., of Cranbury, NJ. (Hearing site: New York, NY, or Washington, DC.)

MC 133095 (Sub-287F), filed December 21, 1979. Applicant: TEXAS-CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: Kim G. Meyer, P.O. Box 56387, Atlanta, GA 30343. Transporting *cleaning, buffing and polishing compounds, and toiletries* (except commodities in bulk), from the facilities of American Cynamid Company, at or near Jackson, MS, to points in IA, IL, IN, MI, MO, OH, and WI. (Hearing site: New York, NY, or Dallas, TX.)

MC 133565 (Sub-17F), filed December 26, 1979. Applicant: TRUE TRANSPORT, INC., 15 Stockton St., Newark, NJ 07101. Representative: Charles J. Williams, 1815 Front St., Scotch Plains, NJ 07076. Transporting (1) *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), in vehicles equipped with mechanical refrigeration, restricted to traffic having a prior or subsequent movement by water, and (2) *empty containers, trailers, and trailer chassis,* between New York, NY, Philadelphia, PA, and Baltimore, MD, and Norfolk, VA, on the one hand, and, on the other, points in CO, IL, IN, IA, KS, KY, MI, MN, MO, NE, ND, OH, SD, WI, and points in that part of Pennsylvania—New York State line at or near Lawrenceville, PA, and extending along U.S. Hwy 15 to junction U.S. Hwy 11, then along U.S. Hwy 11 to the Pennsylvania–Maryland State line. (Hearing site: New York, NY.)

MC 133565 (Sub-18F), filed December 27, 1979. Applicant: TRUE TRANSPORT, INC., 15 Stockton St., Newark, NJ 07101. Representative: Charles J. Williams, 1815 Front St., Scotch Plains, NJ 07076. Transporting (1) *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), in containers or in trailers, having a prior or subsequent movement by water, and (2) *empty containers, trailers, and trailer chassis,* between New York, NY, Philadelphia, PA, and Baltimore, MD, on the one hand, and, on the other, points in that part of Pennsylvania on and west of a line beginning at the Pennsylvania—New York State line at or near Lawrenceville, PA, and extending along U.S. Hwy 15 to junction U.S. Hwy 11, at or near Camp Hill, PA, then along U.S. Hwy 11 to the Pennsylvania–Maryland State line. (Hearing site: New York, NY.)

MC 133735 (Sub-12F), filed December 26, 1979. Applicant: AUDUBON-BROOKHISER TRANSPORT, INC., Wever, IA 52658. Representative: Richard D. Howe, 600 Hubbell Bldg., Des Moines, IA 50309. Transporting *liquid fertilizer,* in bulk, in tank vehicles, from the facilities of FirstMiss Inc., at or near Fort Madison, IA, to points in IL, IN, KS, KY, MI, MN, MO, NE, ND, OH, SD, and WI. (Hearing site: Des Moines, IA, or Kansas City, MO.)

MC 133965 (Sub-16F), filed December 27, 1979. Applicant: CALZONA TRANSPORTATION, INC., P.O. Box 6558, Phoenix, AZ 85005. Representative: William J. Lippman, Suite 330, Steele Park, 50 South Steele St., Denver, CO 80209. Transporting *tallow,* in bulk, in tank vehicles, from the facilities of Iowa Beef Processors, Inc., at or near Holcomb, KS, to points in TX, CO, AZ, NM, CA, NV, UT, and WY. (Hearing site: Omaha, NE, or Sioux City, IA.)

MC 134134 (Sub-55F), filed December 21, 1979. Applicant: MAINLINER MOTOR EXPRESS, INC., 4202 Dahlman Ave., Omaha, NE 68107. Representative: James F. Crosby, I–80 and Hwy 50, P.O. Box 37205, Omaha, NE 68137. Transporting *confectionary and confectionary products,* from the facilities of Just Born, Inc., at or near Bethlehem, PA, to points in CO, NE, KS, MN, IA, MO, WI, IL, MI, IN, OH, and TN. (Hearing site: Washington, DC, Philadelphia, PA.)

MC 135325 (Sub-8F), filed December 26, 1979. Applicant: WEMCO, INC., 3969 Wyoming Ave., Dearborn, MI 48126. Representative: James R. Striverson, 1396 West Fifth Ave., Columbus, OH 43212. Transporting *cement and mortar,* from points in Charlevoix and Emmet Counties, MI, to points in IL, IN, OH, and WI. (Hearing site: Chicago, IL, or Washington, DC.)

MC 135524 (Sub-94F), filed December 26, 1979. Applicant: G. F. TRUCKING CO., a corporation, P.O. Box 229, 1028 West Rayen Ave., Youngstown, OH 44501. Representative: George Fedorisin, 914 Salts Springs Road, Youngstown, OH 44509. Transporting *lumber, lumber mill products, forest products, wood products and sawmill products,* from points in Calvert, Charles, and St. Marys, Counties, MD, and Westmoreland, VA, to points in the US (except AK and HI). (Hearing site: Columbus, OH, or Richmond, VA.)

MC 135524 (Sub-101F), filed December 26, 1979. Applicant: G. F. TRUCKING CO., a corporation, P.O. Box 229, 1028 West Rayen Ave., Youngstown, OH 4501. Representative: George Fedorisin, 914 Salts Springs Road, Youngstown, OH 44509. Transporting *iron and steel articles* (1), from the facilities of Republic Steel Corporation, at Chicago, IL, and Gary, IN, to points in MI, and OH, and (2) from the facilities of Republic Steel Corporation, at Canton, Cleveland, Elyria, Massillon, Niles, Warren, and Youngstown, OH, to points in IL, IN, and MI. (Hearing site: Columbus, or Cleveland, OH.)

MC 139495 (Sub-515F), filed December 20, 1979. Applicant: NATIONAL CARRIERS, INC., 1501 East 8th St., P.O. Box 1358, Liberal KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwich Lane, Silver Spring MD 20910. 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, from the facilities of Farmlands Foods, Inc., at (a) Carroll, Denison, Iowa Falls, Sioux City, Des Moines, and Ft. Dodge, IA, and (b) Crete, Lincoln, and Omaha, NE, to points in the US (except AK and HI). (Hearing site: Washington, DC.)

MC 139495 (Sub-516F), filed December 26, 1979. Applicant: NATIONAL CARRIERS, INC., 1501 East 8th St., P.O. Box 1358, Liberal KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwich Lane, Silver Spring MD 20910. Transporting *foodstuffs,* from Fresno and Kingsburg, CA, to points in the US (except AK, and HI). (Hearing site: Washington, DC.)

MC 139495 (Sub-517F), filed December 26, 1979. Applicant: NATIONAL CARRIERS, INC., 1501 East 8th St., P.O. Box 1358, Liberal KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwich Lane, Silver Spring MD 20910. Transporting *hunting ammunition, and equipment,* from Oroville, CA, and Lewiston, ID, to points in the US (except AK, and HI). (Hearing site: Washington, DC.)

MC 139495 (Sub-518F), filed December 26, 1979. Applicant: NATIONAL CARRIERS, INC., 1501 East 8th St., P.O. Box 1358, Liberal KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwich Lane, Silver Spring MD 20910. Transporting *fungicides, insecticides, and agricultural chemicals* (except commodities in bulk, in tank vehicles), between points in the US (except AK, and HI), restricted to transportation of traffic originating at or destined to the facilities of Gustafson, Inc. (Hearing site: Washington, DC.)

MC 14002 (Sub-172F), filed December 26, 1979. Applicant: J. B. MONTGOMERY, INC., 5565 East 52nd Ave., Commerce City, CO 80022. Representative: Don L. Bryce (same address as applicant). Transporting *adhesives* (except in bulk), in vehicles equipped with mechanical refrigeration, from Columbus, OH, to Anaheim and Hayward, CA Atlanta, GA, Brighton, MA, Chicago, IL, Denver, CO, Detroit, MI, Ft. Smith, AR, Ft. Worth, TX, Kansas City, KS, Memphis, TN, North Bergen, NJ, Portland, OH, St. Louis, MO, Salt Lake City, UT, and Seattle, WA. (Hearing site: Denver, CO, or Columbus, OH.)

MC 140024 (Sub-173F), filed December 26, 1979. Applicant: J. B. MONTGOMERY, INC., 5565 East 52nd Ave., Commerce City, CO 80022. Representative: Don L. Bryce (same address as applicant). Transporting *lag screw bolts* from Slovay, NY, to points in McKinley County, NM. (Hearing site: Denver, CO or Syracuse, NY.)

MC 140665 (Sub-81F), filed December 27, 1979. Applicant: PRIME, INC., Route 1, Box 115–B, Urbana, MO 65767. Representative: Clayton Geer, P.O. Box 786, Ravenna, OH 44266. Transporting *general commodities,* (except articles of unusual value, Classes A and B explosives, household goods as defined by the Commission, articles requiring special equipment, and commodities in bulk), between points in the US (except AK, and HI), restricted to the transportation of traffic originating at or destined to the facilities of the B. F. Goodrich Company. (Hearing site: Cleveland, OH or Washington, DC.)

MC 142804 (Sub-330F), filed December 20, 1979. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *television parts and accessories,* from Forrest City, AR, to Little Ferry, NJ. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-331F), filed December 20, 1979. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *vehicle parts, accessories, and supplies,* from (1) Culver City, CA, to those points in the US in and west of ND, SD, NE, KS, OK, and TX (except AK and HI), and (2) from points in the US (except AK and HI), to Culver City, CA. (Hearing site: Los Angeles, CA.)

MC 143775 (Sub-135F), filed December 27, 1979. Applicant: PAUL YATES, INC., 6601 West Orangewood, Glendale, AZ 85301. Representative: Michael R. Burke (same address as applicant). Transporting *canned and preserved foodstuffs,* from Wenatchee, WA, to the facilities of Heinz USA, at or near Grand Prairie, TX, Greenville, SC, Harrison, NJ, Iowa City, IA, Jacksonville, FL, Mechanicsburg, PA, Pittsburgh, PA, and Toledo, OH, restricted to transportation of traffic originating at the named origin and destined to the named facilities. (Hearing site: Pittsburgh, PA or Washington, DC.)

Note.—Dual operations may be involved.

MC 146115 (Sub-2F), filed December 27, 1979. Applicant: SPECIAL SERVICES DELIVERY, INC., P.O. Box 243, Towanda, PA 18848. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Rd., NE., Atlanta, GA 30326. *Contract carrier* transporting *commodities* dealt in or used by a manufacturer of cosmetics, between Newark, DE, on the one hand, and, on the other, points in Berks, Bradford, Bucks, Carbon, Chester, Columbia, Daulphin, Delaware, Lackawanna, Lehigh, Lucerne, Lycoming, Monroe, Montgomery,

Northampton, Northumberland, Philadelphia, Pike, Schuylkill, Snyder, Sullivan, Susquehanna, Union, Wayne, Wyoming, and York Counties, PA, and points in NJ, under continuing contract(s) with Avon Products, Inc., of Newark, DE. (Hearing site: Washington, DC.)

MC 147415 (Sub-4F), filed December 20, 1979. Applicant: SKY CORPORATION, P.O. Box 838, Bismarck, ND 58501. Representative: Charles E. Johnson, 3rd and Rosser Ave., Gate City Savings & Loan Building, P.O. Box 1982, Bismarck, ND 58501. Transporting *sugar*, in bags, from the facilities of American Crystal Sugar Company, at or near Moorhead, Crookston, and East Grand Forks, MN, to points in ND, MN, IL, and WI. (Hearing site: Fargo, ND, or Minneapolis, MN.)

MC 147504 (Sub-4F), filed December 27, 1979. Applicant: RSSI TRUCK LINE, INC., 2909 North Emporia, Wichita, KS 67219. Representative: William B. Barker, 641 Harrison St., Topeka, KS 66603. *Contract carrier*, transporting (1) *asphalt and roofing materials*, from the facilities of Roofers Service Supply, Inc., at Wichita, KS, to points in AR, CO, IL, IN, IA, KY, MN, MO, NE, NM, OK, SD, TN, TX, and WY and (2) *materials and supplies* used in the manufacture and distribution of commodities in (1) in the reverse direction, under continuing contract(s) with Roofers Service Supply, Inc., of Wichita, KS. (Hearing site: Wichita, KS, or Kansas City, MO.)

MC 147625 (Sub-2F), filed September 17, 1979, previously noticed in the **Federal Register** issue of March 25, 1980 as MC 147625. Applicant: AAA AIR ENTERPRISES, INC., P.O. Box 19130, Eppley Airfield, Omaha, NE 68119. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Rd., Omaha, NE 68106.

Note.—This partial republication corrects the docket and sub number, which is MC 147625 (Sub-2F).

MC 148354 (Sub-3F), filed December 26, 1979. Applicant: TWIN CITY DISTRIBUTING, INC., 611 8th St., P.O. Box 637, Greeley, CO 80631. Representative: Wm. Fred Cantonwine, 6785 E. 50th Ave., Suite 201, Commerce City, CO 80022. *Contract carrier*, transporting *meats and meat byproducts* used as or in manufacture of animal feed and feed ingredients (except hides and commodities in bulk, in tank vehicles), from Greely and Denver, CO, to Livingston, Los Angeles and San Diego, CA, Kankakee, IL, Algona, Ft. Dodge and Des Moines, IA, Topeka, KS, Independence, Kansas City and St. Joseph, MO, Crete, Fremont, Hastings, Lincoln, Omaha, and York NE, Forest Grove and Portland, OR, and Jefferson, WI, under continuing contract(s) with J. R. Nylen, Ltd., Valley Feed & Provision Company, of Greeley, CO. (Hearing site: Denver, CO.)

MC 148414 (Sub-2F), filed December 27, 1979. Applicant: UNIDYNE CORPORATION, 981 Scott St., Norfolk, VA 23502. Representative: Dale E. Forwood (same address as applicant). *Contract carrier*, transporting (1) *aluminum and steel fabricated products, fixtures, and accessories*, such as are used in department stores, (2) *iron, steel and plastic articles, athletics goods, sporting and gymnastic equipment*, in tubular form and boxed; (3) *wood display products, fixtures, and accessories*, such as are used in department stores, from the facilities of Advance Metal Products Company, at or near Los Angeles, CA, to New Orleans, LA; St. Paul, MN; Chicago, IL, and points in CT, MO, OH, TX, WV, FL, NC, SC, VA, MD, PA, NY, NJ, DE, and DC, under continuing contract(s) with Advance Metal Products Company, of Compton, CA. (Hearing site: Washington, DC, or Los Angeles, CA.)

MC 148785 (Sub-2F), filed December 21, 1979. Applicant: SUDDEN MOVING & STORAGE, INC., d.b.a. SUDDEN TRUCKING COMPANY, 5154 Kennedy Ave., Cincinnati, OH 45213. Representative: Kevin R. Reichley, 50 West Broad St., Columbus, OH 43215. Transporting *such commodities* as are dealt in or used by manufacturers of *auto parts*, between Columbus, OH, on the one hand, and, on the other, points in MO, GA, CA, IL, IN, and MI. (Hearing site: Columbus or Cincinnati, OH.)

MC 149025F, filed December 21, 1979. Applicant: VAN NORTWICK BROS. INC., 129 State Highway 36, East Keansburg, NJ 07734. Representative: L. C. Major, Jr., Suite 400 Overlook Bldg., 6121 Lincolnia Road, Alexandria, VA 22312. Transporting *passengers and their baggage*, in the same vehicle with passengers in round-trip charter operations, beginning and ending at points in Ocean County, NJ, and extending to points in the U.S. (excluding AK and HI). (Hearing site: Toms River or Lakewood, NJ.)

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Decided: March 3, 1980.

By the Commission, Review Board Number 2, Members Eaton, Liverman and Jensen. Member Jensen not participating.

MC 8310 (Sub-12F), filed December 20, 1979. Applicant: JEFF'S TRUCKING, INC., 408½ Main St., Waupun, WI 53963. Representative: Allan B. Torhost, 217 E. Jefferson St., Burlington, WI 53105. Transporting *foodstuffs* (except commodities in bulk), and *equipment, materials and supplies* used in the manufacture and sale of foodstuffs, between the facilities used by Green Giant Co., in WI and IL, on the one hand, and, on the other, points in IL and WI. (Hearing site: Minneapolis, MN or Chicago, IL.)

MC 11220 (Sub-188F), filed December 14, 1979. Applicant: GORDONS TRANSPORTS, INC., 185 West McLemore Ave., Memphis, TN 38101. Representative: Harold D. Miller, Jr., 17th Floor, Deposit Guaranty Plaza, P.O. Box 22567, Jackson, MS 39205. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, 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), (1) between Chicago, IL, and Green Bay, WI, over U.S. Hwy 41, (2) between Chicago, IL, and Two Rivers, WI, from Chicago, IL, over U.S. Hwy 14 to Madison, WI, then over U.S. Hwy 151 to Manitowoc, WI, then over WI Hwy 42 to Two Rivers, and return over the same route, (3) between Beloit and Green Bay, WI, from Beloit over WI Hwy 15 to Milwaukee, WI, then over U.S. Hwy 141 to Green Bay, and return over the same route, (4) between Janesville and Oshkosh, WI, over WI Hwy 26, (5) between Madison and Milwaukee, WI, over U.S. Hwy 18, (6) between Bloomington, IL, and Madison, WI, over U.S. Hwy 51, serving all intermediate points in (1) through (6) above, and serving as off-route points, points in Cook, Lake, McHenry, Boone, Winnebago, Ogle, DeKalb, Lee, Bureau, Putnam, LaSalle, Grundy, Kendall, Kane, Dupage, and Will Counties, IL, and Kenosha, Racine, Walworth, Rock, Dane, Jefferson, Waukesha, Milwaukee, Washington, Dodge, Ozaukee, Sheboygan, Fond du Lac, Manitowoc, Calument, Winnebago, Outagamie, and Brown Counties, WI, (7) between Hammond, IN, and Lincoln, NE, over U.S. Hwy 6, (8) between Chicago Heights, IL, and Cedar Rapids, IA, over U.S. Hwy 30, (9) between Chicago IL, and Des Moines, IA, from Chicago over U.S. Hwy 34, to Ottumwa, IA, and then over U.S. Hwy 63 to Oskaloosa, IA, then over IA Hwy 163 to Des Moines, and return over the same route, (10) between Chicago IL, and Waterloo, IA, over U.S. Hwy 20, (11) between Quincy, IL, and Dubuque, IA, from Quincy over U.S. Hwy 24 to junction U.S. Hwy 61, then over U.S. Hwy 61 to Dubuque, and return over the same route, (12) between

Davenport and Dubuque, IA, from Davenport over U.S. Hwy 67 to junction U.S. Hwy 52, then over U.S. Hwy 52 to Dubuque, and return over the same route, serving all intermediate points in (7) through (12) above, and serving as off-route points, points in McHenry, Boone, Winnebago, Stephenson, Jo Daviess, Carroll, Ogle, DeKalb, Kane, DuPage, Cook, Will, Grundy, Kendall, LaSalle, Bureau, Putnam, Lee, Whiteside, and Rock Island Counties, IL, Lee, DeMoines, Louisa, Muscatine, Scott, Clinton, Jackson, Dubuque, Black Hawk, Linn, Johnson, and Polk Counties, IA, Lancaster, Cass, Sarpy, Douglas, Saunders, Dodge, and Washington Counties, NE, and Oelwein, Amana, Knoxville and Marshalltown, IA, (13) between Albert Lea and Minneapolis, MN, from Albert Lea over MN Hwy 13 to junction Interstate Hwy 35W, then over Interstate Hwy 35W to Minneapolis, and return over the same route, (14) between Albert Lea and Owatonna, MN, from Albert Lea over U.S. Hwy 65 to junction Interstate Hwy 35, then over Interstate Hwy 35 to junction Interstate Hwy 90, then over Interstate Hwy 90 to Austin, MN, then over U.S. Hwy 218 to Owatonna, and return over the same route, (15) between Faribault and St. Paul, MN, over MN Hwy 3 (16) between St. Cloud and New Ulm, MN, from St. Cloud over U.S. Hwy 52 to Rochester, MN, then over U.S. Hwy 14 to New Ulm, and return over the same route, (17) between Mankato and Minneapolis, MN, over U.S. Hwy 169, serving all intermediate points in (13) through (17) above, (18) between St. Paul and Duluth, MN, from St. Paul over Interstate Hwy 35E, to junction Interstate Hwy 35, then over Interstate Hwy 35 to Duluth, and return over the same route, serving no intermediate points, and serving the off-route points of Cloquet, MN, and Superior, WI, (19) between Minneapolis, MN, and Kansas City, MO, from Minneapolis over Interstate Hwy 35W, to junction Interstate Hwy 35, then over Interstate Hwy 35 to Kansas City, and return over the same route, serving all intermediate points in MN and Des Moines, IA, (20) between Rochester, MN, and Waterloo, IA, over U.S. Hwy 63, serving no intermediate points, (21) between Kansas City, MO, and Council Bluffs, IA, over Interstate Hwy 29, serving the intermediate point of St. Joseph, MO, and the off-route points of Glenwood, Red Oak, and Shenandoah, IA, and serving junction Interstate Hwy 29 and IA Hwy 2 for the purpose of joinder only, (22) between Kansas City, MO, and Peoria, IL, over U.S. Hwy 24, serving the intermediate points of Taylor, MO, and Quincy, IL, (23) between Lincoln, NE and junction Interstate Hwy 29 and IA Hwy 2 from Lincoln, over NE Hwy 2 to the NE–IA state line, then over IA Hwy 2 to junction Interstate Hwy 29 and return over the same route, serving no intermediate points, and serving junction Interstate Hwy 29 and IA Hwy 2 for purposes of joinder only, and (24) between Hampton, MN and junction MN Hwy 50 and Interstate Hwy 35, over MN Hwy 50, serving all intermediate points. (Hearing site: Memphis, TN, or Atlanta, GA.)

Note.—Applicant proposes to join the requested routes with existing regular routes at common joinder points in MN, WI, IL, IN, and MO.

MC 35320 (Sub-540F), filed February 7, 1980. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). Over regular routes 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), serving the facilities of Young & Vann Supply, Co., Inc. at or near Birmingham, AL, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Birmingham, AL, or Washington, DC.)

Note.—Applicant intends to tack to its existing authority.

MC 35320 (Sub-541F), filed February 7, 1980. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). Over regular routes, 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), serving the facilities of Birkelbach Machine and Pump Inc., at or near Little field, TX, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Lubbock, TX or Dallas, TX.)

Note.—Applicant intends to tack to its existing authority.

MC 35320 (Sub-542F), filed February 7, 1980. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). Over regular routes, 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), serving the facilities of the Ludlow Corporation at or near Indianola, MS, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Memphis, TN or Washington, DC.)

Note.—Applicant intends to tack to its existing authority.

MC 35320 (Sub-543F), filed February 7, 1980. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). Over regular routes, 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), serving the facilities of Duval Corporation at or near Rustler Springs, TX, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: El Paso, TX or Dallas, TX.)

Note.—Applicant intends to tack to its existing authority.

MC 35320 (Sub-544F), filed February 7, 1980. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). Over regular routes, 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), serving the facilities of Montgomery Rubber and Gasket Co., at or near Montgomery, AL, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Montgomery, AL or Atlanta, GA.)

Note.—Applicant intends to tack to its existing authority.

MC 35320 Sub-545F), filed February 7, 1980. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). Over regular routes, 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), serving the facilities of Denson Oil and Tire Co., at or near Gadsden, AL, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Chattanooga, TN or Washington, DC.)

Note.—Applicant intends to tack to its existing authority.

MC 35320 (Sub-546F), filed February 7, 1980. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). Over regular routes, 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), serving the facilities of The Noland Co., at or near Gadsden, AL, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Chattanooga, TN or Washington, DC.)

Note.—Applicant intends to tack to its existing authority.

MC 35320 (Sub-547F), filed February 7, 1980. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). Over regular routes, 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), serving the facilities of Modern Tables, Inc., at or near Gadsden, AL, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Chattanooga, TN or Washington, DC.)

Note.—Applicant intends to tack to its existing authority.

MC 42011 (Sub-62F), filed January 25, 1980. Applicant: D. Q. WISE & CO., INC., P.O. Drawer L, Tulsa, OK 74112. Representative: J. G. Dail, Jr., P.O. Box LL, McLean, VA 22101. Transporting (1) *recycled ceiling fiber and additives* (except commodities in bulk), from the facilities of Montello, Inc., at Sand Springs, OK, to points in the United States (except AK and HI), and (2) *materials, equipment, and supplies* used in the manufacture of the commodities named in (1), above (except commodities in bulk), in the reverse direction. (Hearing site: Tulsa, OK.)

MC 47171 (Sub-160F), filed February 5, 1980. Applicant: COOPER MOTOR LINES, INC., P.O. Box 2820 Greenville, SC 29602. Representative: Harris G. Andrews (same address as applicant). Transporting *chemicals* (except in bulk), from Bridgeville and Neville Island, PA, to Gastonia, NC. (Hearing site: Charlotte, NC.)

MC 52921 (Sub-37F), filed January 31, 1980. Applicant: RED BALL, INC., P.O. Box 520, Sapulpa, OK 74066. Representative: Wilburn L. Williamson, Suite 615-East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. Transporting *alcoholic liquors,* and *materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors (except commodities in bulk, in tank vehicles), (1) between Ft. Smith, AR, on the one hand, and, on the other, points in the United States (except AK and HI), and (2) between New Orleans, LA, on the one hand, and, on the other, points in AL, AZ, AR, CA, FL, GA, LA, MS, NM, and TX, restricted in (1) and (2) to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc. (Hearing site: New Orleans, LA.)

MC 53841 (Sub-40F), filed February 8, 1980. Applicant: W. H. CHRISTIE & SONS, INC., Box 517, East State Street, Knox, PA 16232. Representative: John A. Pillar, Esq., 1500 Bank Tower, 307 Fourth Avenue, Pittsburgh, PA 15222. Transporting (1) *petroleum and petroleum products, vehicle body sealers,* and *sound deadener compounds* (except commodities in bulk), and (2) *containers,* in mixed shipments with the commodities in (1) above, from the facilities of Pennzoil Company at Oil City and Rouseville, PA, and the facilities of Wolf's Head Oil Refining Company at Reno, PA, to points in KY, NJ, OH and WV. (Hearing site: Pittsburgh, PA or Washington, DC.)

MC 53841 (Sub-41F), filed February 8, 1980. Applicant: W. H. CHRISTIE & SONS, INC., Box 517, East State Street, Knox, PA 16232. Representative: John A. Pillar, Esq., 1500 Bank Tower, 307 Fourth Avenue, Pittsburgh, PA 15222. 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), between the facilities of General Warehousing of Dubois, Inc., at Dubois, PA, on the one hand, and, on the other, those points in the United States east of a line beginning at the mouth of the Mississippi River, and extending along the Mississippi River to its junction with the western boundary of Itasca County, MN, then northward along the western boundaries of Itasca and Koochiching Counties, MN, to the international boundary line between the United States and Canada. (Hearing site: Pittsburgh, PA or Washington, DC.)

MC 61440 (Sub-180F), filed December 10, 1979. Applicant: LEE WAY MOTOR FREIGHT, INC., 3401 N.W. 63rd Street, Oklahoma City, OK 73116. Representative: Richard H. Champlin, P.O. Box 12750, Oklahoma City, OK 73157. Over regular routes, 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): (1) Between Chicago, IL, and Des Moines, IA, as an alternate route for operating convenience only, over Interstate Hwy 80, serving no intermediate points and serving Des Moines as a point of joinder only; (2) Between Des Moines, IA, and Los Angeles, CA, as an alternate route for operating convenience only: From Des Moines over Interstate Hwy 80 to junction 76, then over interstate Hwy 76 to Denver CO then over Interstate Hwy 70 to junction Interstate Hwy 15, then over Interstate Hwy 15 to junction Interstate Hwy 10, then over Interstate Hwy 10 to Los Angeles, Ca, and return over the same routes, serving no intermediate points. (Hearing site: Oklahoma City, OK, or Washington, D.C.)

Note.—The alternate route authority sought here is in conjunction with carrier's presently authorized regular route operations between Chicago, IL, and Des Moines, IA, and Los Angeles, CA. Lee Way presently operates over regular routes from Chicago, IL, via St. Louis, MO, Oklahoma City, OK, San Antonio, and El Paso, TX, Phoenix, AZ and Los Angeles, CA and from Des Moines, IA, via Kansas City, MO, Oklahoma City, OK, San Antonio and El Paso, TX, Phoenix, AZ and Los Angeles, CA.

MC 67450 (Sub-102F), filed February 7, 1980. Applicant: PETERLIN CARTAGE CO., a corporation, 9651 S. Ewing Avenue, Chicago, IL 60617. Representative: Joseph Winter, 29 South LaSalle Street, Chicago, IL 60603. Transporting *corn products and soybean products* (except in bulk), from Muscatine, IA, to points in the United States (except AK and HI). (Hearing site: Chicago, IL.)

MC 93840 (Sub-55F), filed December 10, 1979. Applicant: GLESS BROTHERS, INC., Box 219, Blue Grass, IA 52726. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. Transporting *salt* and *salt products,* (1) from the facilities of Cargill, Inc., at points in Scott County, IA to points in MO and those in WI north and east of a line beginning at Milwaukee, WI, and extending along Interstate Hwy 94 to junction U.S. Hwy 16, then along U.S. Hwy 16 to junction U.S. Hwy 51, to the MI–WI State line, and (2) from the facilities of Cargill, Inc., at Pekin, IL to points in IA. (Hearing site: St. Paul, MN.)

MC 95540 (Sub-1154F), filed December 10, 1979. Applicant: WATKINS MOTOR LINES, INC., 1144 West Griffin Road, P.O. Box 1636, Lakeland, FL 33802. Representative: Benjy W. Fincher (same

address as applicant). Transporting (1) *lawn and garden equipment, motor bikes, and go-carts,* (2) *parts and accessories* for the commodities in (1) and (2), and (3) *equipment, materials and supplies* used in the manufacture of commodities in (1) and (2) above, between points in IA, and the facilities used by Bird Engineering Co., in NE, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Chicago, IL or Washington, DC.)

MC 111201 (Sub-50F), filed January 28, 1980. Applicant: J. N. ZELLNER & SON TRANSFER COMPANY, a corporation, P.O. Box 91247, East Point, GA 30364. Representative: Archie B. Culbreth, 2200 Century Parkway, Suite 202, Atlanta, GA 30345. Transporting *metal containers,* from Salisbury, NC, to the facilities of Shasta Beverage Co., at or near Birmingham, AL. (Hearing site: Atlanta, GA.)

MC 112801 (Sub-251F), filed December 10, 1979. Applicant: TRANSPORT SERVICE CO., a corporation, 15 Salt Creek Lane, Hinsdale, IL 60521. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. Transporting *chemicals,* in bulk, in tank vehicles, from the facilities of McIntyre Chemical Company, at or near Chicago, IL, to points in CA, GA, MA, TX, NY, NJ, and PA. (Hearing site: Chicago, IL.)

MC 112801 (Sub-252F), filed January 31, 1980. Applicant: TRANSPORT SERVICE CO., a corporation, 15 Salt Creek Lane, Hinsdale, IL 60521. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. Transporting *liquid chemicals,* in bulk, in tank vehicles, from the facilities of Inland Specialty Chemical Corp., at or near New Haven, IN, to those points in the United States in and east of MN, IA, MO, AR, and LA. (Hearing site: Fort Wayne, IN.

MC 112801 (Sub-253F), filed February 6, 1980. Applicant: TRANSPORT SERVICE CO., a corporation, 15 Salt Creek Lane, Hinsdale, IL 60521. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street NW., Washington, DC 20001. Transporting (1) *polyvinyl adhesives and dry animal glue,* in tank vehicles, from Oak Creek, WI, to points in IL, MI MN, WI, and IN; and (2)(a) *metal cutting fluids and soaps,* and (b) *materials and supplies* used in the manufacture of the commodities in (2)(a), in bulk, in tank vehicles, between St. Charles, IL, on the one hand, and, on the other, points in CA, CO, TX, OK, LA, NY, NJ, VA, NC, GA, PA, OH, KY, MI, MO, WI, and MN. (Hearing site: Chicago, IL.)

MC 114211 (Sub-445F), filed January 8, 1980. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, IA 50704. Representative: Kurt E. Vragel, Jr. (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers, distributors, and dealers of agricultural and industrial equipment, between Allentown, WI, on the one hand, and, on the other, points in the United States (including Alaska, but excluding Hawaii), restricted to traffic originating at or destined to the facilities of Kasten Manufacturing Company. (Hearing site: Milwaukee or Madison, WI.)

MC 115331 (Sub-536F), filed February 4, 1980. Applicant: TRUCK TRANSPORT INC., 29 Clayton Hills Lane, St. Louis, MO 63131. Representative: J. R. Ferris, 11040 Manchester Road, St. Louis, MO 63122. Transporting *alcohol, and neutral and distilled spirits,* from Jacksonville, FL, Columbus, OH, Merrimack, NH, and Williamsburg, VA, to those points in the United States in and east of ND, SD, NE, KS, OK, and TX and those in CA, CO, and WA. (Hearing site: St. Louis, MO.)

MC 115601 (Sub-27F), filed December 26, 1980. Applicant: BROOK ARMORED CAR SERVICE, INC., 13 East 35th Street, Wilmington, DE 19802. Representative: Charles Ephraim, Suite 600, 1250 Connecticut Avenue, NW., Washington, DC 20036. *Contract carrier,* transporting *precious metals* and *precious metal solutions,* between Newark and Union, NJ, on the one hand, and, on the other, Huntsville, AL, under continuing contract(s) with Engelhard Industries Division of Engelhard Minerals and Chemicals Corporation, of Iselin, NJ. (Hearing site: Philadelphia, PA.)

Note.—Dual operations are involved.

MC 115841 (Sub-754F), filed February 11, 1980. 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 *foodstuffs* (except commodities in bulk), from points in GA to points in CA, IL, IN, KS, MI, NC, NJ, NY, OH, OK, OR, and SC. (Hearing site: Atlanta, GA or Washington, DC.)

MC 115931 (Sub-104F), filed December 10, 1979. Applicant: BEE LINE TRANSPORTATION, INC., P.O. Box 3987, Missoula, MT 59801. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, ND 58108. Transporting (1) *weed killing compounds, ice melting compounds,* and *dry fertilizer,* and (2) *containers,* for the commodities in (1) above, from Kenosha, WI, to points in MN, MT, ND, and SD. (Hearing site: Milwaukee, WI.)

MC 119741 (Sub-257F), filed February 8, 1980. Applicant: GREEN FIELD TRANSPORT CO., INC., 1515 Third Avenue, N.W., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson (same address as applicant). 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, in tank vehicles), from the facilities of DPM of Kansas, Inc., at or near Wichita, KS, to points in AL, AZ, AR, CA, CO, CT, DE, DC, FL, GA, ID, KS, LA, ME, MD, MA, MS, MT, NV, NH, NJ, NM, NC, OK, OR, RI, SC, TN, TX, UT, VT, VA, WA, WV, WY, and DC, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Wichita, KS.)

MC 124821 (Sub-83F), filed January 28, 1980. Applicant: GILCHRIST TRUCKING, INC., 105 North Keyser Avenue, Old Forge, PA 18518. Representative: John W. Frame, Box 626, 2207 Old Gettysburg Road, Camp Hill, PA 17011. Transporting: (1) *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), between points in Cortland, Chenango, Broome, Chemung, and Steuben Counties, NY, and Franklin, Columbia, Montour, Bradford, Lackawanna, Luzerne, Wayne, Lehigh, Northampton, Tioga, and Schuylkill Counties, PA, on the one hand, and, on the other, points in CA, OR, WA, CO, TX, MO, MN, IL, WI, MI, GA, FL, and OH, restricted to the transportation of traffic originating at or destined to the facilities used by Northeastern Pennsylvania Shippers Cooperative Association, Inc.; and (2) *printed matter,* and *materials, supplies,* and *equipment* used in the manufacture and distribution of printed matter (except commodities in bulk), between points in CT, IL, IN, KY, MD, MA, ME, MI, MN, MO, NJ, NY, OH, PA, RI, TN, VT and WI, restricted to the transportation of traffic originating at or destined to the facilities of Harper and Row Publishers, Incorporated. (Hearing site: Harrisburg, PA.)

MC 128371 (Sub-9F), filed February 14, 1980. Applicant: BELLEVUE AGGREGATE HAULERS, INC., 9410 Airport Highway, Holland, OH 43528.

Representative: Boyd B. Ferris, 50 West Broad Street, Columbus, OH 43215. Transporting *scrap metal,* in dump vehicles, (1) from Pittsburgh, PA, to Bryan, Montpelier, Cincinnati, Defiance, and Cleveland, OH, Aurora, IN, and Detroit, MI, (2) from Cleveland, OH, to Detroit, MI, and (3) from Cincinnati, OH, to Aurora, IN, and Detroit, MI. (Hearing site: Columbus or Cincinnati, OH.)

MC 129191 (Sub-14F), filed February 1, 1980. Applicant: RICHARD T. PLATTNER, d.b.a. JANS MOTOR SERVICE, 12600 South Laramie Avenue, Alsip, IL 60658. Representative: Albert A. Andrin, 180 North La Salle Street, Chicago, IL 60601. Transporting *iron and steel articles,* from the facilities of Jones & Laughlin Steel Corporation, at or near Chicago, IL, to points in IL, St. Louis, MO, and Davenport, IA. (Hearing site: Chicago, IL.)

MC 129631 (Sub-79F), filed February 11, 1980. Applicant: PACK TRANSPORT, INC., 3975 South 300 West, Salt Lake City, UT 84107. Representative: Truman A. Stockton, The 1650 Grant Street Building, Denver, CO 80203. Transporting *iron and steel* articles, between points in CO, ID, MT, OR, UT, NV, WA, and WY. (Hearing site: Portland, OR.)

MC 129951 (Sub-7F), filed February 8, 1980. Applicant: HARLEY I. KEETER, JR., 6379 Valmont Drive, Boulder, CO 80301. Representative: Harley I. Keeter, Jr. (same address as applicant). Transporting *ore* and *ore concentrates,* from points in Boulder, Teller, Gilpin, Clear Creek, and Jefferson Counties, CO, to East Helena, MT, Kellogg, ID, Bartlesville, OK, and points in Randall, Potter, Galveston, El Paso, and Harris Counties, TX, and Orleans Parish, LA. (Hearing site: Boulder, CO.)

MC 133591 (Sub-97F), filed January 25, 1980. Applicant: WAYNE DANIEL TRUCK, INC., P.O. Box 303, Mount Vernon, MO 65712. Representative: Harry Ross, 58 South Main Street Winchester, KY 40391. Transporting *alcoholic liquors,* and *materials, equipment,* and *supplies* used in the manufacture and distribution of alcoholic liquors (except commodities in bulk, in tank vehicles), between Fort Smith, AR, New Orleans, LA, Bardstown and Louisville, Ky, and Plainfield, IL on the one hand, and, on the other, points in MI, IN, TN, KY, MS, IL, LA, AR, MO, IA, MN, ND, SD, NE, KS, OK, TX, MT, WY, CO, NM, AZ UT, ID, WA, OR, NV, and CA. (Hearing site: Chicago, IL or St. Louis, MO.)

Note.—Dual operations may be involved.

MC 134501 (Sub-76F), filed January 28, 1980. Applicant: INCORPORATED CARRIERS, LTD., P.O. Box 3128, Irving, TX 75061. Representative: T. M. Brown, P.O. Box 1540, Edmond, OK 73034. Transporting (1) *new furniture,* from ponts in WI, to points in IN, on and south of U.S. Hwy 50, and those in IA, KS, MO, NE, NH, NY, OH, PA, VT, and WY; and (2) *custom architectural woodwork, fixtures,* and *equipment,* from points in WI to points in the United States (except AK and HI). (Hearing site: Milwaukee, WI or Dallas, TX.)

MC 134501 (Sub-77F), filed January 28, 1980. Applicant: INCORPORATED CARRIERS, LTD., P.O. Box 3128, Irving, TX 75061. Representative: T. M. Brown, P.O. Box 1540, Edmond, OK 73034. Transporting (1) *new furniture,* from points in AR (except Ft. Smith and Van Buren) to points in AL, AZ, CA, FL, IN, IA, KS, LA, MS, MO, NE, NM, OH, TN (except Shelby County), and WV; and (2) *fixtures,* from points in AR (except Ft. Smith and Van Buren) to points in the United States (except AK and HI), restricted in (1) and (2) above against transportation of commodities which because of their size or weight require the use of special equipment. (Hearing site: Little Rock, AR, or Dallas, TX.)

MC 134501 (Sub-78F), filed January 25, 1980. Applicant: INCORPORATED CARRIERS, LTD., P.O. Box 3128, Irving, TX 75061. Representative: T. M. Brown, P.O. Box 1540, Edmond, OK 73034. Transporting (1) *new furniture,* from Lowell, MA, to ponts in AL, CO, CT, DE, FL, GA, ID, IL, IN, IA, KS, KY, ME, MD, MI, MN, MO, MT, NE, NV, NH, NJ, NY, NC, ND, OH, PA, RI, SC, SD, TN (except Shelby County), UT, VT, VA, WA, WV, WI, WY, and DC and (2) *fixtures,* from Lowell, MA, to points in the United States (except AK and HI). (Hearing site: Boston, MA or Dallas, TX.)

MC 135070 (Sub-153F), filed February 4, 1980. Applicant: JAY LINES, INC., P.O. Box 30180, Amarillo, TX 79120. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. Transporting *petroleum products and lubricating oils,* (except commodities in bulk), and *such commodities* as are dealt in or used by retail fuel stations, and automobile service centers, between the facilities of Exxon Company, U.S.A., at or near (a) Bayonne and Bayway, NJ, (b) Baton Rouge, LA, (c) Baytown, TX, and (d) Pittsburgh, PA, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Houston or Dallas TX.)

Note.—Dual operations may be involved.

MC 135691 (Sub-42F), filed February 8, 1980. Applicant: DALLAS CARRIERS CORP., P.O. Box 402626 Dallas, TX 75240. Representative: J. Max Harding, P.O. Box 82028, Lincoln, NE 68501. *Contract carrier* transporting *materials, supplies and equipment* used in the manufacture and distribution of foodstuffs, (except commodities in bulk) from those points in the United States on and east of a line beginning at the mouth of the Mississippi River and extending along the Mississippi River to its junction with the western boundary of Itasca County, MN, then northward along the western boundaries of Itasca and Koochiching Counties, MN, to the United States-Canada boundary line, to the facilities used ty Tenneco West, Inc., at points in CA, under continuing contract(s) with Tenneco West, Inc., of Bakersfield, CA. (Hearing site: Los Angeles, CA.)

Note.—Dual operations maybe involved.

MC 135950 (Sub-7F), filed December 27, 1979. Applicant: KERN TRUCKING, INC., R.R. 1 Box 162, Bedford, IN 47421. Representative: Walter F. Jones, Jr., 601 Chamber of Commerce Bldg., 320 N. Meridian St., Indianapolis, IN 46204. *Contract carrier,* transporting *gypsum and gypsum rock; and materials* used in the manufacture of gypsum products, in bulk, between points in Martin County, IN, on the one hand, and, on the other, points in IL, IA, KY, MI, MO, OH, PA, TN, and WI, under continuing contract(s) with National Gypsum Company, Gold Bond Building Products, Div., of Charlotte, NC. (Hearing site: Indianapolis, IN, or Washington, DC.)

MC 138741 (Sub-106F), filed February 11, 1980. Applicant: AMERICAN CENTRAL TRANSPORT, INC., 2005 North Broadway, Joliet, IL 60435. Representative: Tom B. Kretsinger, 20 East Franklin, Liberty, MO 64068. Transporting (1) *gypsum, gypsum products, and building materials* (except commodities in bulk), and (2) *materials, equipment, and supplies* used in the manufacture, installation, and distribution of the commodities in (1) above (except commodities in bulk), between points in AL, AR, CO, DE, GA, IL, IN, IA, KS, KY, LA, MD, MI, MN, MS, MO, NE, NJ, NY, NC, ND, OH, OK, PA, SC, SD, TN, TX, VA, WV, WI, and DC, restricted to the transportation of traffic originating at or destined to the facilities of Georgia-Pacific Corporation, Gypsum Division. (Hearing site: Washington, DC.)

MC 141951 (Sub-1F), filed February 1, 1980. Applicant: MARY DICK AND HOLLIS A. DICK, d.b.a. H.O. DICK TRANSFER CO., P.O. Box 307, Bethany, IL 61914. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. Transporting *corn products* and *soybean products,* in bulk, in tank vehicles, from Decatur, IL, to points in

FL, GA, IN, IA, KY, MI, MO, OH, TN, and WI, restricted to the transportation of traffic originating at the facilities of A. E. Staley Manufacturing Company, at Decatur, IL. (Hearing site: Chicago, IL.)

Note.—Dual operations may be involved.

MC 144061 (Sub-13F), filed February 15, 1980. Applicant: SICOMAC CARRIERS, INC., 347 Sicomac Avenue, Wyckoff, NJ 07481. Representative: Jack L. Schiller, 345 Webster Avenue, Brooklyn, NY 11230. *Contract carrier,* transporting (1) *cleaning* and *polishing compounds, textile softeners, lubricants, hypoclorite solutions, deodorants, disinfectants, paints, plastic bags, filters,* and *cleaning* and *sanitizing equipment* from the facilities of Economics Laboratory, Inc., at points in NJ, IL, MN, TX, and CA to points in the United States (except AK and HI), and (2) *materials* used in the manufacture of the commodities in (1) above, in the reverse direction, (3) *materials* used in the manufacture of cleaning and polishing compounds, textile softeners, lubricants, hypoclorite solutions, deodorants, disinfectants and paints, between the facilities of Economics Laboratory, Inc., at or near (a) Avenel and Palisades Park, NJ, (b) Joliet, IL, (c) St. Paul, MN, (d) Garland, TX, and (e) San Jose and City of Industry, CA under continuing contract with Economics Laboratory, Inc., of St. Paul, MN. (Hearing site: Minneapolis, MN.)

MC 145011 (Sub-7F), filed September 18, 1979. Applicant: R. F. WESTBURY, 1617 Willis Road, Richmond, VA 23224. Representative: Carroll B. Jackson, 1810 Vincennes Road, Richmond, VA 23229. To oprate as a *contract carrier,* by motor vehicle, in interstate or foreign commerce, over irregular routes, transporting (1) *cleaning, scouring, and washing compounds, maintenance supplies,* and *such commodities* as are dealt in by grocery and food business houses (except commodities in bulk), and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, (except commodities in bulk), (a) between points in VA, NC, SC, GA, and TN, on the one hand, and, on the other, points in CA, OR, WA, ID, NV, UT, AZ, CO, NM, and OK, and (b) from Portsmouth, VA, to points in TX and IL, under continuing contract(s) in both (1) and (2) above with The Procter & Gamble Company, The Procter & Gamble Distributing Company, and The Procter & Gamble Manufacturing Company, of Cincinnati, OH. (Hearing site: Cincinnati, OH, or Washington, DC.)

MC 145441 (Sub-103F), filed February 11, 1980. Applicant: A.B.C. TRUCKING INC., P.O. Box 5130, North Little Rock, AR 72119. Representative: Ralph E. Bradbury (same address as applicant). Transporting *foodstuffs* (except in bulk), from Lake Wales, FL, to those points in the United States in and east of MI, IL, MO, KS, OK, and TX. (Hearing site: Little Rock, AR or Miami, FL.)

Note.—Dual operations may be involved.

MC 145651 (Sub-4F), filed February 4, 1980. Applicant: DUNCAN & SONS, INC., P.O. Box 775, Lewis, CO 81327. Representative: James F. Crosby, P.O. Box 37205, Omaha, NE 68137. Transporting *petroleum products* (except in bulk, in tank vehicles), from Los Angeles, CA, to points in AZ, CO, MN, and UT. (Hearing site: Los Angeles, CA.)

MC 145651 (Sub-5F), filed February 5, 1980. Applicant: DUNCAN & SONS, INC., P.O. Box 775, Lewis, CO 81327. Representative: James F. Crosby, P.O. Box 37205, Omaha, NE 68137. Transporting *burlap,* from Los Angeles, CA, to Monte Vista, CO. (Hearing site: Denver, CO or Albuquerque, NM.)

MC 146101 (Sub-2F), filed January 31, 1980. Applicant: MIDSTATES REFRIGERATED EXPRESS, INC., P.O. Box 420, East Chicago, IN 46312. Representative: Stephen H. Loeb, Suite 2027, 33 North LaSalle St., Chicago, IL 60602. Transporting *frozen foods,* between the facilities of Continental Freezers of Illinois, at Chicago, IL , on the one hand, and, on the other, points in IN, MI, OH, KY, MO, KS, WI, IA, NE, and those points in PA on and west of Interstate Hwy 79. Condition: The person or persons who appear to be engaged in common control of applicant and another regulated carrier must either file an application for approval of common control under 49 U.S.C. 11343, or submit an affidavit indicating why such approval is unnecessary. (Hearing site: Chicago, IL.)

MC 146821 (Sub-4F), filed January 29, 1980. Applicant: RONALD BESTEMAN PRODUCE, INC., 2240 Byron Center Road SW., Wyoming, MI 49509. Representative: Edward Malinzak, 900 Old Kent Bldg., Grand Rapids, MI 49509. Transporting *meats, meat products, poultry products,* and *materials equipment, and supplies* used in the production of meats, meat products, and poultry products, (except commodities in bulk), in vehicles equipped with mechanical refrigeration, between points in MI, on the one hand, and, on the other, points in WV, KY, MO, IN, IL, WI, IA, MN, TN, OH, NY, and PA. (Hearing site: Lansing, MI or Chicago, IL.)

MC 146890 (Sub-19F), filed February 8, 1980. Applicant: C & E Transport, INC., d.b.a. C. E. ZUMSTEIN CO., P.O. Box 27, Lewisburg, OH 45338. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street, NW., Washington, DC 20001. Transporting *confectionery products and cough drops,* from the facilities of Luden's, Inc., at Reading, PA, to points in OH, MI, IL, IN, MO, and KY. (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 147841 (Sub-3F), filed February 5, 1980. Applicant: CENTENNIAL TRUCK LINES, INC., 301 Broadway, Jersey City, NJ. Representative: Thomas F. X. Foley, State Highway 34, Colts Neck, NJ 07722. Transporting *building materials,* between the facilities of Barclay Industries, Inc., at or near Lodi, NJ, on the one hand, and, on the other, points in CT, MD, MA, NY, OH, PA, and VA. (Hearing site: New York, NY, or Newark, NJ.)

MC 147880F filed July 12, 1979. Applicant: AQUA–TERRA ORGANIC FARMS, INC., 257 Oak St., San Francisco, CA 94102. Representative: Ray Hills, 1826 Divisadero St., San Francisco, CA 94115. *Contract carrier,* 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), (1) from San Francisco, CA, to Buffalo, NY, and Gainesville, FL, and (2) from Gainesville, FL, to points in CO and CA, under continuing contract(s) with (a) Leather Luggage, Inc., of Gainesville, FL, and (b) McLavish Equity, of Lockport, NY. (Hearing site: San Francisco or Sacramento, CA.)

MC 148430 (Sub-2F), filed December 14, 1979. Applicant: ROBERT E. CREAGER, d.b.a. POISON SPIDER HOT SHOT SERVICE, 3100 Knollwood Drive, Casper, WY 82601. Representative: Clifford J. Neilson, 430 East 1st Street, Casper WY 82601. Transporting (1) *material, equipment, and supplies* used in, or in connection with the discovery, development, production, refining, manufacture, processing, storage, transmission, and distribution of natural gas and petroleum and their products and by products, and (2) *materials, equipment, and supplies* used in or in connection with the contstruction, operation, repair, servicing, mantenance and dismantling of pipelines, including the stringing and picking up thereof, between points in CO, ID, MT, NM, ND, SD, UT, and WY, restricted against the transportation of complete oil drilling

rigs. (Hearing site: Casper, WY, or Cheyenne, Wy.)

MC 148451 (Sub-1F), filed February 11, 1980. Applicant: HOLSTINE TRUCKING, INC., 125th Old Brighton Road, Henderson, CO 80640. Representative: Edward C. Hastings, 666 Sherman Street, Denver, CO 8023. Transporting (1) *bananas, and* (2) *seafood and agricultural* commodities otherwise exempt from economic regulation under 49 U.S.C. 10526(a)(6), in mixed loads with bananas, from Houston and Galveston, TX, Gulfport, MS, and New Orleans, LA, to points in CO. (Hearing site: Washington, DC.)

MC 148500 (Sub-3F), filed December 10, 1979. Applicant: BULK HAULERS, INC., P.O. Box 4186, Macon, GA 31208. Representative: Clyde W. Carver, P.O. Box 720434, Atlanta, GA 30328. Transporting *fertilizer* and *fertilizer materials*, in bulk, in dump vehicles, (1) from Brunswick and Albany, GA, to points in AL, and (2) from Dothan, AL, to points in GA.

MC 148791 (Sub-3F), filed February 1, 1980. Applicant: TRANSPORT-WEST, INC., 247 West 1400 South, Salt Lake City, UT 84115. Representative: William S. Richards, Post Office Box 2465, Salt Lake City, UT 84110. *Contract carrier*, transporting *such commodities* as are dealt in or used by department, discount, variety stores, between Salt Lake City, UT, and Reno, NV, under continuing contract(s) with Groud Central Stores, of Salt Lake City, UT. (Hearing site: Salt Lake City, UT.)

MC148801 (Sub-2F), filed February 8, 1980. Applicant: RAYMOND L. EDGE d.b.a. R. L. EDGE TRUCKING, 6750 Fielder Road, Rex, GA 30273. Representative: Ralph B. Matthews, P.O. Box 872, Atlanta, GA 30301. Transporting *viedo broadcasting equipment, and component parts and supplies for viedo* broadcasting equipment between the facilities of Bell System Video Pool at or near Conyers, GA, on the one hand, and, on the other points in AL, FL, KYLA, MD, MS, NJ, NY, OH, PA, TN, VA, WV, NC, SC, IN, AR, MO, IA, WI, IL, MI DE, NH, CT, ME, MA, and DC, and those in TX on and east of Interstate Hwy 35. (Hearing site: Atlanta, Ga.)

MC 148930 (Sub-1F), filed January 28, 1980. Applicant: AERO DELIVERIES, INC., 529 Gidley Drive, P.O. BOX 416, Grand Haven, MI 49417. Representative: Edward Malinzak, 900 Old Kent Building, Grand Rapids, MI 49503. *Contract carrier* transporting *industrial chemicals* from South Bend, IN, to points in MI, under continuing contracts, with Van Waters & Rogers, Division of Univar, of South Bend, IN. (Hearing site: Chicago, IL or Lansing, MI.)

Passenger

MC 142630 (Sub-2F), filed September 17, 1979. Applicant: FUGAZY CONTINENTAL CORPORATION OF NEW JERSEY, INC., 645 Madison Avenue, New York, NY 10022. Representative: Arthur Wagner, 600 Madison Avenue, New York, NY 10022. Over regular routes transporting (1) *passengers and their baggage*, between Ramsey, NJ, and Suffern, NY, from Ramsey over NJ Hwy 17 to the NJ–NY State line, then over NY Hwy 17 to junction Interstate Hwy 87, then over Interstate Hwy 87 to junction Airmont Road, and then over Airmont Road to Suffern, and return over the same route, serving no intermediate points, and (2) over irregular routes, transporting *passengers and their baggage*, in special operations, in non-scheduled door-to-door service, between points in Bergen, Essex, Hudson, Middlesex, Morris, Passaic, Somerset, and Union Counties, NJ, on the one hand, and, on the other, New York, NY. (Hearing site: New York, NY, Newark, NJ.)

Note.—Applicant intends to tack part (1) with existing regular-route authority to provide service between New York City airports and Suffern, NY.

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Decided: March 7, 1980.

By the Commission, Review Board Number 3, members Parker, Fortier and Hill,

MC 200 (Sub-434F), filed December 26, 1979. Applicant: RISS INTERNATIONAL CORPORATION, 903 Grand Avenue., Kansas City, MO 64106. Representative: H. Lynn Davis (same address as applicant). Transporting *confectionery*, serving Bryan, OH as an off-route point in connection with carrier's regular-route authority. (Hearing site: Kansas City, MO.)

MC 200 (Sub-436F), filed December 26, 1979. Applicant: RISS INTERNATIONAL CORPORATION, 903 Grand Ave., Kansas City, MO 64106. Representative: H. Lynn Davis (same address as applicant). Transporting *containers, container ends, and container closures, and materials and supplies* used in the manufacture and or distribution of the foregoing commodities, from Golden, CO, to Milwaukee, WI. (Hearing site: Kansas City, MO.)

MC 720 (Sub-77F), filed February 11, 1980. Applicant: BIRD TRUCKING COMPANY, INC., P.O. Box 227, Waupun, WI 53963. Representative: Tom Westerman (same address as applicant). Transporting *foodstuffs* from the facilities of Northern Star Company at Minneapolis, MN, to Chicago, IL, restricted to the transportation of traffic originating at the facilities of Northern Star Company. (Hearing site: Minneapolis, MN or Madison, WI.)

MC 720 (Sub-78F), filed February 11, 1980. Applicant: BIRD TRUCKING COMPANY, INC., P.O. Box 227, Waupun, WI 53963. Representative: Tom Westerman (same address as applicant). Transporting (1) *plastic articles and paper products*, (2) *materials, equipment and supplies* used in the manufacture and distribution of plastic articles and paper products, (3) *aluminum foil*, and (4) *deodorizers*, between points in the United States in and east of ND, SD, NE, KS, OK, and TX, restricted to the transportation of traffic originating at or destined to the facilities of Presto Products, Inc. (Hearing site: Appleton or Milwaukee, WI.)

MC 730 (Sub-484F), filed December 12, 1979. Applicant: PACIFIC INTERMOUNTAIN EXPRESS CO., a corporation, 25 North Via Monte, Walnut Creek, CA 94598. Representative: A. G. Krebs (same address as applicant). Over regular routes transporting *general commodities* (except those of unusual value, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) (1) between Missoula, MT, and Superior, WI: from Missoula over Interstate Hwy 90 to Billings, then over Interstate Hwy 94 to Fargo, ND, then over US Hwy 10 to junction MN Hwy 210, then over MN Hwy 210 to junction Interstate Hwy 35, then over Interstate Hwy 35 to junction US Hwy 2 (also from Fargo, ND, over Interstate Hwy 94 to junction MN Hwy 23, then over MN Hwy 23 to junction Interstate Hwy 35, and then over Interstate Hwy 35 to junction US Hwy 2), then over US Hwy 2 to Superior, and return over the same routes, serving the intermediate points of Butte, Bozeman, Livingston, Laurel, Billings, and Miles City, MT, Bismarck and Fargo, ND, and Fergus Falls, Brainerd, St. Cloud, Cloquet, and Duluth, MN, the off-route point of Anaconda, MT, and serving the junction of Interstate Hwy 90 and US Hwy 12, the junction of Interstate Hwy 94 and MT Hwy 200S, and the junction of Interstate Hwy 35 and MN Hwy 23 for purposes of joinder only, (2) between Sioux City, IA, and Pembina, ND, over Interstate Hwy 29, serving the intermediate points of Sioux Falls and Brookings, SD, and Fargo and Grand Forks, ND, and the off-route points of Vermillion, Yankton, and Watertown, SD, and Grafton and Wahpeton, ND, (3) between St. Paul and St. Cloud, MN, over US Hwy 10, serving no

intermediate points, (4) between St. Paul, MN, and the junction of Interstate Hwy 35 and MN Hwy 23, at or near Sandstone from St. Paul over Interstate Hwy 35 to its junction with MN Hwy 23, and return over the same route, serving no intermediate points, and serving the junction of Interstate Hwy 35 and MN Hwy 23 for purposes of joinder only, (5) between Sioux Falls, SD, and Billings, MT, from Sioux Falls over Interstate Hwy 90 to junction US Hwy 85, then over US Hwy 85 to junction US Hwy 212, then over US Hwy 212 to Billings, and return over the same route, serving the intermediate point of Rapid City, SD, the off-route points of Lead and Deadwood, SD, and serving the junction of Interstate Hwy 90 and US Hwy 14 for purposes of joinder only, (6) between Winona, MN, and the junction of Interstate Hwy 90 and US Hwy 14 at or near Wall, SD, from Winona over US Hwy 14 to its junction with Interstate Hwy 90 and return over the same route, serving the intermediate points of Rochester and New Ulm, MN, and Brookings and Pierre, SD, and serving the junction of US Hwy 14 and Interstate Hwy 35, the junction of US Hwy 14 and MN Hwy 13, the junction of US Hwys 14 and 169, and the junction of US Hwy 14 and Interstate Hwy 29 for purposes of joinder only, (7) between Bridgeport, NE, and Rapid City, SD, from Bridgeport over US Hwy 385 to its junction with SD Hwy 79, then over SD Hwy 79 to Rapid City, and return over the same route, serving no intermediate points, and serving the junction of US Hwy 385 and US Hwy 20 for purposes of joinder only, (8) between Cheyenne, WY, and the junction of US Hwy 87 and MT Hwy 200 at or near Grassrange, MT, from Cheyenne over US Hwy 87, to its junction with MT Hwy 200, and return over the same route, serving the intermediate points of Casper, Sheridan, and Buffalo, WY, and Billings, MT, (9) between Butte and Sweetgrass, MT, over US Hwy 91 (also Interstate Hwy 15), serving the intermediate points of Helena and Great Falls, MT, (10) between the junction of Interstate Hwy 90 and US Hwy 12 at or near Garrison and Helena, MT, from the junction of Interstate Hwy 90 and US Hwy 12 over US Hwy 12, to Helena, and return over the same route, serving no intermediate points, (11) between Great Falls, MT, and Portal, ND, from Great Falls over US Hwy 87 to junction MT Hwy 200, then over MT Hwy 200 to junction MT Hwy 200S, then over MT Hwy 200S to junction Interstate Hwy 94, then over Interstate Hwy 94 to junction MT Hwy 16, then over MT Hwy 16 to junction MT Hwy 200, then over MT Hwy 200 to junction ND Hwy 200, then over ND Hwy 200 to junction US Hwy 85, then over US Hwy 85 to junction ND Hwy 5, then over ND Hwy 5 to junction US Hwy 52, then over US Hwy 52 to Portal, and return over the same route, serving the junction of US Hwy 87 and MT Hwy 200, and the junction of Interstate Hwy 94 and MT Hwy 200S for purposes of joinder only, (12) between Minot, ND and Eau Claire, WI, from Minot over US Hwy 2 to junction US Hwy 53, then over US Hwy 53 to Eau Claire, and return over the same route serving the intermediate points of Grand Forks, ND, Crookston, Bemidji and Duluth, MN, and Superior and Chippewa Falls, WI, (13) between St. Paul, MN and Green Bay, WI, from St. Paul over Interstate Hwy 94 to junction WI Hwy 29, then over WI Hwy 29 to Green Bay (also from junction Interstate Hwy 94 and WI Hwy 29 over Interstate Hwy 94 to junction US Hwy 10, then over US Hwy 10 to junction US Hwy 41, and then over US Hwy 41 to Green Bay), and return over the same route, serving the intermediate points of Menomonie, Eau Claire, Chippewa Falls, Wausau, and Stevens Point, WI, and the off-route point of New London, WI, and those in Wood and Portage Counties, WI, (14) between Chicago, IL, and Eau Claire, WI, from Chicago over US Hwy 12 to junction combined Interstate Hwys 90 and 94 at or near Madison, WI, then over combined Interstate Hwys 90 and 94 to junction Interstate Hwy 94, and then over Interstate Hwy 94 to Eau Claire, and return over the same route, serving the intermediate points of Lake Geneva, Whitewater, Fort Atkinson, and Madison, WI, and the off-route point of Wisconsin Dells, WI, (15) between Rockford, IL, and St. Paul, MN, from Rockford over US Hwy 51 to junction IL Hwy 75, then over IL Hwy 75 to junction Interstate Hwy 90, then over Interstate Hwy 90 to junction combined Interstate Hwys 90 and 94, at or near Madison, WI, then over combined Interstate Hwys 90 and 94 to junction Interstate Hwy 90, near Tomah, WI, then over Interstate Hwy 90 to junction US Hwy 61, and then over US Hwy 61 to St. Paul, MN, and return over the same route, serving the intermediate points of Belcoit, Janesville, Edgerton, Madison, and La Crosse, WI, and Winona, MN, and the off-route points of Fort Atkinson, WI, and Rochester, MN, (16) between Milwaukee and Green Bay, WI, over US Hwy 41 (also over US Hwy 141), serving all intermediate points, the off-route points of West Bend and New London, WI, and all off-route points in Calumet, Fond du Lac, Manitowoc, Sheboygan, and Winnebago Counties, WI, (17) between Wausau and Milwaukee, WI, from Wausau over US Hwy 51 to junction combined Interstate Hwys 90 and 94, then over combined Int Hwys 90 and 94 to junction Interstate Hwy 94, at or near Madison, WI, and then over Interstate Hwy 94 to Milwaukee, and return over the same route, serving the intermediate points of Stevens Point and Madison, WI, and the off-route points of Watertown and Oconomowoc, WI, (18) between Charles City, IA, and Madison, WI, over US Hwy 18, serving no intermediate points, (19) between Des Moines, IA and Manitowoc, WI, from Des Moines over Interstate Hwy 235 to junction Intersate Hwy 80, then over Interstate Hwy 80 to junction Interstate Hwy 380, then over Interstate Hwy 380 to Cedar Rapids, IA, and then over US Hwy 151 to Manitowoc, and return over the same route, serving the intermediate points of Dubuque, IA, and Madison, Beaver Dam, and Fond du Lac, WI, and serving Cedar Rapids and the junction of Interstate Hwys 80 and 380 for purposes of joinder only, (20) between Omaha, NE, and Indianapolis, IN, from Omaha over US Hwy 275 to junction US Hwy 34, then over US Hwy 34 to junction Interstate Hwy 74, then over Interstate Hwy 74 to Indianapolis, and return over the same route, serving the intermediate points of Ottumwa, Fairfield, and Burlington, IA, Galesburg, Peoria, Bloomington, Champaign, and Danville, IL, and Crawfordsville, IN, and the off-route points of Ft. Madison and Keokuk, IA, and serving the junction of US Hwys 34 and 218 for purposes of joinder only, and serving Boulder, CO, points in IL and IN on and north of Interstate Hwy 70, and Bloomington, Franklin, Seymour, Columbus, and North Vernon, IN, as off-route points in connection with carrier's regular-route operations in (1) through (20) above, (21) between Kansas City, MO, and Rockford, IL, from Kansas City, over US Hwy 24 to junction US Hwy 51, then over US Hwy 51 to Rockford, and return over the same route, serving the intermediate points of Rochelle and Peoria, IL, and the off-route points of Ft. Madison and Keokuk, IA, (22) between Albert Lea and Burnsville, MN, over MN Hwy 13, serving all intermediate points, (23) between Duluth and Bemidji, MN, from Duluth over US Hwy 53 to International Falls, then over US Hwy 71 to Bemidji, and return over the same route, serving the intermediate point of International Falls, MN, (24) between Pierre, SD and Portal, ND, from Pierre over US Hwy 83 to junction US Hwy 52, then over US Hwy 52 to Portal, and return over the same route, serving the intermediate points of Bismarck and Minot, ND, and the off-route point of

Minot Air Force Base, (25) between Coeur D'Alene and New Meadows, ID, over US Hwy 95, serving the intermediate points of Moscow, Lewiston, and Grangeville, ID, (26) between Missoula and Port of Roosville, MT over US Hwy 93, serving the intermediate points of Polson, Kalispell, and Whitefish, MT, (27) between Lewiston, ID, and Lolo, MT, over US Hwy 12, serving no intermediate points, and serving the junction of US Hwy 12 and Idaho Hwy 13 for purposes of joinder only, (28) between Duluth, MN, and the port of entry on the international boundary line between the United States and Canada at or near Grand Portage, MN, over US Hwy 61, serving no intermediate points, (29) between the junction of Interstate Hwys 80 and 380 and the junction of US Hwys 34 and 218, from the junction of Interstate Hwys 80 and 380 over Interstate Hwy 80 to junction US Hwy 218, then over US Hwy 218 to its junction with US Hwy 34, and return over the same route, serving no intermediate points, and serving the termini for purposes of joinder only, (30) between Grangeville, ID, and the junction of ID Hwy 13 and US Hwy 12, from Grangeville over Idaho Hwy 13 to junction US Hwy 12, and return over the same route, serving no intermediate points and serving the junction of ID Hwy 13 and US Hwy 12 for purposes of joinder only, and (31) between Butte, MT, and Idaho Falls, ID, over US Hwy 91, serving no intermediate points. (Hearing site: Milwaukee, WI or Los Angeles, CA.)

MC 5470 (Sub-213F), filed January 11, 1980. Applicant: TAJON, INC., R.D. 5, Mercer, PA 16137. Representative: Brian L. Troiano, 918 16th St. NW., Washington, DC 20006. Transporting *such commodities* as are transported in dump vehicles, between Buffalo, NY, on the one hand, and, on the other, those points in the United States in and east of MN, IA, MO, OK, and TX. (Hearing site: Buffalo, NY or Washington, DC.)

MC 5470 (Sub-215F), filed January 30, 1980. Applicant: TAJON, INC., R.D. 5, Mercer, PA 16137. Representative: Brian L. Troiano, 918 16th St. NW., Washington, DC 20006. Transporting *coke,* in dump vehicles, from Swedeland, PA, to points in VA. (Hearing site: Philadelphia, PA or Washington, DC.)

MC 5470 (Sub-216F), filed January 30, 1980. Applicant: TAJON, INC., R.D. 5, Mercer, PA 16137. Representative: Brian L. Troiano, 918 16th St. NW., Washington, DC 20006. Transporting *crude clay,* in bulk, from Albany, NY to Aspers, PA. (Hearing site: New York, NY or Washington, DC.)

MC 5470 (Sub-218F), filed February 1, 1980. Applicant: TAJON, INC., R.D. 5, Mercer, PA 16137. Representative: Brian L. Troiano, 918 16th St. NW., Washington, DC 20006. Transporting *coconut charcoal,* in bulk, in dump vehicles, from Baltimore, MD to Pittsburgh, PA. (Hearing site: Pittsburgh, PA or Washington, DC.)

MC 5470 (Sub-219F), filed February 1, 1980. Applicant: TAJON, INC., R.D. 5, Mercer, PA 16137. Representative: Brian L. Troiano, 918 16th St. NW., Washington, DC 20006. Transporting *sponge iron,* in dump vehicles, from Georgetown, SC, to points in the United States (except AK and HI). (Hearing site: Georgetown, SC, or Washington, DC.)

MC 11220 (Sub-201F), filed January 28, 1980. Applicant: GORDONS TRANSPORTS, INC., 185 West McLemore Avenue, Memphis, TN 38101. Representative: James J. Emigh, P.O. Box 59, Memphis, TN 38101. 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), between the facilities of Game Time, Inc., at or near Fort Payne, AL, on the one hand, and, on the other, points in AL, AR, GA, IL, IN, IA, KS, KY, LA, MI, MN, MS, MO, OH, OK, PA, TN, TX, WV, and WI. (Hearing site: Birmingham, AL.)

MC 13651 (Sub-25F), filed February 13, 1980. Applicant: PEOPLES TRANSFER, INC., 1430 West 11th St., Long Beach, CA 90813. Representative: Edward J. Hegarty, 100 Bush St., 21st Floor, San Francisco, CA 94104. Transporting *such commodities* as are dealt in or used by grocery and food business houses, discount and variety houses, and suppliers of the foregoing, between points in AZ, CA, NV, OR, WA, ID, MT, UT, WY, CO, TX and NM. (Hearing site: San Francisco or Los Angeles, CA.)

MC 22311 (Sub-27F), filed February 6, 1980. Applicant: A. LINE, INC., P.O. Box 765, Hammond, IN 46325. Representative: Marvin Mickow (same address as applicant). Transporting *wrought steel pipe* between the facilities of Plexco, Division of Amsted Industries at Franklin Park, IL and North Lima OH, on the one hand, and, on the other, points in IL, IN, IA, KY, MI, MO, MN, NY, NC, OH, PA, SC, TN, WV, and WI. (Hearing site: Chicago, IL or Washington, DC.)

MC 35320 (Sub-463F), filed December 31, 1979. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). 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), serving the facilities of the Livingston Carton Co., Inc. at or near Livingston, AL, as an off-route point in connection with carrier's otherwise authorized regular route operations (Hearing site: Birmingham, AL or Atlanta, GA.)

Note.—Applicant intends to tack to its existing authority.

MC 35320 (Sub-464F), filed December 31, 1979. Applicant: T.I.M.E.-DC, INC., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). 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), serving the facilities of the Ford Motor Company at or near Listerhill and Sheffield, AL, as off-route points in connection with carrier's otherwise authorized regular route operations. (Hearing site: Nashville, TN or Atlanta, GA.)

Note.—Applicant intends to tack its sought rights to its existing authority.

MC 35320 (Sub-474F), filed December 31, 1979. Applicant: T.I.M.E.-DC, Inc., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). 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), serving the facilities of Huyck Corporation at or near Aliceville, AL, as an off-route point in connection with carrier's otherwise authorized regular route operations. (Hearing site: Chattanooga, TN or Washington, DC.)

Note.—Applicant intends to tack its sought rights to its existing authority.

MC 35320 (Sub-522F), filed December 31, 1979. Applicant: T.I.M.E.-DC, Inc., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). 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), serving the facilities of Roberson Advertising Service at or near New Orleans, LA, as an off-route

point in connection with carrier's otherwise authorized regular route operations. (Hearing site: New Orleans, LA or Washington, DC.)

Note.—Applicant intends to tack its sought rights to its existing authority.

MC 35320 (Sub-523F), filed December 31, 1979. Applicant: T.I.M.E.–DC, Inc., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). 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), serving the facilities of Reily Chemical Inc. at or near New Orleans, LA, as an off-route point in connection with carrier's otherwise authorized regular route operations. (Hearing site: New Orleans, LA or Washington, DC.)

Note.—Applicant intends to tack its sought rights to its existing authority.

MC 35320 (Sub-524F), filed December 31, 1979. Applicant: T.I.M.E.–DC, Inc., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). 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), serving the facilities of Bailey Division, U. S. M. Corp. at or near Belvidere, IL, as an off-route point in connection with carrier's otherwise authorized regular route operations. (Hearing site: Chicago, IL or Washington, DC.)

Note.—Applicant intends to tack its sought rights to its existing authority.

MC 35320 (Sub-557F), filed February 7, 1980. Applicant: T.I.M.E.–DC, Inc., 2598 74th Street, P.O. Box 2550, Lubbock, TX 79408. Representative: Kenneth G. Thomas (same address as applicant). 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), serving the facilities of Climate Control Equipment Co., Inc., at or near Montgomery, AL, as an off-route point in connection with carrier's otherwise authorized regular route operations. (Hearing site: Montgomery, AL or Atlanta, GA.)

Note.—Applicant intends to tack its sought rights to its existing authority.

MC 38320 (Sub-23F), filed January 28, 1980. Applicant: CENTRAL MOTOR EXPRESS, INC., P.O. Drawer "C", Campbellsville, KY 42718. Representative: Louis J. Amato, P.O. Box E, Bowling Green, KY 42101. Transporting (1) *textiles and textile products* and (2) *materials, equipment and supplies* used in the manufacture and distribution of textiles and textile products, between the facilities of Union Underwear Company, Inc., at or near Jamestown, KY, Campbellsville, KY, and Bowling Green, KY, on the one hand, and, on the other, points in AL, GA, IL, IN, KY, LA, MS, MO, NC, OH, PA, SC, TN, VA, WV, and WI, restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Nashville, TN, or Louisville, KY.)

MC 56270 (Sub-38F), filed February 8, 1980. Applicant: LEICHT TRANSFER & STORAGE CO., a corporation, 1401–55 State St., P.O. Box 2385, Green Bay, WI 54306. Representative: Dennis L. Sedlacek (same address as applicant). Transporting *iron and steel articles, and fabricated steel* from St. Paul and Edina, MN to points in IA, IL, IN, ND, NE, SD, and WI. (Hearing site: Madison or Milwaukee, WI.)

MC 56270 (Sub-39F), filed January 30, 1980. Applicant: LEICHT TRANSFER & STORAGE CO., a corporation, 1401–55 State St., P.O. Box 2385, Green Bay, WI 54306. Representative: Dennis L. Sedlacek (same address as applicant). Transporting *such commodities* as are manufactured, distributed or used by a manufacturer or distributor of bituminous fibre products and plastic products (except commodities in bulk) between the facilities of Bermico Company at or near West Bend, WI, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Madison or Milwaukee, WI.)

MC 56270 (Sub-40F), filed January 30, 1980. Applicant: LEICHT TRANSFER & STORAGE CO., a corporation, 1401–55 State St., P.O. Box 2385, Green Bay, WI 54306. Representative: Dennis L. Sedlacek (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers and distributors of plastic pipe between Fairfield, IA, on the one hand, and, on the other, points in the United States in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: Madison or Milwaukee, WI.)

MC 61231 (Sub-167F), filed December 31, 1979. Applicant: EASTER ENTERPRISES, INC., d.b.a. ACE LINES, INC., P.O. Box 1351, Des Moines, IA 50305. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. Transporting *iron and steel articles* from the facilities of Nucor Corporation at or near Norfolk, NE, to points in AR, AZ, CO, ID, IL, IN, IA, KS, KY, LA, MI, MN, MS, MO, MT, NM, ND, OH, OK, SD, TN, TX, WA, WI and WY. (Hearing site: Omaha, NE.)

MC 61401 (Sub-23F), filed February 8, 1980. Applicant: MARX TRUCK LINE, INC., 220 Lewis, Sioux City, IA 51101. Representative: Robert A. Wichser, P.O. Box 417, Sioux City, IA 51102. *Contract carrier* transporting *meats, meat products, meat byproducts and articles distributed by meat-packing houses* as described in sections A, B, and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766 (except hides and commodites in bulk), between the facilities used by Swift and Company at or near Sioux City, IA, on the one hand, and, on the other, points in IL, IN, IA, MN, MO, NE, SD, and WI, under continuing contract(s) with Swift & Company of Chicago, IL. (Hearing site: Chicago, IL, or Washington, DC.)

MC 67450 (Sub-103F), filed January 31, 1980. Applicant: PETERLIN CARTAGE CO., a corporation, 9651 S. Ewing Avenue, Chicago, IL 60617. Representative: Joseph Winter, 29 South LaSalle Street, Chicago, IL 60603. Transporting (1) *such commodities as are dealt in or used by manufacturers and distributors of bathroom accessories and plumbing supplies*, and (2) *outdoors barbeque grills*, between Atlanta, GA Somerset, PA, and Cook, DuPage and Kane Counties, IL, on the one hand, and, on the other, points in the United States in and east of ND, SD, NE, KS, OK, and NM. (Hearing site: Chicago, IL.)

MC 75840 (Sub-131F), filed December 26, 1979. Applicant: MALONE FREIGHT LINES, INC., P.O. Box 11103, 3400 Third Avenue, South, Birmingham, AL 35202. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Rd. NE., Atlanta, GA 30326. Transporting *chemicals, paint and paint products, textile fibres, film, pigments, rubber products, photo products, and fluorocarbons (except in bulk)*, between the facilities of E. I. duPont De Nemours & Company, Inc., in WV, VA, OH, PA, TN, GA, NJ, NY, DE, KY, SC & NC, on the one hand, and, on the other, Houston, TX. (Hearing site: Washington, D.C.)

MC 82841 (Sub-283F), filed January 28, 1980. Applicant: HUNT TRANSPORTATION, INC., 10770 "I" Street, Omaha, NE 68127. Representative: Donald L. Stern, 717 Mercy Rd., Suite 610, Omaha, NE 68106. Transporting *pipe* (except iron and steel) and *fittings*, from Lindsay, Santa Ana and Stockton, CA to points in CO, KS, NE, UT, and WY. (Hearing site: Los Angeles, CA.)

MC 82841 (Sub-284F), filed January 28, 1980. Applicant: HUNT TRANSPORTATION, INC., 10770 "I" St., Omaha, NE 68127. Representative: Donald L. Stern, 7171 Mercy Rd., Suite 610, Omaha, NE 68106. Transporting (1) *concrete pumps, conveyors, scaffolding,* and (2) *accessories* and *parts* for the foregoing commodities between Yankton, SD, on the one hand, and, on the other, points in SD, ND, NE, KS, OK, TX, MT, WY, CO, NM, WA, OR, ID, NV, UT, CA, and AZ. (Hearing site: Omaha, NE.)

MC 93980 (Sub-88F), filed February 13, 1980. Applicant: VANCE TRUCKING COMPANY, INC., P.O. Box 1119, Henderson, NC 27536. Representative: Edward G. Villalon, 1032 Pennsylvania Building, Pennsylvania Ave. and 13th Street NW., Washington, DC 20004. Transporting *boards, building wall or insulation, fibre board or pulpboard,* from Woodstock,VA, to points in FL, SC, NC, KY, and TN. (Hearing site: Washington, DC.)

MC 97251 (Sub-11F), filed February 8, 1980. Applicant: TURNER TRUCKING COMPANY, INC., 1215 W. Main St., Lebanon, IN 46052. Representative: Alki E. Scopelitis, 1301 Merchants Plaza, Indianapolis, IN 46204. 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 Chesebrough Pond's, Inc. at Monticello, IN, to Chicago, IL. (Hearing site: Indianapolis, IN or Chicago, IL.)

MC 97310 (Sub-36F), filed January 31, 1980. Applicant: SHARRON MOTOR LINES, INC., P.O. Box 5636, Meridian, Mississippi 39301. Representative: Bruce E. Mitchell, Suite 520, Lenox Towers South, 3390 Peachtree Road, NE., Atlanta, Georgia 30326. Over regular routes, 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) (1) between Birmingham, AL, and Huntsville, AL, (a) from Birmingham over U.S. Hwy 31 to Decatur, AL, then over alternate U.S. Hwy 72 to Huntsville, and return over the same route serving all intermediate points. (b) from Birmingham over U.S. Hwy 31 to junction AL Hwy 26, then over U.S. Hwy 231 to Huntsville, and return over the same routes serving all intermediate points; and (2) between Memphis, TN, and Huntsville, LA, (a) from Memphis over U.S. Hwy 72 to Huntsville, LA, and return over the same route, serving only those intermediate points located in AL, (b) from Memphis over U.S. Hwy 72 to junction alternate U.S. Hwy 72, then over alternate U.S. Hwy 72 to Huntsville, and return over the same routes, serving all intermediate points located in AL and serving points in Crittenden County, AR, as off route points in connection therewith. (Hearing site: Birmingham, AL or Memphis, TN.)

MC 105881 (Sub-63F), filed February 12, 1980. Applicant: MR & R TRUCKING COMPANY, P.O. Box 1000, Staunton, VA 24401. Representative: Francis W. McInerny, 1000 16th Street NW., Suite 502, Washington, DC 20036. Transporting *general commodities* (except those of unusual value, household goods as defined by the Commission, classes A and B explosives, commodities in bulk, and those requiring special equipment), serving points in Marion County, FL, as intermediate or off-route points in connection with carrier's regular routes. (Hearing site: Gainesville, FL or Ocala, FL.)

Note.—Applicant intends to tack.

MC 106400 (Sub-122F), filed December 31, 1979. Applicant: KAW TRANSPORT COMPANY, P.O. Box 8510, Sugar Creek, MO 64054. Representative: Robert L. Hawkins, Jr., P.O. Box 456, Jefferson City, MO 65102. Transporting *asphalt,* in bulk, in tank vehicles, from Kansas City, KS, to points in Boone County, AR. (Hearing site: Kansas City, MO.)

MC 108341 (Sub-178F), filed December 31, 1979. Applicant: MOSS TRUCKING COMPANY, INC., 3027 N. Tryon St., P.O. Box 26125, Charlotte, NC 28213. Representative: Mr. Jack F. Counts (same address as applicant). Transporting (1) *buildings, building panels, building parts,* and (2) *materials, accessories, equipment, and supplies* used in the installation, erection, manufacture and construction of buildings, building panels and building parts (except commodities in bulk), between the facilities of Butler Manufacturing Company at or near San Marcos, TX, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Butler Manufacturing Company at or near San Marcos, TX. (Hearing site: Washington, DC.)

MC 111231 (Sub-294F), filed December 26, 1979. Applicant: JONES TRUCK LINES, INC., 610 East Emma Ave., Springdale, AR 72764. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood Ave., Fort Smith, AR 72902. Transporting (1) *iron and steel articles,* and (2) *materials equipment and supplies* (except commodities in bulk) used in the manufacturing, processing and distribution of steel forgings and forging dies, between the facilities of West Chicago Forge, Inc., at or near Doniphan, MO, and points in AL, AR, GA, IL, IN, IA, KS, KY, LA, MI, MS, MO, NB, OK, TN, TX and WI. (Hearing site: Washington, DC or Chicago, IL.)

MC 114211 (Sub-437F), filed December 31, 1979. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, IA 50704. Representative: Kurt E. Vragel, Jr. (same address as applicant). Transporting *such commodities* as are dealt in, distributed by, or used by manufacturers, distributors, dealers and brokers of lumber, lumber mill products, wood products, and forest products, from points in AR, LA, OK, and TX, to points in ND, SD, WY, CO, NE, TX, OK, KS, MO, IA, MN, WI, IL, IN, MI, OH, and PA. (Hearing site: Boise, ID.)

MC 114211 (Sub-438F), filed December 31, 1979. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, IA 50704. Representative: Kurt E. Vragel, Jr. (same address as applicant). Transporting *such commodities* as are manufactured, dealt in, distributed or used by manufacturers, dealers, and distributors of agricultural, industrial and construction machinery and equipment, between Menasha, WI, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Green Bay or Manitowoc, WI.)

MC 114211 (Sub-444F), filed February 8, 1980. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, IA 50704. Representative: Kurt E. Vragel, Jr. (same address as applicant). Transporting *iron and steel articles,* between Channelview, TX, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Chicago or Kankakee, IL.)

MC 115331 (Sub-517F), filed August 28, 1979. Applicant: TRUCK TRANSPORT INC., 29 Clayton Hills Lane, St. Louis, MO 63131. Representative: Steve Vogt, 11040 Manchester Road, St. Louis, MO 63122. Transporting (1) *paper and paper products* and (2) *materials, equipment and supplies* used in the manufacture of the commodities in (1) between Hawesville, KY, on the one hand, and, on the other, points in AL, AR, FL, GA, IL, IN, IA, KS, LA, MI, MS, MO, NE, NC, OH, OK, PA, SC, TN, TX, WV and WI, restricted to the transportation of traffic originating at or destined to the facilities of Western Kraft Paper Group, Williamette Industries. (Hearing site: Washington, DC or Louisville, KY.)

MC 115651 (Sub-82F), filed February 6, 1980. Applicant: KANEY TRANSPORTATION, INC., 7222 Cunningham Rd., Rockford, IL 61102. Representative: E. Stephen Heisley, 666–11th St., Washington, DC 20001. Transporting *petroleum products,* in bulk, in tank vehicles, from Rochelle, IL, to points in WI. (Hearing site: Chicago, IL, or Milwaukee, WI.)

MC 115841 (Sub-757F), filed February 11, 1980. Applicant: COLONIAL REFRIGERATED TRANSPORTATION, INC., 9041 Executive Part Dr., Suite 110, Building 100, Knoxville, TN 37919. Representative: D. R. Beeler (same address as applicant). Transporting (1) *alcoholic beverages* and (2) *materials, equipment and supplies* used in the manufacture and distribution of alcoholic beverages, (a) between Ft. Smith, AR, on the one hand, and, on the other, points in the United States (except AK and HI), and (b) beween New Orleans, LA, on the one hand, and, on the other, points in AL, AR, AZ, CA, FL, GA, LA, MS, NM, OK, and TX, restricted in (a) and (b) to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc. (Hearing site: Chicago, IL or Washington, DC.)

MC 119741 (Sub-256F), filed February 8, 1980. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Ave. NW., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson (same address as applicant). Transporting *meats, meat products, meat byproducts, and articles distributed by meat-packinghouses,* 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 Kor-Bert, Inc., at or near Klemme, IA to points in AR, CO, CT, DE, FL, GA, IL, IN, KS, KY, MD, MA, MI, MN MO, NE, NJ, NY, ND, OH, OK, PA, RI, SD, TX, VA, WV, WI, and DC. (Hearing site: Fort Dodge, IA.)

MC 123201 (Sub-8F), filed February 1, 1980. Applicant: HORVATH BROS. TRUCKING, INC., 322 Schuyler Ave., Kearny, NJ 07032. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. Transporting *iron and steel, and iron and steel articles,* between points in NJ, on the one hand, and, on the other, points in CT, DE, MA, MD, NY, PA, RI, VA, and DC. (Hearing site: New York, NY or Washington, DC.)

MC 124711 (Sub-103F), filed December 26, 1979. Applicant: BECKER CORPORATION, P.O. Box 1050, El Dorado, KS 67042. Representative: Rod Parker (same address as applicant). Transporting *petroleum and petroleum products,* in bulk, from KS and Kansas City, MO, to points in IA. (Hearing site: Kansas City, KS or Omaha, NE.)

MC 124821 (Sub-81F), filed February 13, 1980. Applicant: GILCHRIST TRUCKING, INC., 105 North Keyser Avenue, Old Forge, PA 18518. Representative: John W. Frame, Box 626, 2207 Old Gettysburg Road, Camp Hill, PA 17011. Transporting (1) *charcoal* and *charcoal briquettes,* and (2) *materials, equipment, and supplies* used in the the manufacture or distribution of the commodities in (1) (except commodities in bulk), from points in NY, to points in PA, ME, IN, IL, OH and NJ, restricted to the transportation of traffic originating at or destined to facilities used by Husky Industries, Inc. (Hearing site: Harrisburg, PA.)

MC 124821 (Sub-82F), filed February 7, 1980. Applicant: GILCHRIST TRUCKING, INC., 105 North Keyser Avenue, Old Forge, PA 18518. Representative: John W. Frame, Box 626, 2207 Old Gettysburg Road, Camp Hill, PA 17011. Transporting (1) *leather and leather products,* and (2) *materials* used in the manufacture and distribution of leather and leather products, between Wilkes-Barre, PA, on the one hand, and, on the other, points in MA and ME. (Hearing site: Harrisburg, PA.)

MC 125951 (Sub-54F), filed February 13, 1980. Applicant: SILVEY REFRIGERATED CARRIERS, INC., 7000 West Center Road, Suite 325, Omaha, NE 68106. Representative: Robert M. Cimino (same as applicant). Transporting *meat, 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 *Description in Motor Carrier Certificates,* 61 M.C.C. 209 and 766, (except hides and commodities in bulk), from the facilties of Hygrade Foods at or near Storm Lake and Cherokee, IA, to points in TX and LA, and points in the United States east of WI, IL, MO, AR, and LA, restricted to the transportation of traffic originating at the named origins and destined to the named destinations. (Hearing site: Omaha, NE.)

MC 128030 (Sub-131F), filed February 1, 1980. Applicant: THE STOUT TRUCKING CO., INC., P.O. Box 98, Urbana, IL 61801. Representative: James R. Madler, 120 W. Madison St., Chicago, IL 60602. Transporting *waste and scrap paper,* from points in MO, MI, OH, and KY to Cayuga, IN. (Hearing site: Chicago, IL.)

MC 129191 (Sub-13F), filed February 15, 1980. Applicant: RICHARD T. PLATTNER d.b.a. JANS MOTOR SERVICE, 12600 South Laramie Avenue, Alsip, IL 60658. Representative: Albert A. Andrin, 180 North LaSalle Street, Chicago, IL 60601. Transporting *iron and steel articles,* from the facilities of United States Steel Corporation at or near Gary, IN and South Chicago, Joliet and Waukegan, IL, to points in IL (from Gary only), IN (from IL origins only), IA, KY, MO, Lower Peninsula or MI, OH (on and west Interstate Hwy 75) and WI (except points in Kenosha, Milwaukee and Racine counties, WI) and Kansas City, MO restricted to the transportation of traffic originating at the named facilities. (Hearing site: Chicago, IL.)

MC 129291 (Sub-15F), filed February 15, 1980. Applicant: McDANIEL MOTOR EXPRESS, INC., 1115 Winchester Road, Lexington, KY 40505. Representative: William L. Willis, 708 McClure Building, Frankfort, KY 40601. Over regular routes 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), between Lexington, KY, and Atlanta, GA over Interstate Hwy 75, serving no intermediate points. (Hearing site: Lexington, KY or Atlanta, GA.)

MC 133591 (Sub-90F), filed December 26, 1979. Applicant: WAYNE DANIEL TRUCK, INC., P.O. Box 303, Mt. Vernon, MO 65712. Representative: A. J. Swanson, P.O. Box 1103, 226 N. Phillips Avenue, Sioux Falls, SD 57101. Transporting *fabrics, towels, cloths, apron,* and *textile products,* from North Little Rock, AR, to points in CA. (Hearing site: Sioux Falls, SD or New Brunswick, NJ.)

MC 133591 (Sub-94F), filed January 28, 1980. Applicant: WAYNE DANIEL TRUCK, INC., P.O. Box 303, Mount Vernon, MO 65712. Representative: Harry Ross, 58 S. Main St., Winchester, KY 40391. Transporting *frozen foodstuffs* from Chickasha and Tulsa, OK, to Memphis, TN and points in IL, MN, IA, MO, AR, LA, TX, KS, NE, SD, ND, MT, WY, CO, NM, AZ, UT, ID, NV, CA, OR, and WA. (Hearing site: St. Louis, MO.)

MC 134300 (Sub-46F), filed February 8, 1980. Applicant: TRIPLE R EXPRESS, INC., 498 First Street, NW., New Brighton, MN 55112. Representative: Samuel Rubestein, P.O. Box 5, Minneapolis, IN 55440. 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), between points in the United States in and east of ND, SD, NE, KS, OK, AR, and LA, restricted to transportation of traffic originating at or

destined to facilities used by K-Tel International, Inc. Hearing site: Minneapolis or St. Paul MN.

MC 135070 (Sub-155F), filed February 6, 1980. Applicant: JAY LINES, INC., P.O. Box 30180, Amarillo, TX 79120. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. Transporting *paper and paper products and equipment, materials and supplies* used in the manufacture and distribution of the foregoing commodities, between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Scott Paper Company. (Hearing site: Philadelphia, PA Or Dallas, TX.)

Note.—Dual operations may be involved.

MC 135691 (Sub-43F), filed January 28, 1980. Applicant: DALLAS CARRIERS CORP., P.O. Box 402626, Dallas, TX 75240. Representative: J. Max Harding, P.O. Box 82028, Lincoln, NE 68401. *Contract carrier* transporting (1) *processed nuts and seeds, carob mix, carob coated almonds, ambrosia mix, banana chips and dried fruits,* and (2) *agricultural commodities exempt from economic regulation* under 49 U.S.C. Section 10526(a)(6) of the Interstate Commerce Act when transported in mixed loads with the commodities in (1), from the facilities used by Tenneco West, Inc., at points in CA to points in the United States (except AK and HI), under continuing contract(s) with Tenneco West, Inc., of Bakersfield, CA. (Hearing site: Los Angeles, CA.)

MC 136080 (Sub-6F), filed December 26, 1979. Applicant: ELIZABETH S. & BERNIE L. LAFOE, d.b.a. E. S. LAFOE, RFD 1, Route No. 7, Ferrisburg, VT 05456. Representative: Norman A. Cooper, 145 W. Wisconsin Ave., Neenah, WI 54956. *Contract carrier, transporting bakery products,* from the facilities of Koffee Kup Bakery, Inc., at Burlington, VT, to points in CT, MA, ME, NH, NJ, NY, PA, and RI, under continuing contract(s) with Koffee Kup Bakery, Inc. of Burlington, VT. (Hearing site: Boston, MA or Montpelier, VT.)

MC 136500 (Sub-12F), filed November 20, 1979. Applicant: SERVICE EQUIPMENT & TRUCKING, INC., Box 162, Mattoon, IL 61932. Representative: Robert T. Lawley, 300 Reisch Building, Springfield, IL 62701. *Contract carrier* transporting *steel articles* used in the manufacture of railroad freight cars (1) from points in the United States (except AK and HI) to Clinton, IL, and (2) from Clinton, IL to Novi, MI, Waukesha, WI, and Winder and Columbus, GA, under continuing contract(s) with Portec, Inc., Midwest Railcar Operations of Clinton, IL. (Hearing site: Chicago, IL.)

MC 136500 (Sub-13F), filed November 23, 1979. Applicant: SERVICE EQUIPMENT & TRUCKING, INC., Box 162, Mattoon, IL 61932. Representative: Robert T. Lawley, 300 Reisch Building, Springfield, IL 62701. *Contract carrier* transporting *roll-over protective structures* from Portland, OR to points in the United States (except AK and HI) under continuing contracts(s) with Tub-Lok Products, Div. of Portland Wire & Iron Works Co., of Portland, OR. (Hearing site: St. Louis, MO, or Chicago, IL.)

MC 138000 (Sub-53F), filed August 30, 1979. Applicant: ARTHUR H. FULTON, INC., P.O. Box 86, Stephens City, VA 22655. Representative: Edward N. Button, 1329 Pennsylvania Avenue, P.O. Box 1417, Hagerstown, MD 21740. Transporting *such commodities* as are dealt in by retail chain department stores from the facilites of K-Mart, Inc., at Chicago, IL to Detroit, MI. (Hearing site: Chicago, IL.)

Note.—Dual operations may be involved.

MC 138741 (Sub-105F), filed February 11, 1980. Applicant: AMERICAN CENTRAL TRANSPORT, INC., 2005 North Broadway, Joliet, IL 60435. Representative: Tom B. Kretsinger, 20 E. Franklin, Liberty, MO 64068. Transporting (1) *roofing and building materials,* (except in bulk), and (2) *equipment, machinery, materials and supplies* used in the manufacture, packaging, storage, distribution and installation of the commodities in (1) (except in bulk), between points in AL, AR, CO, GA, IL, IN, IA, KS, KY, LA, MI, MS, MO, NE, OH, OK, PA, TN, TX and WI. (Hearing site: Dallas, TX.)

MC 140201 (Sub-5F), filed December 26, 1979. Applicant: SONELL, INC., Neshaminy Plaza, Building 1, Suite 111, Cornwells Heights, PA 19020. Representative: Steven M. Tannenbaum, 133 N. 4th St., Philadelphia, PA 19106. Transporting *confectionery and foodstuffs,* (except in bulk), in vehicles equipped with mechanical refrigeration (1) between the facilities utilized by (a) Hershey Chocolate Company, at Hershey and Derry Township, Dauphin County, PA, (b) Y&S Candies, Inc., in East Hempfield Township, Lancaster County, PA, and (c) Dauphin Distribution Services, Inc., in Hampden Township, Cumberland County, PA, and Mechanicsburg, PA, and (c) Dauphin Distribution Services, Inc., in Hampden Township, Cumberland County, PA, and Mechancisburg, PA, and (2) from the facilities utilized by (a) Hershey Chololate Company at Hershey and Derry Township, Dauphin County, PA, (b) Y&S Candies, Inc., in East Hempfield Township, Lancaster County, PA, and (c) Dauphin Distribution Services, Inc., in Hampden Township, Cumberland County, PA, and Mechanicsburg, PA, to New York, NY, points in Suffolk and Westchester Counties, NY, and points in Suffolk and Westchester Counties, NY, and points in Bergen, Middlesex and Somerset Counties, NJ. (Hearing site: Philadelphia, PA.)

MC 142181 (Sub-18F), filed January 28, 1980. Applicant: LIBERTY CONTRACT CARRIER, INC., 214 Hermitage Avenue, Nashville, TN 37202. Representative: Robert L. Baker, 618 United American Bank Building, Nashville, TN 37219. *Contract carrier,* transporting (1) *such merchandise as is dealt in by catalogue showroom stores and* (2) *materials, equipment, fixtures and supplies* utilized in the business of a catalogue showroom company, between points in the United States in and east of KS, NE, ND, OK, SD and TX, under continuing contract(s) with Service Merchandise Company, Inc., of Nashville, TN. (Hearing site: Nashville, TN.)

MC 143320 (Sub-3F), filed January 29, 1980. Applicant: POTAWATOMI TRAILS, INC., 51585 Winding Waters Lane, Elkhart, IN 46514. Representative: Richard P. Miller (same address as applicant). Transporting *such commodities* as are used in the manufacture and distribution of mobile homes, buildings in sections, and recreational vehicles (except commodities in bulk) between points in the United States (except AK and HI), restricted to transportation of traffic originating at or destined to the facilites used by G. M. Distributors, Inc., G. M. Industrial Corporation. (Hearing site: Elkhart, IN.)

MC 144140 (Sub-48F), filed January 22, 1980. Applicant: SOUTHERN FREIGHTWAYS, INC., P.O. Box 158, Eustis, FL 32726. Representative: John L. Dickerson (same address as applicant). Transporting *foodstuffs* (except in bulk) from the facilities of American Home Food, Division of American Home Products Corporation, at or near Milton, PA to points in AL, GA, FL, NC, OH, SC, and TN. (Hearing site: Orlando, FL or Washington, DC.)

MC 144630 (Sub-42F), filed February 8, 1980. Applicant: STOOPS EXPRESS, INC., 2239 Malibu Court, Anderson, IN. Representative: Donald W. Smith, P.O. Box 00248, Indianapolis, IN 46240. Transporting *such commodities* as are dealt in or used by manufacturers of glass, plastic, metal and earthenware products, between the facilities used by Anchor Hocking Corporation at points in CA, FL, IL, IN, MD, MN, NJ, OH, PA, TX, and WV, on the one hand, and, on the other, points in the United States

(except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities used by Anchor Hocking and its subsidiaries Phoenix Glass, Moldcraft, Inc., and Amerock, Inc. (Hearing site: Columbus, OH or Indianapolis, IN.)

MC 144910 (Sub-13F), filed January 30, 1980. Applicant: TYREE D. PRUITT, d.b.a. TY PRUITT, TRUCKING, 811 Landay Avenue, Baltimore, MD 21237. Representative: Chester A. Zyblut, 366 Executive Building, 1030 15th Street NW., Washington, D.C. 20005. Transporting *malt beverages and advertising material,* from the facilities of Pabst Brewing Company at Newark, NJ, and Pabst (Houston County), GA, to points in MD and OH. (Hearing site: Washington, DC.)

MC 145011 (Sub-8F), filed September 18, 1979. Appliant: R. F. WESTBURY, 1617 Willis Road, Richmond, VA 23224. Representative: Carroll B. Jackson, 1810 Vincennes Road, Richmond, VA 23229. *Contract carrier,* transporting (1) *aluminum foil, aluminum, aluminum products, boxes, plastic articles, paper, and paper articles,* and (2) *materials, equipment,* and *supplies* used in the manufacture, and storage of the commotities in (1) (except in bulk in tank vehicles), between Bellwood, Richmond and Grottoes, VA, on the one hand, and, on the other, points in CO, FL, GA, IL (except Chicago), IN, MI, and TX, under continuing contract(s) with Reynolds Metals Company of Richmond, VA. (Hearing site: Richmond, VA or Washington, DC.)

MC 145011 (Sub-9F), filed September 23, 1979. Applicant: R. F. WESTBURY, 1617 Willis Road, Richmond, VA 23224. Representative: Carroll B. Jackson, 1810 Vincennes Road, Richmond, VA 23229. *Contract carrier,* transporting (1) *bakery products, food products, dust, meal, peanuts, racks, stands, paper, paper articles, advertising matter,* and (2) *materials, supplies and equipment* used in the manufacture, or distribution of the commodities in (1) above, (except in bulk in tank vehicles), between Richmond, VA, and points in Henrico County, VA, on the one hand, and, on the other, points in CA, IL, IN, MI, OH, OR, TX, WA, and WI, under continuing contract(s) with Nabisco, Inc. of East Hanover, NJ. (Hearing site: New York, NY or Newark, NJ.)

MC 145240 (Sub-7F), filed January 28, 1980. Applicant: L. D. BRINKMAN TRUCKING CORP., 520 N. Wildwood, Irving, TX 75060. Representative: Lawrence A. Winkle, P.O. Box 45538, Dallas, TX 75245. *Contract carrier,* transporting (1) *such merchandise* as is dealt in by wholesale, retail, chain grocery and food business houses, and (2) *materials, ingredients and supplies* used in the manufacture, and distribution of the commodities in (1), from the facilities of the Ralston Purina Company at or near Oklahoma City, OK, to points in AR, LA, and TX, under continuing contract(s) with Ralston Purina Company of Edmond, OK. (Hearing site: Dallas, TX or Oklahoma City, OK.)

MC 145441 (Sub-99F), filed February 11, 1980. Applicant: A.C.B. TRUCKING, INC., P.O. Box 5130, N. Little Rock, AR 72119. Representative: Ralph E. Bradbury (same address as applicant). Transporting *foodstuffs* (except in bulk) from the facilities of Lykes Pasco Packing Co. at or near Dade City, FL, to points in WA, ID, OR, CA, NV, AZ, TX, OK, KS, AR, LA, IL, IN, MI, OH, KY, and PA. (Hearing site: Little Rock, AR or Miami, FL.)

MC 145441 (Sub-100F), filed January 28, 1980. Applicant: A.C.B. TRUCKING, INC., P.O. Box 5130, N. Little Rock, AR 72119. Representative: E. Lewis Coffey (same address as applicant). Transporting (1) *television sets, radios, phonographs, stereo systems, recorders and players, speaker systems, and audio equipment;* and (2) *accessories, components, and parts* for the commodities set forth in (1) above, from the facilities of RCA Corporation at Bloomington, IN, to points in AR, KS, OK, LA, and TX. (Hearing site: Indianapolis, IN or Little Rock, AR.)

MC 145441 (Sub-101F), filed January 28, 1980. Applicant: A.C.B. TRUCKING, INC., P.O. Box 5130, N. Little Rock, AR 72119. Representative: Ralph E. Bradbury (same address as applicant). Transporting *iron castings* from Memphis, TN, to points in CA, CT, FL, GA, IL, IN, KS, MI, NH, NM, NY, NC, OH, OK, OR, PA, RI, SC, TX, UT, VA, WA, WV, and WI. (Hearing site: Little Rock, AR or Memphis, TN.)

MC 145441 (Sub-102F), filed February 13, 1980. Applicant: A.C.B. TRUCKING, INC., P.O. Box 5130, N. Little Rock, AR 72119. Representative: E. Lewis Coffey (same address as applicant). Transporting *paper and paper products,* between points in the United States in and east of ND, SD, NE, KS, OK, and TX, restricted to the transportation of traffic originating at or destined to the facilities of Scott Paper Company. (Hearing site: Philadelphia, PA or Little Rock, AR.)

MC 146021 (Sub-5F), filed February 8, 1980. Applicant: RALPH OWENS TRUCKING CO., INC., P.O. Box 711, Hereford, TX 79045. Representative: Richard Hubbert, P.O. Box 10236, Lubbock, TX 79408. Transporting *sugar,* refined, in packages, from Sugar Land, TX, to points in AR, CO, KS, LA, MO, and OK. (Hearing site: Houston or Dallas, TX.)

MC 146360 (Sub-21F), filed February 15, 1980. Applicant: FLOYD SMITH, JR. TRUCKING, INC., P.O. Box 816, Meridian, ID 83642. Representative: Timothy R. Stivers, P.O. Box 162, Boise, ID 83701. Transporting *such commodities* dealt in by grocery and food business houses and materials, equipment and supplies used in the conduct of such business between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities used by Allied Sysco Food Services, Inc. (Hearing site: Boise, ID.)

MC 146361 (Sub-11F), filed February 15, 1980. Applicant: WOLTER TRUCK LINES, INC., R.D. 1, Box 197, Greenwood, DE 19950. Representative: Chester A. Zyblut, 366 Executive Bldg., 1030 Fifteenth St. NW., Washington, DC 20005. Transporting *ammonium sulfate fertilizer,* in bulk, in dump trucks, from Wilmington, DE, to points in MD, DE, NJ, PA, and NY. (Hearing site: Washington, DC.)

MC 146671 (Sub-5F), filed September 4, 1979. Applicant: PRODUCE SERVICE, INC., d.b.a. PSI, 1120 Erie St., North Kansas City, MO 64116. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. Transporting *charcoal, charcoal briquets, fireplace logs, wood chips, and lighter fluid* (except commodities in bulk), from Meta, MO, to points in AZ, CA, CO, FL, GA, KS, MS, NE, NM, OK, OH, SD, TX, UT, and WA. (Hearing site: Kansas City, MO.)

MC 146671 (Sub-6F), filed September 4, 1979. Applicant: PRODUCE SERVICE, INC., d.b.a. PSI, 1120 Erie St., North Kansas City, MO 64116. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. Transporting *foodstuffs* (except commodities in bulk), from Booner Springs, KS, to points in OK, TX, MO, AR, LA, NM, and AZ. (Hearing site: Kansas City, MO.)

MC 146671 (Sub-7F), filed September 4, 1979. Applicant: PRODUCE SERVICE, INC., d.b.a. PSI, 1120 Erie Street, North Kansas City, MO 64116. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. Transporting *charcoal, charcoal briquets, fireplace logs, wood chips, and lighter fluid* (except commodities in bulk), from Dickinson, ND to points in MN, SD, IA, NE, MO, AR, LA, TX, OK, KS, MT, ID, WA, OR, WY, CA, NV, AZ, CO, UT and NM. (Hearing site: Kansas City, MO.)

MC 146671 (Sub-8F), filed September 4, 1979. Applicant: PRODUCE SERVICE, INC., d.b.a. PSI, 1120 Erie Street, North Kansas City, MO 64116. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. Transporting *charcoal, charcoal briquets, fireplace logs, wood chips, and lighter fluid* (except commodities in bulk), from Branson, MO to points in AR, LA, MS, IN, TN, IL, OH, TX, OK, KY, NE, IA, WV, VA, PA, CA, CO, KS, UT, AL, and NV. (Hearing site: Kansas City, MO.)

MC 146671 (Sub-10F), filed November 9, 1979. Applicant: PRODUCE SERVICE, INC., d.b.a. PSI, 1120 Erie Street, North Kansas City, MO 64116. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. Transporting *cider, apple* (except in bulk), from Alton and Olney, IL, to points in IA, MO, KS, NE, OK, TX, AR, and CO. (Hearing site: Kansas City, MO.)

MC 146730 (Sub-8F), filed January 28, 1980. Applicant: L & W TRANSPORTATION, INC., Route 3, Box 195, Sedalia, MO 65301. Representative: Charles J. Fain, 333 Madison Street, Jefferson City, MO 65101. Transporting (1) *iron and steel pipe* from the facilities of Progressive Fabricators, Inc., at St. Louis, MO to Hope Creek Generating Station, Salem County, NJ and Bailly Station Nuclear Plant near Baillytown, IN; and (2) *steel plate* from the facilities of US Steel and Bethlehem Steel, at or near South Chicago, Gary, and Burns Harbor, IN to the facilities of Progressive Fabricators, Inc., at or near St. Louis, MO. (Hearing site: Jefferson City or St. Louis, MO.)

MC 146751 (Sub-4F), filed February 14, 1980. Applicant: J. C. LAWRENCE TRUCKING, INC., 1519 Ripley Street, P.O. Box 5331, Lake Station, IN 46405. Representative: Fred H. Daly, 2550 M Street NW., Suite 475, Washington, D.C. 20037. Transporting *iron and steel articles,* from the facilities of Connors Steel Company at or near Birmingham, AL, to points in IL, IN, IA, MI, MO, OH, PA, WV, WI, NY, MD, and DE. (Hearing site: Birmingham, AL or Chicago, IL.)

MC 146780 (Sub-3F), filed February 11, 1980. Applicant: MABE BROTHERS ENTERPRISES, INC., 5591 Williams Rd., Norcross, GA 30093. Representative: Thomas M. Mabe, 744 Buckskin Circle, Norcross, GA 30093. *Contract carrier,* transporting *yearbooks and printed matter, and material and supplies* used in the manufacture, printing and assembling of yearbooks between points in Forsyth County, NC, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with Hunter Publishing Company of Winston-Salem, NC. (Hearing site: Charlotte, NC or Columbia, SC.)

MC 147770 (Sub-2F), filed February 11, 1980. Applicant: WEST AMERICAN TRANSPORT, INC., 1260 W. North Temple, Salt Lake City, UT 84116. Representative: Mark K. Boyle, 10 West Broadway Bldg., Suite 400, Salt Lake City, UT 84101. *Contract carrier* transporting *machinery, equipment and supplies* used in or in connection with environmental and pollution control systems, filtration and sedimentation processes, and mining operations, (except commodities in bulk), between points in UT, on the one hand, and, on the other, points in the United States (except AK and HI) under continuing contract(s) with Envirotech Corporation of Menlo Park, CA. (Hearing site: Salt Lake City, UT.)

MC 148001 (Sub-2F), filed February 11, 1980. Applicant: M. G. Broaddus, III, Route 1, Box 113H, Bowling Green, VA 22427. Representative: Calvin F. Major, 200 W. Grace St., Richmond, VA 23220. *Contract carrier* transporting (1) *kiln dried lumber and bedframes,* from Fredericksburg, VA, to points in CT, MA, NY, OH, WV, NJ, MD, PA, MI, DE, NC, SC, GA, and KY, and (2) *lumber* used in the manufacture of picture frames and moldings, from points in CT, MA, NY, OH, WV, NJ, MD, PA, MI, DE, NC, SC, GA, and KY, to Bowling Green, VA, under continuing contract(s) in (1) with Clayborne C. Beck & Son, Inc., of Fredericksburg, VA, and in (2) with Foreign and Domestic Woods, Inc., of Bowling Green, VA. (Hearing site: Richmond, VA.)

MC 148521 (Sub-2F), filed February 13, 1980. Applicant: ALLEN TRANSIT, INC., 308 Leasure Way, New Bethlehem, PA 16242. Representative: David M. O'Boyle, 2310 Grant Bldg., Pittsburgh, PA 15219. *Contract carrier* transporting (1) *coal* from points in PA and MD to points in NY and OH, (2) *salt* from points in NY and MD to points in PA, and (3) *calcium chloride* from points in NY to points in PA under continuing contract(s) in (1) with Reddinger Coal Company, Inc., of Distant, PA, and Kittanning Freeport Coal Company of Brookville, PA, in (2) with Keystone Salt Service, Inc., of New Bethlehem, PA, and in (3) with Keystone Salt Service, Inc., of New Bethlehem, PA. (Hearing site: Washington, DC or Pittsburgh, PA.)

MC 149120 (Sub-1F), filed January 8, 1980. Applicant: WORLD WIDE THEATRICAL RENTALS, INC., 695 So. Glenwood Place, Burbank, CA 91506. Representative: Robert J. Nachshin, One Wilshire Building, Suite 1600, Wilshire Boulevard at Grand Avenue, Los Angeles, CA 90609. Transporting *equipment, materials, and supplies* for television, motion picture, live theatrical, industrial and promotional productions between points in the United States (except AK or HI). (Hearing site: Los Angeles, CA or Washington, DC.)

MC 149170 (Sub-3F), filed February 11, 1980. Applicant: ACTION CARRIER, INC., 1000 East 41st St., Sioux Falls, SD 57105. Representative: Carl L. Steiner, 39 South LaSalle St., Chicago, IL 60603. Transporting *such commodities* as are dealt in by retail or wholesale department stores (except commodities 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 Target Stores, a Division of Dayton-Hudson Corporation. Condition: The person or persons engaged in common control of applicant and another regulated carrier must file an application for approval under 49 U.S.C. 11343, or submit an affidavit indicating why such approval is unnecessary. (Hearing site: Montgomery or Dothan, AL.)

MC 149321F, filed February 4, 1980. Applicant: SCHMIDT TRUCKING, INC., 520 East 8th Street, Garner, IA 50438. Representative: Robert S. Lee, 1000 First National Bank Bldg., Minneapolis, MN 55402. *Contract carrier* transporting (1) *corrugated plastic tubing* between Lake Mills, IA, Montpelier, IN, Towanda and Lawrence, IL, Ann Arbor, MI and Geneva, NY, on the one hand, and, on the other, points in CO, ID, IL, IN, IA, KS, KY, MI, MN, MO, MT, NE, NY, ND, OH, PA, SD, UT, WI and WY (2) *equipment, material and supplies* used in the manufacture, distribution and installation of corrugated plastic tubing (except commodities in bulk) from points in CO, ID, IL IN, IA, KS, KY, MI, MN, MO, MT, NE, NY, ND, OH, PA, SD, UT, WI and WY to Lake Mills, IA, Towanda and Lawrence, IL, Montpelier, IN, Ann Arbor, MI and Geneva, NY, under continuing contract(s) with Certain-Teed/Daymond Company of Ann Arbor, MI. (Hearing site: Lansing, MI or Des Moines, IA.)

MC 149331F, filed February 4, 1980. Applicant: CITY CAR RELEASING CO., INC., 11631 Mt. Elliott, Detroit, MI 48212. Representative: William B. Elmer, 21635 East Nine Mile Rd., St. Clair Shores, MI 48080. Transporting *automobiles, truck, chassis, and vans,* in truckaway service, between Detroit, MI, and points in MI, OH, IN, IL, PA, IA and WI. (Hearing site: Detroit, MI.)

MC 149370F, filed February 12, 1980. Applicant: SEABOARD EXPRESS, INC., 5724 New Peachtree Road, Atlanta, GA 30341. Representative: E. Stephen

Heisley, 805 McLachlen Bank building, 666 Eleventh Street, NW., Washington, DC 20001. Transporting (1) *glass products, metal products, plastic products, paper products, wax products, clay products, feldspar products, wood products, foodstuffs, antipollution and biochemical apparatus, products used in radiological research, organic chemistry kits, talc, feldspar, candles, pottery, chinaware, ceramics, gift items, molds,* and *machinery,* (2) *parts and accessories* for the foregoing commodities, and (3) *materials, equipment and supplies* used in the manufacture or distribution of the foregoing commodities (except in bulk, in tank vehicles), between the facilities of Wheaton Industries at or near Des Plaines, IL, on the one hand, and, on the other, points in the U.S. (except AK and HI). (Hearing site: Washington, DC.)

MC 149370 (Sub-1F), filed February 12, 1980. Applicant: SEABOARD EXPRESS, INC., 5724 New Peachtree Road, Atlanta, GA 30341. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street, NW., Washington, DC 20001. Transporting (1) *glass products, metal products, plastic products, clay and clay products, feldspar, and talc* (except commodities in bulk), (2) *molds and machinery used in the manufacture of glass products* (except commodities in bulk), (3) *bottle coating systems* (except commodities in bulk), (4) *parts and accessories for the commodities in (2) and (3) above* (except commodities in bulk), and (5) *materials, equipment and supplies used in the manufacture and distribution of the commodities in (1), (2), (3), and (4) above* (except commodities in bulk), between the facilities of Flat River Glass Co., at or near Flat River, MO, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 149370 (Sub-2F), filed February 12, 1980. Applicant: SEABOARD EXPRESS, INC., 5724 New Peachtree Road, Atlanta, GA 30341. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street, NW., Washington, DC 20001. Transporting (1) *glass products, metal products, plastic products, clay and clay products, feldspar, and talc* (except commodities in bulk), (2) *molds and machinery used in the manufacture of glass products* (except commodities in bulk), (3) *bottle coating systems* (except commodities in bulk), (4) *parts and accessories for the commodities in (2) and (3) above* (except commodities in bulk); and (5) *materials, equipment and supplies used in the manufacture and distribution of the commodities in (1), (2), (3), and (4) above* (except commodities in bulk), between the facilities of Wheaton Industries at or near Centralia, IL, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 149380F, filed October 9, 1979. Applicant: NEYRINCK BROS., INC., 7140 Riga Highway, Riga, MI 49228. Representative: Wilhelmina Boersma, 1600 First Federal Building, Detroit, MI 48226. Transporting *feed* between points in IN, IL, MI and OH. (Hearing site: Detroit, MI or Washington, DC.)

MC 149380 (Sub-1F), filed October 9, 1979. Applicant: NEYRINCK BROS., INC., 7140 Riga Highway, Riga, MI 49228. Representative: Wilhelmina Boersma, 1600 First Federal Building, Detroit, MI 48226. Transporting *fertilizer* between points in IN, IL, MI, OH and WI. (Hearing site: Detroit, MI or Washington, DC.)

MC 150030 (Sub-1F), filed February 4, 1980. Applicant: NICHOLAS POLSELLI, d.b.a TEMPERATURE CONTROL TRANSPORT, 74 South Street, Troy, NH 03465. Representative: Robert G. Parks, 20 Walnut Street, Suite 101, Wellesley Hills, MA 02181. *Contract carrier,* transporting (1) *meats, smoked,* and (2) *cured meats,* in containers, in vehicles equipped with mechanical refrigeration, from the facilities of Colonial Provision Co., Inc., at Boston, MA to points in FL, under continuing contract(s) with Colonial Provision Co., Inc. of Boston, MA. (Hearing site: Boston, MA.)

MC 149320F, filed February 5, 1980. Applicant: EDWARD J. DOUGLAS AND LILLIAN M. DOUGLAS, d.b.a., DOUGLAS MOTOR COACH, 8 Surfside Ave., Winthrop, MA 02152. Representative: Frederic Pike, 18 Tremont St. Boston, MA 02108. Transporting *passengers and their baggage* in the same vehicle with passengers, in special operations, beginning and ending at Winthrop, MA and extending to points in FL. (Hearing site: Boston, MA.)

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Decided: March 12, 1980.

By the Commission, Review Board Number 2, Members Eaton, Liberman and Jensen.

MC 3062 (Sub-48F), filed January 14, 1980. Applicant: INMAN FREIGHT SYSTEM, INC., 321 N. Spring Ave., Cape Girardeau, MO 63701. Representative: Guy H. Boles (same address as applicant). Over regular routes, 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), serving Calvert City, KY as an off-route point in connection with carriers otherwise authorized regular-route operations. (Hearing site: St. Louis or Jefferson City, MO.)

MC 4963 (Sub-112F), filed January 14, 1980. Applicant: JONES MOTOR CO., INC., Bridge Street & Schuylkill Road, Spring City, PA 19475. Representative: Roland Rice, Suite 501, Perpetual Bldg., 1111 E Street, NW., Washington, DC 20004. Transporting *metal articles,* between the facilities of King Fifth Wheel, at Marshville, NC, on the one hand, and, on the other, points in WI, SC, IA, MI, AL, TN, KY, IN, WV, MO, IL, GA, PA, NY, ME, NH, and MD. (Hearing site: Charlotte, NC or Washington, DC.)

MC 20992 (Sub-60F), filed January 21, 1980. Applicant: DOTSETH TRUCK LINE, INC., Knapp, WI 54749. Representative: Bradfore E. Kistler, P.O. Box 82020, Lincoln, NE 68501. Transporting *such commodities as are dealt in or used by agricultural, industrial and materials handling equipment distributors and manufacturers* (except commodities in bulk, in tank vehicles), between points in Lake County, SD on the one hand, and, on the other, points in the United States (except AK, HI, and SD), restricted to the transportation of traffic originating at or destined to points in Lake County, SD. (Hearing site: Sioux Falls, SD.)

MC 32882 (Sub-136), filed Januaray 18, 1980. Applicant: MITCHELL BROS. TRUCK LINES, a corporation, 3841 North Columbia Boulevard, Portland, OR 97217. Representative: David J. Lister, P.O. Box 17039, Portland, OR 97217. Transporting *Motor graders* and *hydraulic asphalt paver extensions,* from the facilities of Bower Industries Inc., at or near Orange, CA, to points in the United States (except AK and HI). (Hearing site: Los Angeles, CA.)

MC 32882 (Sub-137F), filed January 18, 1980. Applicant: MITCHELL BROS. TRUCK LINES, a corporation, 3841 North Columbia Blvd., Portland, OR 97217. Representative: David J. Lister, P.O. Box 17039, Portland, OR 97217. Transporting (1) *self-propelled tractors* (except truck tractors), *loaders, backhoes, and bulldozers,* and (2) *parts, attachments and accessories for the commodities in* (1) above, from the facilities of J. I. Case Company, at or near Burlington and Bettendorf, IA to points in AZ, UT, WY, MT, ID, NV, CA, OR, NM, CO, and WA, restricted to traffic originating at the named origins. (Hearing site: Portland, OR.)

Note.—The person or persons who appear to be engaged in common control with another carrier must either file an application

under 49 U.S.C. § 11343(a)(1978) (formerly Section 5(2), of the Interstate Commerce Act), or submit an affidavit indicating why such approval is unncessary.

MC 61592 (Sub-484F), filed January 17, 1980. Applicant: JENKINS TRUCK LINE, INC., P.O. Box 697, Jeffersonville, IN 47130. Representative: E. A. DeVine, P.O. Box 737, Moline, IL 61265. Transporting (1) *fabricated plastic products, heating and air conditioning systems, sheet metal products, and pipe,* and (2) *equipment, materials,* and *supplies* used in the distribution and installation of the commodities in (1) above, between the facilities of Acme Manufacturing Company at Medina, NY, on the one hand, and, on the other, points in the United States (except AK and HI), restricted (a) to traffic originating at or destined to the named facilities and (b) against the transportation of commodities in bulk and those requiring special equipment. (Hearing site: Washington, DC.)

MC 87103 (Sub-45F), filed January 22, 1980. Applicant: MILLER TRANSFER AND RIGGING CO., a corporation, P.O. Box 322, Cuyahoga Falls, OH 44222. Representative: Edward P. Bocko (same address as applicant). Transporting (1) *boilers, parts, and accessories* for boilers, and (2) *equipment, materials, and supplies* used in the manufacture and distribution of the commodities in (1) above (except in bulk), between the facilities of Bryan Steam Corporation at Peru, IN on the one hand, and, on the other, points in the United States (except AK and HI), restricted to shipments originating at or destined to the named facilities. (Hearing site: Washington, DC.)

MC 96992 (Sub-24F), filed January 31, 1980. Applicant: HIGHWAY PIPELINE TRUCKING CO., P.O. Box 1517, Edinburg, TX 78539. Representative: Kenneth R. Hoffman, P.O. Box 2165, Austin, TX 78768. 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 commodities in bulk), from points in Cameron and Hidalgo Counties, TX to points in the United States (except AK and HI). (Hearing site: McAllen, TX.)

MC 99123 (Sub-8F), filed February 4, 1980. Applicant: QUAST TRANSFER, INC., P.O. Box 7, Winsted, MN 55395. Representative: James E. Ballenthin, 630 Osborn Bldg., St. Paul, MN 55102. 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) (1) between Hutchinson, MN, and junction MN Hwy 7 and MN Hwy 621, over MN Hwy 7, and (2) between Cokato, MN, and junction MN Hwy 7 and McLeod County Road at or near Silver Lake, MN, from Cokato over Wright County Road to the Wright-McLeod County line, then over McLeod County Road to the named junction at or near Silver Lake, and return over the same route. (Hearing site: St. Paul, MN.)

Note.—Applicant intends to tack the authority sought herein with its existing regular route authority which authorizes operations wholly within the state of MN.

MC 107012 (Sub-480F), filed January 18, 1980. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Highway 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: David D. Bishop (same address as applicant). Transporting *carpeting* from Dillon, SC and East Dublin, GA, to Minneapolis, MN. (Hearing site: Amsterdam, NY or Washington, DC.)

MC 107012 (Sub-481F), filed January 14, 1980. Applicant: NORTH AMERCIAN VAN LINES, INC., 5001 U.S. Highway 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: Bruce W. Boyarko (same address as applicant). Transporting *plastic bottles,* from the facilities of Hussey Molding, at or near Manchester, NH, to Charleston, TN. (Hearing site: New York, NY or Washington, DC.)

MC 107012 (Sub-486F), filed January 31, 1980. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Highway 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: David D. Bishop (same address as applicant). Transporting (1) *paper, paper products, plastics, plastic products, corrugated boxes, and pulp board* and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities named in (1) above, between points in the United States (exept AZ, CA, ID, MT, NM, NV, OR, UT, WA and WY), restricted to the transportation of traffic originating at or destined to the facilities of Crown Zellerbach Corporation. (Hearing site: New York, NY or Washington, DC.)

MC 107103 (Sub-26F), filed February 8, 1980. Applicant: ROBINSON CARTAGE CO., 2712 Chicago Drive, S.W., Grand Rapids, MI 49509. Representative: Ronald J. Mastej, 900 Guardian Building, Detroit, MI 48226. Transporting *gypsum, gypsum products, and materials, equipment and supplies used in the manufacture, installation and distribution of the aforenamed commodities,* between the facilities of Grand Rapids Gypsum Co., Inc. at Grand Rapids, MI, on the one hand, and, on the other, points in IL, IN, IA, KY, OH and WI. (Hearing site: Lansing or Detroit, MI.)

MC 108053 (Sub-172F), filed January 17, 1980. Applicant: LITTLE AUDREY'S TRANSPORTATION CO., INC., P.O. Box 129, Fremont, NE 68025. Representative: Arnold L. Burke, 180 N. LaSalle Street, Chicago, IL 60601. Transporting *general commodites,* (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) between the facilities of Bridgeview Distribution Centers, Inc., at or near Bridgeview, IL, on the one hand, and, on the other, points in AZ, CA, CO, ID, MT, NV, NM, OR, UT, WA, and WY, restricted to the transportation of traffic which originates at or is destined to the named facilities. (Hearing site: Chicago, IL.)

MC 111812 (Sub-709F), filed January 14, 1980. Applicant: MIDWEST COAST TRANSPORT, INC., P.O. Box 1233, Sioux Falls, SD 57101. Representative: Lamoyne Brandsma (same address as applicant). Transporting *arc welders, battery chargers, and parts for arc welders and battery chargers,* from the facilities of Century Manufacturing Company, at or near Minneapolis, MN, to points in AZ, CA, CO, ID, MT, NV, NM, OR, UT, WA and WY. (Hearing site: Minneapolis, MN.)

MC 115523 (Sub-201F), filed December 3, 1979. Applicant: CLARK TANK LINES COMPANY, a corporation, 1450 Beck St., Salt Lake City, UT 84116. Representative: William S. Richards, P.O. Box 2465, Salt Lake City, UT 84110. Transporting *clay,* from points in Nye County, NV to points in AZ, CA, CO, ID, KS, MT, NE, NV, ND, OK, OR, SD, TX, UT, WA, and WY. (Hearing site: Salt Lake City, UT.)

MC 115523 (Sub-204F), filed January 21, 1980. Applicant: CLARK TANK LINES COMPANY, a corporation, 1450 Beck St., Salt Lake City, UT 84116. Representative: William S. Richards, P.O. Box 2465, Salt Lake City, UT 84110. Transporting (1) *chemicals,* between points in Salt Lake, Davis, Weber, Utah, and Wasatch Counties, UT, on the one hand, and, on the other, points in the United States on and west of a line beginning at the mouth of the Mississippi River, and extending along the Mississippi River to its junction with the western boundary of Itasca County, MN, then northward along the western boundaries of Itasca and Koochiching Counties, MN, to the International

Boundary line between the United States and Canada, restricted to the transportation of shipments moving from or to the facilities of Nalco Chemical Company; and (2) *chemicals* (in bulk), from Casper, WY, to points in AZ, CA, CO, ID, MT, NV, NM, ND, OR, UT, WA, and WY. (Hearing site: Salt Lake City, UT.)

MC 116763 (Sub-644F), filed January 21, 1980. Applicant: CARL SUBLER TRUCKING, INC., North West St., Versailles, OH 45380. Representative: Gary J. Jira (same address as applicant). Transporting *such commodities* as dealt in or used by wholesale, retail chain grocery and food business houses and *foodstuffs* (except commodities in bulk, in tank vehicles), from points in the U.S. in and east of MN, IA, MO, OK, and TX (except MI), to points in MI, restricted to the transportation of traffic originating at the named origins and destined to the facilities of Allied Supermarkets, Inc., in MI. (Hearing site: Detroit, MI.)

MC 118202 (Sub-149F), filed January 17, 1980. Applicant: SCHULTZ TRANSIT, INC., P.O. Box 406, 323 Bridge St., Winona, MN 55987. Representative: Robert S. Lee, 1000 First National Bank Bldg., Minneapolis, MN 55402. Transporting *sauerkraut*, from North Norwich and Ontario Center, NY to points in IL, IN, IA, MI, MN, NE, ND, OH, SD, and WI. (Hearing site: Buffalo, NY.)

MC 118263 (Sub-102F), filed January 22, 1980. Applicant: COLDWAY CARRIERS, INC., P.O. Box 2038, Clarksville, IN 47130. Representative: William P. Whitney, Jr., 708 McClure Bldg., Frankfort, KY 40601. Transporting *foodstuffs* (except in bulk), from the facilities of Beatrice Foods Company at or near Archbold and Napoleon, OH, to points in AL, FL, GA, MS, NC, SC, and TN, restricted to shipments moving from above named origins. (Hearing site: Toledo or Cleveland, OH.)

MC 118263 (Sub-103F), filed January 22, 1980. Applicant: COLDWAY CARRIERS, INC., P.O. Box 2038, Clarksville, IN 47130. Representative: William P. Whitney, Jr., 708 McClure Building, Frankfort, KY 40601. Transporting *animal feed* (except in bulk), from the facilities of the Hubbard Milling Co., at Louisville, KY, to points east of MN, IA, MO, AR, and LA. (Hearing site: Louisville or Lexington, KY.)

MC 118263 (Sub-104F), filed January 22, 1980. Applicant: COLDWAY CARRIERS, INC., P.O. Box 2038, Clarksville, IN 47130. Representative: William P. Whitney, Jr., 708 McClure Building, Frankfort, KY 40601. Transporting *frozen foods* (1) from the facilities of Pet Incorporated, Frozen Foods Division, at Allentown and Chambersburg, PA, and public storage facilities used by Pet Incorporated at Fogelsville and Waynesboro, PA, Winchester, VA, and Martinsburg and Ranson, WV, to points in AL, GA, IL, IN, KY, LA, MI, MS, NY, NC, OH, OK, SC, TN, TX, VA, and WV; and (2) from the facilities of Pet Incorporated, Frozen Foods Division, Chickasha, OK, and public storage facilities used by Pet Incorporated at Tulsa, OK, to points in IL, IN, KY, MI, OH, and PA. (Hearing site: St. Louis, MO or Louisville, KY.)

MC 119493 (Sub-352F), filed January 15, 1980. Applicant: MONKEM COMPANY, INC., P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone (same address as applicant). Transporting *canned and preserved foodstuffs*, from the facilities of Heinz USA, at or near Muscatine and Iowa City, IA, to points in AR, KY, OK, IN, and TX, restricted to traffic originating at the named facilites and destined to the named States. (Hearing site: Pittsburgh, PA or Chicago, IL.)

MC 119493 (Sub-355F), filed January 7, 1980. Applicant: MONKEM COMPANY, INC., P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone (same address as applicant). Transporting *alcoholic liquors* (except in bulk, in tank trucks), and *materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors, between Ft. Smith, AR, Bardstown and Louisville, KY, Plainfield, IL, and New Orleans, LA, on the one hand, and, on the other, points in and east of MT, WY, CO, and NM, restricted to traffic from or to the facilities of Hiram Walker & Sons, Inc., at the above locations. (Hearing site: Peoria or Chicago, IL.)

MC 126822 (Sub-80F), filed January 28, 1980. Applicant: WESTPORT TRUCKING COMPANY, a corporation, 15580 South 169 Highway, Olathe, KS. Representative: John T. Pruitt (same address as applicant). 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 the use of special equipment), between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of GAF Corporation. (Hearing site: Washington, DC.)

MC 129032 (Sub-124F), filed January 11, 1980. Applicant: TOM INMAN TRUCKING, INC., 5656 South 129th East Avenue, Tulsa, 74145. Representative: David R. Worthington (same address as applicant). Transporting *alcoholic liquors*, and *materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors (except commodities in bulk, in tank vehicles), between Ft. Smith, AR, Bardstown, KY, Louisville, KY, New Orleans, LA, Plainfield, IL, on the one hand, and, on the other, points in the United States (except AK and HI) restricted to traffic originating at or destined to the facilities of Hiram Walker and Sons, Inc. (Hearing site: Chicago, IL or St. Louis, MO.)

MC 129712 (Sub-29F), filed January 14, 1980. Applicant: GEORGE BENNETT MOTOR EXPRESS, INC., P.O. Box 569, McDonough, GA 30253. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Rd., N.E., Atlanta, GA 30326. *Contract carrier* transporting (1) *metal buildings*, knocked down, and *parts* for metal buildings, (2) *meter enclosures*, and (3) *materials, equipment, and supplies* used in the installation, maintenance and manufacture of the commodities named in (1) and (2) above, between the facilities of Parkline, Inc., in (a) Putnam County, WV, and (b) Creek County, OK, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with Parkline, Inc. (Hearing site: Atlanta, GA.)

MC 133403 (Sub-4F), filed December 17, 1979. Applicant: HUDSON TRANSIT CORPORATION, 17 Franklin Turnpike, Mahwah, NJ 07430. Representative: Samuel B. Zinder, 98 Cutter Mill Rd., Great Neck, NY 11021. Transporting *passengers and their baggage* and *express and newspapers*, in the same vehicle with passengers, (1) between Painted Post, NY and Andover, NY, from junction NY Hwy 17 and NY Hwy 417 at or near Painted Post, NY over NY Hwy 17 to junction NY Hwy 36 (Exit 34) near Hornell, NY, then over NY Hwy 36 to junction NY Hwy 21, then over NY Hwy 21 to junction NY Hwy 417, and return over the same route, serving all intermediate points, (2) between junction county Hwy 11 and NY Hwy 17 (Exit 39) and junction NY Hwy 415 and NY Hwy 17 (Exit 38) at Bath, NY, from junction county Hwy 11 and NY Hwy 17 (Exit 39) over county Hwy 11 to NY Hwy 415, then over NY Hwy 415 to NY Hwy 17 (Exit 38) and return over the same route, serving all intermediate points, and (3) between Afred Station, NY, and Alfred, NY, over NY Hwy 244, serving all intermediate points. (Hearing site: Binghamton or Elmira, NY.)

MC 134183 (Sub-13F), filed February 13, 1980. Applicant: C & E TRANSPORT, INC., d.b.a. C. E. ZUMSTEIN CO., P.O. Box 27, Lewisburg, OH 45338. Representative: E. Stephen Heisley, 805

McLachlen Bank Bldg., 666 Eleventh St. NW., Washington, DC 20001. *Contract carrier* transporting (1) *carpet strip and adhesives,* from Asheville, NC, to points in and east of MT, WY, CO, and NM, and (2) *nails,* from Savannah, GA, to Asheville, NC, under continuing contract(s) with Roberts Consoldiated Industries, Inc., City of Industry, CA. (Hearing site: Los Angeles, CA.)

MC 134922 (Sub-319F), filed January 28, 1980. Applicant: B. J. McADAMS, INC., Route 6, Box 15, North Little Rock, AR 72118. Representative: Bob McAdams (same address as applicant). Transporting *wire* and *cable,* from Ashton and Phillipsdale, RI, to points in AR, LA, MS, OK, TN, and TX. (Hearing site: Washington, DC or Philadelphia, PA.)

Note.—Applicant states the purpose of this application is to replace interline service it is presently providing (in part) in conjunction with other carriers, with single-line service.

MC 135152 (Sub-39F), filed January 31, 1980. Applicant: CASKET DISTRIBUTORS, INC., Rural Route No. 2, P.O. Box No. 327, West Harrison, IN 45030. Representative: Jack B. Josselson, 700 Atlas Bank Bldg., Cincinnati, OH 45202. Transporting (1) *household appliances,* and (2) *equipment, materials and supplies* used in the manufacture and distribution of household appliances, (except commodities in bulk), from the facilities of the General Electric Company, at Louisville and Appliance Park, KY to points in IL and MO. (Hearing site: Washington, DC.)

Note.—Dual operations maybe involved.

MC 138313 (Sub-68F), filed January 30, 1980. Applicant: BUILDERS TRANSPORT, INC., 409 14th St. SW., Great Falls, MT 59404. Representative: Irene Warr, 430 Judge Building, Salt Lake City, UT 84111. Transporting *barite mud treating compound,* from points in Missoula County, MT, to points on the international boundary line between the United States and Canada in ID and MT. (Hearing site: Washington, DC.)

MC 139193 (Sub-115F), filed February 12, 1980. Applicant: ROBERTS & OAKE, INC., 4240 Blue Ridge Blvd., Kansas City, MO 64133. Representative: Terrence D. Jones, 2033 K St. NW., Washington, DC 20006. Contract carrier transporting (1) *frozen foods,* from the facilities of Banquet Foods Corporation, at or near Kansas City, Marshall, Macon, Moberly, Milan, and Carrollton, MO, to points in AL, AR, FL, GA, LA, MS, and TN, and (2) *such commodities, materials, equipment, and supplies* dealt in or utilized by manufacturers of frozen foods, in the reverse direction, under continuing contract(s) with Banquet Foods Corporation of St. Louis, MO. (Hearing site: Washington, DC.)

MC 140563 (Sub-51F), filed January 30, 1980. Applicant: W. T. MYLES TRANSPORTATION CO., a corporation, P.O. Box 321, Conley, GA 30027. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345. Transporting *scrap or waste newspapers,* from points in NJ, NY, and DC, to points in Laurens County, GA. (Hearing site: Atlanta, GA.)

MC 140612 (Sub-80F), filed January 30, 1980. Applicant: ROBERT F. KAZIMOUR, P.O. Box 2207, Cedar Rapids, IA 52406. Representative: J. L. Kazimour (same address as applicant). Transporting *general commodities,* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, in tank vehicles, and those requiring special equipment), between these points in the United States in and west of MI, OH, KY, TN, NC, SC, GA, and FL, restricted to traffic originating at or destined to the facilities used by the Carnation Co. (Hearing site: Los Angeles, CA.)

MC 141002 (Sub-1F), filed January 28, 1980. Applicant: ARNEL TOURS, a corporation, 229 Peachtree St., N.E., Atlanta, GA 30303. Representative: Bruce E. Mitchell, 3390 Peachtree Road, N.E., Atlanta, GA 30326. Transporting *passengers and their baggage,* in the same vehicle with passengers, (1) in charter operations, between points in Fulton, Clayton, Cobb, Douglas, Gwinett, DeKalb, Dougherty, Clarke, Walton, Barrow, Oconee, Morgan, Putnam, Hall, Haralson, Fayette, Coweta, Spalding, Cherokee, Forsyth, Rockdale, Newton, Henry, Carroll, Bartow, Paulding, Jackson, Upson, and Madison Counties, GA, to points in the United States (including AK, but except HI); and (2) in round trip special operations, beginning and ending at points in GA, those points in AL on and east of a line beginning at the AL–TN State line, and extending along U.S. Hwy 31 to Flomation, and then along U.S. Hwy 29 to the AL–FL State line, those points in TN on and east of U.S. Hwy 231, and those points in SC on, south and west of Interstate Hwy 26, and extending to points in the United States (except AK and HI); and (3) in special and charter operations from points in the United States (except AK and HI) to those points in GA, AL, TN, and SC described in (2) above, restricted to traffic having an immediately prior movement by air. (Hearing site: Atlanta, GA.)

MC 141252 (Sub-11F), filed January 21, 1980. Applicant: PAN WESTERN CORPORATION, 4105 Las Lomas Ave.; Las Vegas, NV 89102. Representative: Irene Warr, 430 Judge Building, Salt Lake City, UT 84111. Transporting *clay pipe* and *fittings,* from the facilities of Mission Clay Products, at or near Corona, CA, to points in Clark and Nye Counties, NV, and Coconio and Navajo Counties, AZ. (Hearing site: Las Vegas, NV.)

MC 141403 (Sub-2F), filed February 8, 1980. Applicant: ROBERT RUPPRECHT d.b.a. REPCO, 900 North Watertown Road, Jefferson, WI 53549. Representative: Michael S. Varda, 121 South Pinckney Street, Madison, WI 53703. Transporting *malt beverages,* from Milwaukee, WI, to points in the Upper Peninsula of MI (except Sault Ste. Marie). Condition: Applicant shall maintain separate accounts and records for its for-hire carrier operations, distinct from its other business activities. (Hearing site: Milwaukee, WI or Chicago, IL.)

MC 141532 (Sub-64F), filed January 14, 1980. Applicant: PACIFIC STATES TRANSPORT, INC., 3328 East Valley Road, Renton, WA 98055. Representative: Henry C. Winters, 525 Evergreen Building, Renton, WA 98055. Transporting *lumber and wood products,* from points in LA and TX, to points in CO and NM. (Hearing site: San Francisco, CA.)

MC 141532 (Sub-65F), filed January 14, 1980. Applicant: PACIFIC STATES TRANSPORT, INC., 3328 East Valley Road, Renton, WA 98055. Representative: Henry C. Winters, 525 Evergreen Building, Renton, WA 98055. Transporting *olivene sand,* in bags, from Hamilton, WA, to points in Alameda, Contra Costa, San Francisco, and Santa Clara Counties, Ca. (Hearing site: San Francisco, CA.)

MC 141532 (Sub-66F), filed January 19, 1980. Applicant: PACIFIC STATES TRANSPORT, INC., 3328 East Valley Road, Renton, WA 98055. Representative: Henry C. Winters, 525 Evergreen Building, Renton, WA 98055. Transporting *pipe and pipe fittings,* from the facilities of Wheeling Machine Products, at or near (a) Wheeling, WV and (b) Cambridge, OH, to Los Angeles and Woodlake, CA and Vancouver, WA. (Hearing site: Los Angeles, CA.)

MC 141533 (Sub-15F), filed February 7, 1980. Applicant: LYN TRANSPORT, INC., 37 North Central Ave., Elmsford, NY 10532. Representative: Bruce J. Robbins, 118–21 Queens Blvd., Forest Hills, NY 11375. Transporting *such commodities* as are dealt in or used by chain grocery and food business houses (except commodities in bulk, in tank vehicles), in vehicles equipped with

mechanical refrigeration, between New York, NY on the one hand, and, on the other, points in AL, FL, and GA. (Hearing site: New York, NY.)

MC 141533 (Sub-16F), filed February 7, 1980. Applicant: LYN TRANSPORT, INC., 37 North Central Ave., Elmsford, NY 10532. Representative: Bruce J. Robbins, 118–21 Queens Blvd., Forest Hills, NY 11375. Transporting *such commodities* as are dealt in or used by chain grocery and food business houses (except commodities in bulk, in tank vehicles), in vehicles equipped with mechanical refrigeration, between New York, NY on the one hand, and, on the other, points in IL, IN, MI, OH, WV, and WI. (Hearing site: New York, NY.)

MC 141533 (Sub-17F), filed February 8, 1980. Applicant: LYN TRANSPORT, INC., 37 North Central Ave., Elmsford, NY 10532. Representative: Bruce J. Robbins, 118–21 Queens Blvd., Forest Hills, NY 11375. Transporting *foodstuffs* (except in bulk), from the facilities of Valley Distributing & Storage Company, at or near Wilkes-Barre and Scranton, PA, to New York, NY. (Hearing site: New York, NY.)

MC 142672 (Sub-114F), filed January 14, 1980. Applicant: DAVID BENEUX PRODUCE & TRUCKING, INC., P.O. Box Drawer F, Mulberry, AR 72947. Representative: Don Garrison, P.O. Box 1065, Fayetteville, AR 72701. Transporting *expandable polystyrene beads,* from points in IL, NJ, and NY, to the facilities of Electro Foam Packaging Corporation, at or near Sallisaw, OK. (Hearing site: Ft. Smith, AR or Tulsa, OK.)

Note.—Dual operations may be involved.

MC 142672 (Sub-115F), filed January 18, 1980. Applicant: DAVID BENEUX PRODUCE & TRUCKING, INC., P.O. Drawer F, Mulberry, AR 72947. Representative: Don Garrison, P.O. Box 1065, Fayetteville, AR 72701. Transporting *fruitcakes and candy,* from Bogart, GA to points in the United States (except AK and HI). (Hearing site: Philadelphia, PA or FT. Smith, AR.)

Note.—Dual operations may be involved.

MC 142672 (Sub-116F), filed January 18, 1980. Applicant: DAVID BENEUX PRODUCE & TRUCKING, INC., P.O. Drawer F, Mulberry, AR 72947. Representative: Don Garrison, P.O. Box 1065, Fayetteville, AR 72701. Transporting *foodstuffs* (except frozen) from Stockton, Modesto and Ventura, CA, to points in CT, MA, MD, NJ, NY and PA. (Hearing site: Stockton, CA or Ft. Smith, AR.)

Note.—Dual operations may be involved.

MC 142672 (Sub-119F), filed January 18, 1980. Applicant: DAVID BENEUX PRODUCE & TRUCKING, INC., P.O. Drawer F, Mulberry, AR 72947. Representative: Don Garrison, P.O. Box 1065, Fayetteville, AR, 72701. Transporting *alcoholic liquors,* and *materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors, (except commodities in bulk, in tank vehicles), between Ft. Smith, AR, Bardstown and Louisville, KY, New Orleans, LA, and Plainsfield, IL, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc. (Hearing site: Peoria, IL or Ft. Smith, AR.)

Note.—Dual operations may be involved.

MC 144122 (Sub-68F), filed January 31, 1980. Applicant: CARRETTA TRUCKING, INC., S. 160 Route 17 North, Paramus, NJ 07652. Representative: Joseph Carretta (same address as applicant). Transporting *electrical wire and cable* between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Continental Copper and Steel Ind., Inc., Hatfield Wire and Cable Division. (Hearing site: New York, NY or Washington, DC.)

Note.—Dual operations may be involved.

MC 144572 (Sub-35F), filed January 31, 1980. Applicant: MONFORT TRANSPORTATION COMPANY, a corporation, P.O. Box G, Greeley, CO 80631. Representative: John T. Wirth, 717—17th Street, Suite 2600, Denver, CO 80202. Transporting: *alcoholic beverages, and nonalcoholic beverage mixes* (except commodities in bulk), from St. Paul, MN, St. Louis, MO, Phoenix, AZ, Seattle, WA, and Houston, TX, to the facilities of C & C Distributing Company, at Denver, CO. (Hearing site: Denver, CO.)

Note.—Dual operations may be involved.

MC 144622 (Sub-136F), filed January 18, 1980. Applicant: GLENN BROS. TRUCKING, INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Phillip G. Glenn (same address as applicant). 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), between the facilities used by L & M Surco Mfg., Inc., at or near (a) Atlanta, GA, (b) Dallas, TX, (c) South River, NJ, and (d) Emeryville, CA, on the one hand, and, on the other, points in the United States (including AK, but except HI). (Hearing site: Little Rock, AR.)

Note.—Dual operations may be involved.

MC 144622 (Sub-140F), filed January 28, 1980. Applicant: GLENN BROS. TRUCKING, INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Phillip G. Glenn (same address as applicant). Transporting *meats, meat products, meat byproducts, and articles* distributed by meat-packing houses, and *commodities* used by meat packers in the conduct of their businesses, as described in Sections A, C, and D of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766, from St. Joseph, MO to points in the United States (including AK, but except HI), restricted to traffic originating at the facilities of the Armour Company, at St. Joseph, MO. (Hearing site: Little Rock, AR.)

Note.—Dual operations may be involved.

MC 144622 (Sub-141F), filed January 28, 1980. Applicant: GLENN BROS. TRUCKING, INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Phillip G. Glenn (same address as applicant). Transporting *frozen meats,* from Chicago and East Peoria, IL, Oklahoma City, OK, Logansport, IN, Cincinnati, OH, Louisville, KY, Milwaukee, WI, and points in IA, MO, KS, MN, and NE, to Greenville, MS. (Hearing site: Little Rock, AR.)

Note.—Dual operations may be involved.

MC 144793 (Sub-2F), filed January 28, 1980. Applicant: RICHARD PELLETIER, d.b.a. PELLETIER TRUCKING, 8744 Avalon St., Alta Loma, CA 91701. Representative: Richard Pelletier (same address as applicant). Transporting *electric generators and motors,* and *materials and supplies* used in the manufacture thereof, between points in CA, on the one hand, and, on the other, points in OK, MO, and MI. (Hearing site: Los Angeles, CA.)

MC 145102 (Sub-49F), filed January 14, 1980. Applicant: FREYMILLER TRUCKING, INC., P.O. Box 188, Shullsburg, WI 53588. Representative: Michael J. Wyngaard, 150 East Gilman Street, Madison, WI 53703. Transporting *such commodities* as are dealt in or used by manufacturers or distributors of plastic, wooden and health care products, from the facilities of Bemis Manufacturing Company, at or near Sheboygan Falls, WI, to points in the United States (except AK and HI) (Hearing site: Madison or Milwaukee, WI.)

MC 145152 (Sub-172F), filed January 22, 1980. Applicant: BIG THREE TRANSPORTATION, INC., Post Office Box 706, Springdale, AR 72764. Representative: Don Garrison, Post Office 1065, Fayetteville, AR 72701. Transporting *such commodities* as are dealt in or used by manufacturers or

distributors of barbeque materials and supplies (except commodities 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 used by Husky Industries, Inc. (Hearing site: Atlanta, GA or Fayetteville, AR.)

MC 145743 (Sub-16F), filed January 24, 1980. Applicant: T.F.S., INC., RR 2, Box 126, Grand Island, NE 68801. Representative: A. J. Swanson, P.O. Box 1103, 226, N. Phillips Ave., Sioux Falls, SD 57101. Transporting *beverages and alcoholic liquors and wines,* from points in MN, MO, KY, OH, IA and CA, to points in Hall County, NE. (Hearing site: Lincoln, NE or Sioux Falls, SD.)

MC 145802 (Sub-5F), filed January 28, 1980. Applicant: RONALD E. REED, d.b.a. TRIPLE R TRUCKING, RFD, Laurens, IA 50554. Representative: James M. Hodge, 1980 Financial Center, Des Moines, IA 50309. Transporting *frozen bakery products,* from Nashville, TN, to points in AR, IA, IL, KS, MI, MN, MO, NE, OK, OR, TX, WA, and WI. (Hearing site: Nashville, TN.)

MC 145842 (Sub-10F), filed December 3, 1979. Applicant: SUNDERMAN TRANSFER, INC., Box 63, Windom, MN 56101. Representative: Carl E. Munson, 469 Fischer Bldg., Dubuque, IA 52001. Transporting *fresh meat, frozen meat, and meat products,* from Kenosha, WI, to points in FL, GA, IL, IN, MI, NY, NC, OH, PA, SC, and Va. (Hearing site: Chicago, IL or Milwaukee, WI.)

Note.—Dual operations may be involved.

MC 145883 (Sub-3F), filed, January 24, 1980. Applicant: DANIEL B. ROEDIGER, Rt. 5, Box 205, Wapakoneta, OH 45895. Representative: David A. Turano, 100 East Broad St. Columbus, OH 43215. Transporting *soybean meal,* in bulk, from the facilities of Cargill, Inc., at or near Sidney, OH, to points in IN, KY, MI, OH, PA, and WV. (Hearing site: Columbus, OH).

MC 146032 (Sub-6F), filed January 28, 1980. Applicant: SKYCAB, INC., 137 North 4th St., Philadelphia, PA 19106. Representative: Steven M. Tannenbaum, 133 North 4th St., Philadelphia, PA 19106. Transporting *such commodities* as are dealt in or used by distributors of photographic equipment and supplies except commodities in bulk, in tank vehicles), from the facilities of Berkey Marketing Companies, Division of Berkey Photo, Inc., In Queens County, NY, to Philadelphia and Pittsburgh, PA, Baltimore, MD, Richmond, VA, Charleston, WV, Charlotte, NC, Atlanta, GA, New Orleans, LA, Orlando, FL, Columbus and Toledo, OH, Detroit, MI, Chicago, IL, St. Louis, MO and Denver, CO. (Hearing site: Philadelphia, PA.)

MC 146193 (Sub-6F), filed January 28, 1980. Applicant: CAMPBELL GRAIN CORPORATION, Box 94 Humeston, IA 50123. Representative: Thomas E. Leahy, Jr., 1980 Financial Center, Des Moines, IA 50309. Transporting *fertilizer,* from the facilities of Kaiser Agricultural Chemicals at (1)(a) East Dubuque and Cordova, IL, (b) Alexandria, Trenton, Brunswick, and Hannibal, MO, and (c) South Sioux City and Omaha, NE, to points in IA, (2) White Cloud, KS, to points in NE and MO, and (3) East Dubuque, IL, to points in WI and MN, restricted to traffic originating at named origins and destined to named destinations. (Hearing site: Omaha, NE or Kansas City, MO.).

MC 146893 (Sub-9F), filed January 14, 1980. Applicant: BROWN TRANSPORT, INC., Box 327A; R.R. 3, West Alexandria, OH 45381. Representative: Lewis S. Witherspoon, 88 E. Broad St., Columbus, Oh 43215. *Contact carrier,* transporting *slag,* in bulk, between Middletown, OH, on the one hand, and, on the other points in IN, under continuing contract(s) with The Calumite Company, of Trenton, NJ. (Hearing site: Cincinnati, OH.)

MC 146972 (Sub-3F), filed January 14, 1980. Applicant: BLUE STAR TRUCKING, INC., 140 Jackson Ave., Edison, NJ 08817. Representative: Thaddeus C. Raczkowski, 3288 Route #27, P.O. Box 9, Kendall Park, NJ 08824. *Contract carrier,* transporting (1) *foodstuffs* (except in bulk), and (2) *materials, supplies and equipment used* in the manufacture and distribution of foodstuffs, between points in MD, NJ, and PA, on the one hand, and, on the other, the facilities of Ragu Foods, at Manchester and Rochester, NY, under continuing contract(s) with Ragu Foods, Inc. (Hearing site: Newark, NJ or New York City, NY.)

MC 147223 (Sub-3F), filed February 15, 1980. Applicant: AMERICAN PRIORITY ENTERPRISES, INC., 408 East Elizabeth Ave., Linden, NJ 07601. Representative: Robert B. Pepper, 168 Woodbridge Ave., Highland Park, NJ 08904. *Contract carrier* transporting *drugs, medicines, pharmaceuticals, stomahesive products, toothbrushes, store displays, printed matter,* (1) between Somerset, NJ, on the one hand, and, on the other, Somerville, MA, Alexandria, VA, and Baltimore, MD; (2) from Greensboro, NC, to New Brunswick, NJ; and (3) between New York, NY, and Kenly, NC, under continuing contract(s) with E. R. Squibb and Son, Inc., of New Brunswick, NJ.(Hearing site: Newark, NJ.)

MC 147413 (Sub-5F), filed December 31, 1979. Applicant: SUNRICH TRANSPORTATION COMPANY, a corporation, 303 South Santa Fe, Pueblo, CO 81002. Representative: William J. Lippman, Suite 330 Steele Park, 50 South Steele Street, Denver, CO 80209. *Contract carrier* transporting *Meats, meat products and 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, 766 from Pueblo, CO to points in NV, restricted to the transportation of traffic originating at or destined to facilities used by Alpha Beta Packing Company, Pueblo, CO under continuing contract(s) with Alpha Beta Packing Company, of Pueblo, CO. (Hearing site: Denver, CO.)

MC 147413 (Sub-6F), filed February 5, 1980. Applicant: SUNRICH TRANSPORTATION COMPANY, a corporation, 303 South Santa Fe, Pueblo, CO 81002. Representative: William J. Lippman, 50 South Steele Street, Denver, CO 80209. *Contract carrier* transporting *flour and taco shells,* from points in CA to Pueblo, CO, under continuing contract(s) with Candy's Tortilla Factory, Inc., of Pueblo, CO. (Hearing site: Denver, CO.)

MC 147553 (Sub-6F), filed January 18, 1980. Applicant: DENNIS MOSS AND GARY MOSS, d.b.a. MOTOR WEST, P.O. Box 1405, Caldwell, ID 83605. Representative: Timothy R. Stivers, P.O. Box 162, Boise, ID 83701. Transporting *insulation and insulating materials,* from points in CA to points in ID. (Hearing site: Boise, ID.)

MC 147612 (Sub-3F), filed January 31, 1980. Applicant: WILLARD D. VAN ZUIDEN, Box 333, Albany, IL 61230. Representative: Joseph Winter, 29 South LaSalle Street, Chicago, IL 60603. Transporting: *iron and steel articles,* from the facilities of Northwestern Steel and Wire Company, at Sterling and Rock Falls, IL, to points in AL, AR, CO, CT, GA, IL, IN, IA, KS, KY, MI, MN, MO, NE, NY, NC, ND, OH, OK, PA, SD, TN, TX, and WI, restricted to the transportation of traffic originating at the named facilities and destined to the named destinations. (Hearing site: Chicago, IL.)

Note.—Dual operations may be involved.

MC 147783 (Sub-1F), filed February 4, 1980. Applicant: B. L. CARTAGE CO., a corporation, 10735 South Cicero Ave., Oak Lawn, IL 60453. Representative: Leonard R. Kofkin, 39 South La Salle St., Chicago, IL 60603. Transporting *asphalt and asphalt products,* in bulk, in tank vehicles, from Janesville, WI to points in IL on and north of U.S. Hwy 136. (Hearing site: Chicago, IL.)

MC 148363 (Sub-2F), filed February 8, 1980. Applicant: WILLIAM H. BECK, INC., P.O. Box 51, Fulton, NY 13069. Representative: David M. Marshall, 101 State St., Suite 304, Springfield, MA 01103. *Contract carrier,* transporting *liquid brewers condensed solubles, brewers yeast, and grain, and by-products,* resulting from the manufacture of beer, in bulk, between the facilities of Anheuser Busch, Inc., in Merrimack, NH, East Brunswick and Newark, NJ, and Syracuse, NY, under continuing contract(s) with Anheuser Busch, Inc., of St. Louis, MO. (Hearing site: Albany, NY or Boston, MA.)

MC 148723 (Sub-2F), filed January 28, 1980. Applicant: SOUTHWEST FREIGHT DISTRIBUTORS, INC., 1320 Henderson, North Little Rock, AR 72114. Representative: James M. Duckett, 927 Pyramid Life Bldg., Little Rock, AR 72201. *Contract carrier,* transporting *such commodities* as are dealt in by retail variety and discount stores (except commodities in bulk), from Little Rock, AR, to points in TX, LA, MS, TN, and MO, restricted to shipments originating at and destined to the facilities of Sterling Stores Company, Inc., under continuing contract(s) with Sterling Stores Company, Inc., of Little Rock, AR. (Hearing site: Little Rock, AR.)

MC 148732 (Sub-2F), filed January 15, 1980. Applicant: L & J TRUCKING, INC., 8022 Rose Dr., P.O. Box 5566, La Palma, CA 90622. Representative: Vanita Jean Moffit (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers or converters of paper and paper products (except commodities in bulk), from the facilities of Nekoosa Papers, Inc., at points in Portage and Wood Counties, WI, to points in AZ, CA, ID, NM, MT, NV, OR, UT, WA, and WY. (Hearing site: Madison or Wisconsin Rapids, WI.)

MC 149182 (Sub-1F), filed January 14, 1980. Applicant: SAMUEL R. GELDMACHER, Box 411, Mona, UT 84645. Representative: Irene Warr, 430 Judge Building, Salt Lake City, UT 84111. *Contract carrier,* transporting *drilling mud,* from the facilities of Industrial Minerals Venures, at or near Imvite (Nye County), NV, to Nephi, UT, under continuing contract(s) with Drilling Mud, Inc. (Hearing site: Salt Lake City, UT.)

MC 149282F, filed January 9, 1980. Applicant: CLIFFORD A. PARKHURST, 1229 Dakota North, Huron, SD 57350. Representative: Edward A. O'Donnell, 1004 29th St., Sioux City, IA 51104. 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, in tank vehicles), from the facilities of Huron Dressed Beef, Inc., at Huron, SD, to points in CO, IL, IA, KS, MN, MO, ND, NE, and WI, restricted to (except on traffic moving in foreign commerce), to the transportation of traffic originating at the named facilities and destined to the named destination states. (Hearing site: Pierre, SD.)

MC 149292F, filed January 14, 1980. Applicant: CHARLES JOLLEY, JR. d.b.a. C. J. TRUCKING, 4199 N. Ojai Road, Santa Paula, CA 93060. Representative: Donald R. Hedrick, P.O. Box 88, Norwalk, CA 90650. *Contract carrier,* transporting *alcoholic beverages,* from Los Angeles and Long Beach, CA, to Ventura and Santa Barbara, CA, restricted to traffic having a prior movement by water, under continuing contract(s) with Lagomarsino's of Ventura, Ca. (Hearing site: Los Angeles, CA.)

MC 149293F, filed January 14, 1980. Applicant: THREE STAR TRUCKING CO., a corporation, 7871 Ritz, Westland, MI 48185. Representative: Alex J. Miller, P.O. Box 244, Bloomfield Hills, MI 48013. Transporting *iron and steel articles, building materials,* and *roofing materials,* between Chicago, IL, on the one hand, and, on the other, Toledo, OH, and those points in MI in and south of Oceana, Newaygo, Mecosta, Sabella, Midland, and Bay Counties. (Hearing site: Detroit or Lansing, MI, or Chicago, IL.)

MC 149312F, filed January 17, 1980. Applicant: RUDOLPH A. WAGNER, 135th and Derby Rd., Lemont, IL 60439. Representative: Wyatt O. Wagner, 45 N. Orchard St., Madison, WI 53715. *Contract carrier,* transporting *packaged cement products and packaged salt products,* (a) from points in Cook County, IL to points in Adams, Brown, Calumet, Clark, Columbia, Crawford, Dane, Dodge, Door, Fond du Lac, Grant, Green, Green Lake, Iowa, Jackson, Jefferson, Juneau, Kenosha, Kewaunee, Lafayette, Manitowoc, Marathon, Marquette, Menominee, Milwaukee, Monroe, Ozaukee, Outagamie, Portage, Racine, Richland, Rock, Sauk, Shawano, Sheboygan, Taylor, Vernon, Walworth, Washington, Waukesha, Waupaca, Waushara, Winnebago, and Wood Counties, WI; and (b) from points in Milwaukee County, WI, to points in Cook, DuPage, Kane, Lake, McHenry, and Will Counties, IL, under continuing contract(s) in (a) and (b) with Dry Mix Concrete Co., of Franklin Park, IL, and International Salt Co., of Chicago, IL. (Hearing site: Chicago, IL.)

MC 149363 (Sub-1F), filed February 6, 1980. Applicant: HIGHLAND TRUCK COMPANY, a corporation, 25520 Woodvilla, Southfield, MI 48075. Representative: Wilhelmina Boersma, 1600 First Federal Bldg., Detroit, MI 48226. *Contract carrier,* transporting *foodstuffs,* in mechanically refrigerated equipment, between the facilities of Detroit City Dairy, Inc., at Highland Park, MI, on the one hand, and, on the other, St. Louis, MO, New York, NY, Philadelphia, PA, Baltimore, MD, and NJ, and points in WI, IL, OH, and IN, under continuing contract(s) with Detroit City Dairy, Inc., of Highland Park, MI. (Hearing site: Detroit, MI, or Washington, DC.)

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Decided: March 3, 1980.

By the Commission, Review Board Number 3, Members Parker, Fortier and Hill.

MC 5227 (Sub-65F), filed February 8, 1980. Applicant: ECKLEY TRUCKING, INC., P.O. Box 201, Mead, NE 68041. Representative: A. J. Swanson, P.O. Box 1103, 226 N. Phillips Avenue, Sioux Falls, SD 57101. Transporting (1) *malt beverages,* from Milwaukee, WI, and Peoria Heights, IL, to points in KS, MN, NE, IA, CO, MO, OK, and AR; (2) *equipment, materials, and supplies* used in the production and distribution of malt beverages, in the reverse direction; and (3) *containers,* from Northglenn, CO, to points in WI, IL, GA, and NJ. (Hearing site: Kansas City, MO, or Milwaukee, WI.)

MC 11207 (Sub-526F), filed February 15, 1980. Applicant: DEATON, INC., 317 Avenue W, Post Office Box 938, Birmingham, AL 35201. Representative: Kim D. Mann, Suite 1010, 7101 Wisconsin Ave., Washington DC 20014. Transporting (1) *heating, cooling and dust collecting apparatus, blower systems, machinery, machinery parts, furnace coils, dust collectors and arresters, and iron and steel articles;* and (2) *materials, equipment, and supplies* used in the manufacture or distribution of the commodities in (1) (except commodities in bulk) between Birmingham, AL, on the one hand, and, on the other, points in the U.S. (except AK and HI). (Hearing site: Birmingham, AL or Washington, DC.)

MC 21866 (Sub-141F), filed January 28, 1980. Applicant: WEST MOTOR FREIGHT, INC., 740 S. Reading Avenue, Boyertown, PA 19512. Representative: Alan Kahn, 1920 Two Penn Center Plaza, Philadelphia, PA 19102. Transporting: (1) *metal racks and supports,* and (2) *Materials, equipment,*

and supplies used in the manufacture, distribution and installation of metal racks and supports (except commodities in bulk), between the facilities of T. J. Cope, Inc. at Collegeville, PA, on the one hand, and, on the other, points in the United States (except AK, HI and PA). (Hearing site: Philadelphia, PA or Washington, DC.)

MC 26396 (Sub-298F), filed October 9, 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 (1) *livestock handling equipment and feeders*, from the facilities of Westguard Industries, Inc., at or near Cheyenne, WY, to those points in the U.S. in and west of LA, AR, MO, IL and WI, and (2) *materials, equipment* and *supplies* used in the production and distribution of commodities named in (1) above, in the reverse direction. (Hearing site: Casper, WY, or Billings, MT.)

MC 26396 (Sub-344F), filed February 11, 1980. Applicant: THE WAGGONERS TRUCKING, P.O. Box 31357, Billings, MT 59107. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501. Transporting *drilling mud and drilling mud additives*, from points in the United States (except AK and HI) to ports of entry on the International Boundary line between the United States and Canada located in MT. (Hearing site: Billings, MT, or Lincoln, NE.)

MC 52657 (Sub-750F), filed November 28, 1979. Applicant: ARCO AUTO CARRIER, INC., 16 W. 151 Shore Court, Burr Ridge, IL 60521. Representative: James Bouril (same address as applicant). Transporting *motor vehicles*, in secondary movements, in truckaway service, from Pitcarn, PA and points within 20 miles thereof to points in MD, restricted to the transportation of motor vehicles having a prior movement by rail. (Hearing site: Chicago, IL.)

MC 60186 (Sub-67F), filed February 1, 1980. Applicant: NELSON FREIGHTWAYS, INC., 47 East Street, Rockville, CT 06066. Representative: Edward G. Villalon, 1032 Pennsylvania Building, Pennsylvania Avenue & 13th Street, NW, Washington, D.C. 20004. Transporting, *electrical appliances* from Columbia, MD to points in VT. (Hearing site: Washington, DC.)

MC 67646 (Sub-90F), filed February 8, 1980. Applicant: HALL'S MOTOR TRANSIT COMPANY, 6060 Carlisle Pike, Mechanicsburg, PA 17055. Representative: John E. Fullerton, 407 N. Front St., Harrisburg, PA 17101. Over regular transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment) (1) between Randolph, NY, and the junction of U.S. Hwy 15 and NY Hwy 417: from Randolph over NY Hwy 17 to Steamburg, NY (also from Randolph over NY Hwy 394 to Steamburg), then over NY Hwy 17 to its junction with NY Hwy 417, then over NY Hwy 417 to its junction with U.S. Hwy 15, and return over the same route, (2) between Randolph, NY, and the junction of NY Hwy 17 and NY Hwy 415 (formerly U.S. Hwy 15). Serving in (1) and (2) all intermediate points between Randolph and Olean, NY, including Olean, and the off-route point of Little Valley, NY. (Hearing site: Buffalo, NY, or Washington, DC.)

MC 69116 (Sub-246F), filed June 26, 1979. Applicant: SPECTOR INDUSTRIES, INC., d.b.a. SPECTOR FREIGHT SYSTEM, 1050 Kingery Hwy, Bensenville, IL 60106. Representative: Edward G. Bazelon, 39 South LaSalle St., Chicago, IL 60603. Over regular routes, 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) (1) (a) between the GA–FL State line and Chicago, IL, over U.S. Hwy 41, (b) from the GA–FL State line over Interstate Hwy 75 to junction Interstate Hwy 24, then over Interstate Hwy 24 to junction Interstate Hwy 65, then over Interstate Hwy 65 to junction Interstate Hwy 94, the over Interstate Hwy 94 to Chicago, and return over the same route, (2) between the GA–FL State line and Lansing, MI, over U.S. Hwy 27, (3) between junction of U.S. Hwys 27 and 127 (near Rossville, GA), and Lansing, MI, over U.S. Hwy 127, (4) between the GA–FL State line, and Asheville, NC, over U.S. Hwy 19, (5) between the GA–FL State line, and Flint, MI, over U.S. Hwy 23, (6) between the GA–FL State line, and Flint, MI, over Interstate Hwy 75, (7) between Brunswick, GA, and Detroit, MI: From Brunswick over U.S. Hwy 25 to junction Interstate Hwy 25E then over U.S. Hwy 25E to junction U.S. Hwy 25, then over U.S. Hwy 25 to junction Interstate Hwy 75, then over Interstate Hwy 75 to Detroit, and return over the same route, (8) between the GA–FL State line and Wilmington, DE, over U.S. Hwy 301, (9) (a) between the FL–GA State line, and Boston, MA, over U.S. Hwy 1, (b) between the GA–FL State line, and Boston, MA, over Interstate Hwy 95, (10) between the GA–FL State line, and junction U.S. Hwys 17 and 1 (near Fredericksburg, VA), over U.S. Hwy 17, (11) between the GA–AL State line and junction U.S. Hwy 84 and Interstate Hwy 95, over U.S. Hwy 84, (12) between the GA–AL State line and junction of U.S. Hwys 82 and 17, over U.S. Hwy 82, (13) between Brunswick, GA, and junction of U.S. Hwys 341 and 41 (near Griffin, GA), over U.S. Hwy 341, (14) between the GA–AL State line and Petersburg, VA, over Interstate Hwy 85, (15) between the GA–AL State line and junction Interstate Hwys 20 and 95, over Interstate Hwy 20, (16) between the GA–FL State line and junction U.S. Hwys 441 and 23, over U.S. Hwy 441, (17) between Savannah and Macon, GA, over Interstate Hwy 16, (18) between Columbus and Savannah, GA, over U.S. Hwy 80, (19) between Macon and Thomson, GA: From Macon over GA Hwy 49 to Milledgeville, GA, then over GA, then over GA Hwy 22 to Sparta, GA, then over GA Hwy 16 to Thomason, and return over the same route, (20) between Atlanta and Augusta, GA, over U.S. Hwy 78, (21) between junction U.S. Hwy 78 and GA Hwy 17 (near Washington, GA) and junction U.S. Hwy 23 and GA Hwy 17, over GA Hwy 17, (22) between Charleston, SC, and Asheville, NC, over Interstate Hwy 26, (23) between Columbus, SC, and Cleveland, OH, over Interstate Hwy 77, (24) between Charleston, SC, and junction U.S. Hwys 41 and 52 (near Fowler, IN), over U.S. Hwy 52, (25) between Washington, GA, and Conway, SC, over U.S. Hwy 378, (26) between Myrtle Beach, SC, and Lynchburg, VA, over U.S. Hwy 501, (27) between Spartanburg and Dillon, SC, over SC Hwy 9, (28) between Florence, SC, and Wilmington, NC, over U.S. Hwy 76, (29) between Asheville and Wilmington, NC, over U.S. Hwy 74, (30) between junction U.S. Hwy 41 and Interstate 40, and Greensboro, NC, over Interstate Hwy 40, (31) between the GA–AL State line and Washington, DC, over U.S. Hwy 29, (32) between Durham and New Bern, NC, over U.S. Hwy 70, (33) between Lexington and Williamston, NC, over U.S. Hwy 64, (34) between Michigan, IN, and Wilmington, NC, over U.S. Hwy 421, (35) between Winston Salem, NC, and junction of U.S. Hwys 158 and 17, over U.S. Hwy 158, (36) between Ashtabula, OH, and Rockingham, NC: From Ashtabula over OH Hwy 11 to junction U.S. Hwy 30, then over U.S. Hwy 30 to junction Interstate Hwy 79, then over Interstate Hwy 79 to junction WV Hwy 7, then over WV Hwy 7 to junction WV Hwy 92, then over WV Hwy 92 to junction U.S. Hwy 219, then over U.S. Hwy 219 to Interstate Hwy 64, then over

Interstate Hwy 64 to U.S. Hwy 220, then over U.S. Hwy 220 to Rockingham, and return over the same route, (37) between the junction of U.S. Hwy 58 and Interstate Hwy 77 and Portsmouth, VA, over U.S. Hwy 58, (38) between the GA–FL State line and Roanoke, VA, over U.S. Hwy 221, (39) between Danville, VA, and Richmond, VA, over U.S. Hwy 360, (40) between New Harmony, IN, and Norfolk, VA: From New Harmony over IN Hwy 66 (formerly U.S. Hwy 460) to junction IN Hwy 62, then over IN Hwy 62 (formerly U.S. Hwy 460) to junction U.S. Hwy 31E, then over U.S. Hwy 31E (formerly U.S. Hwy 460) to junction U.S. Hwy 60, then over U.S. Hwy 60 (formerly U.S. Hwy 460) to junction U.S. Hwy 460, then over U.S. Hwy 460 to Norfolk, and return over the same route, (41) between junction of U.S. Hwy 41 and Interstate Hwy 64, and Norfolk, VA: From junction of U.S. Hwy 41 and Interstate Hwy 64 over Interstate Hwy 64 to Charleston, WV, then over U.S. Hwy 60 to junction U.S. Hwy 64, then over U.S. Hwy 64 to Norfolk, and return over the same route (also to Charleston, WV, as specified above, then over Interstate Hwy 77 to proposed Interstate Hwy 64 near Beckley, WV, then over proposed Interstate Hwy 64 to junction Interstate Hwy 64, then over Interstate Hwy 64, as specified above, to Norfolk, and return over the same route), (42) between St. Joseph, MI, and junction of U.S. Hwy 31 and Interstate Hwy 64, and over U.S. Hwy 31, (43) between Terre Haute, IN, and junction Interstate Hwy 70 and 77, over Interstate Hwy 70, (44) between Chicago, IL and Richmond, VA: From Chicago, over U.S. Hwy 41 to junction U.S. Hwy 30, then over U.S. Hwy 30 to junction OH Hwy 309, then over OH Hwy 309 to junction of OH Hwy 31, then over OH Hwy 31 to junction of U.S. Hwy 33, then over U.S. Hwy 33 to Richmond, and return over the same route, (45) between Vincennes, IN, and junction of U.S. Hwy 50 and Interstate Hwy 77, over U.S. Hwy 50, (46) between Cleveland, OH, and junction OH Hwy 7 and U.S. Hwy 52, over U.S. Hwy 422, (47) between Michigan City, IN, and junction U.S. Hwy 35 and Interstate Hwy 64, over U.S. Hwy 35, (48) between Baltimore, MD, and junction U.S. Hwy 222 and PA Hwy 309: From Baltimore, MD, over Interstate Hwy 83 to York, PA, then over U.S. Hwy 30 to junction U.S. Hwy 222 (also, from Baltimore over Interstate Hwy 83 to Harrisburg, PA, than over U.S. Hwy 422 to junction U.S. Hwy 222), then over U.S. Hwy 222 to junction of PA Hwy 309, and return over the same route, (49) between Wilmington, DE, and Easton, PA: From Wilmington over U.S. Hwy 13 to Philadelphia, PA, the over PA Hwy 309 to junction U.S. Hwy 22, then over U.S. Hwy 22 to Easton, and return over the same route, (50) between New Haven, CT, and Springfield, MA: (a) From New Haven over U.S. Hwy 5 to Springfield and return over the same route, (b) From New Haven over Interstate Hwy 91 to Springfield Hwy 91 to Springfield, and return over the same route, (51) between Springfield and Boston, MA, over Interstate Hwy 90, (52) between New York, NY, and Boston, MA: From New York City over Interstate Hwy 87 to Albany, NY, then over U.S. Hwy 20 to Pittsfield, MA, then over MA Hwy 9 to Boston, and return over the same route, (53) between Rome, GA and junction Interstate Hwy 78 and PA Hwy 309: From Rome over U.S. Hwy 411 to junction Interstate Hwy 40, then over Interstate Hwy 40 to junction Interstate Hwy 81, then over Interstate Hwy 81 to junction Interstate Hwy 78, then over Interstate Hwy 78 to junction PA Hwy 309, and return over the same route, (54) between junction U.S. Hwys 41 and 6, and Richmond, VA: From junction of U.S. Hwys 41 and 6 over U.S. Hwy 6 to junction U.S. Hwy 250, then over U.S. Hwy 250 to Richmond, and return over the same route, and (55) between Hardeeville, SC, and Boone, NC, over U.S. Hwy 321, (a) serving the termini of all routes and serving as intermediate or off-route points, all points in CT, GA, IN, MA, NJ, NC, OH, RI, SC, VA, those in that part of MI on and south of MI Hwy 21, the District of Columbia, Easton, York, Harrisburg and Philadelphia, PA, and points within 25 miles of Philadelphia, Baltimore, MD, Louisville, KY, and New York City, NY, and (b) serving all points on said routes in KY (except Louisville), WV, TN, MD (except Baltimore), DE, PA (except Easton, York, Harrisburg, and Philadelphia, PA, and points in PA within 25 miles of Philadelphia) and NY (except New York City), for purposes of joinder only, except as otherwise authorized. Applicant proposes to tack the requested authority with its existing authority. (Hearing sites: Boston, MA, Charlotte, NC, Chicago, IL, and Memphis, TN.)

Note.—Applicant is presently authorized to serve the points and areas sought in this application. The purpose of this application is to eliminate gateways and to convert a portion of applicant's Sub-188 Certificate from irregular to regular routes.

MC 76177 (Sub-335F), filed February 14, 1980. Applicant: BAGGETT TRANSPORTATION COMPANY, Two South 32nd Street, Birmingham, AL 35233. Representative: Mel P. Brooker, Jr., 110 South Columbus Street, Alexander, VA 22314. Transporting *Classes A, B and C explosives, ammunition, ingredients and components parts of ammunition, blasting materials and supplies, blasting agents and empty containers* between points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 86247 (Sub-28F), filed February 15, 1980. Applicant: ICL–INTERNATIONAL CARRIERS LIMITED, 7701 West Jefferson Avenue, Detroit, MI 48209. Representative: Alex J. Miller, P.O. Box 244, Bloomfield Hills, MI 48013. Transporting *silca sand, magnesite and refractory sand* in dump vehicles, between Ottawa, IL, and ports of entry on the international boundary line between the United States and Canada at Detroit and Port Huron, MI restricted to the transportation of foreign traffic.

MC 99667 (Sub-4F), filed January 14, 1980. Applicant: TRI–VALLEY TRANSPORTATION, INC., 111 East 4th Street, P.O. Box 2195, Grand Island, NE 68801. Representative: Marshall D. Becker, Suite 610, 7171 Mercy Road, Omaha, NE 68106. Transporting *meat*, from Darr, NE, to points in TX. (Hearing site: Omaha, NE.)

MC 100666 (Sub-526F), filed February 15, 1980. 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 *canned fruit*, from facilities of Wintergarden Warehouse at Brownsville, TX to points in AL, AR, GA, IL, IN, IA, KS, KY, LA, MI, MN, MS, MO, NE, OH, OK, TN and WI. (Hearing site: Fort Worth, TX.)

MC 102616 (Sub-1027F), filed February 13, 1980. Applicant: COASTAL TANK LINES, INC., 250 North Cleveland-Massillion Road, Akron, OH 44313. Representative: David F. McAllister (same address as applicant). Transporting *acrylonitrile*, in bulk, in tank vehicles, from Addyston, OH to points in SC. (Hearing site: St. Louis, MO, or Chicago, IL.)

MC 103926 (Sub-102F), filed February 4, 1980. Applicant: W. T. MAYFIELD SONS TRUCKING CO., P.O. Box 947, Mableton, GA 30059. Representative: K. Edward Wolcott, P.O. Box 56387, 1200 Gas Light Tower, 235 Peachtree St., NE, Atlanta, GA 30343. Transporting *construction equipment, pile driving equipment, piling and pile shells*, between points in the United States except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Raymond International Builders, Inc. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 108676 (Sub-158F), filed February 11, 1980. Applicant: A. J. METLER HAULING & RIGGING, INC., 117 Chicamauga Ave., N.E., Knoxville, TN 37917. Representative: Fred F. Bradley, P.O. Box 773 Frankfort, KY 40602. Transporting *flat glass*, from the facilities of PPG Industries, Inc., at or near Decatur, IL, to points in the US. (Hearing site: Pittsburgh, PA.)

MC 112617 (Sub-471F), filed February 15, 1980. Applicant: LIQUID TRANSPORTERS, INC., 1292 Fern Valley Rd., P.O. Box 21395, Louisville, KY 40221. Representative: Larry W. Thompson (same address as applicant.) Transporting *chemicals and petroleum products*, in bulk, in tank vehicles, from Cavert City, Doe Run and Louisville, KY, to points in AZ, CA, ID, NV, OR, SD, and WA. (Hearing site: Louisville, KY, or Washington, DC.)

MC 114457 (Sub-534F), filed July 30, 1980. Applicant: DART TRANSIT COMPANY, 2102 University Avenue, St. Paul, MN 55114. Representative: James H. Wills (same address as applicant). Transporting (1) *automatic feeders, skinning and fleshing machines, conveyors, wood splitters, cleaning drums, cleaning equipment, parts and accessories*, and (2) *materials, equipment, and supplies* used in the manufacture, sale, and distribution of the commodities named in (1) (except commodities in bulk), between Eden Valley and Litchfield, MN, on the one hand, and on the other, points in the United States (except AK and HI). (Hearing site: Milwaukee, WI, or St. Paul, MN.)

MC 117786 (Sub-90F), filed February 4, 1980. Applicant: RILEY WHITTLE, INC., P.O. Box 19038, Phoenix, AZ 85005. Representative: A. Michael Bernstein, 1441 E. Thomas Rd., Phoenix, AZ 85014. Transporting *such commodities* as are dealt in and distributed by retail department stores (except commodities in bulk), between Cincinnati, OH, on the one hand, and, on the other, points in OH, KY, IN, WV, MI and IL. (Hearing site: Phoenix, AZ.)

MC 119777 (Sub-459F), filed February 11, 1980. Applicant: LIGON SPECIALIZED HAULER, INC., Highway 85—East, Madisonville, KY, 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY, 42431. Transporting *zinc oxide, lead, fertilizer, and insulation materials*, (except in bulk), between points in the United States, restricted to the transportation of traffic originating at or destined to facilities used by Eagle-Picher Industries, Inc. (Hearing site: Kansas City, MO, or Tulsa, OK.)

MC 119777 (Sub-460F), filed February 11, 1980. Applicant: LIGON SPECIALIZED HAULER, INC., Highway 85—East, Madisonville, KY, 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY, 42431. Transporting (1) *wallboard, gypsum board, particleboard, composition board, insulation and construction materials*, and (2) *materials and supplies* used in the manufacture, and distribution of commodities in (1) between West Memphis, AR, on the one hand, and, on the other, points in TX, OK, MO, LA, MS, AL, GA, TN, KY, IL, IN, and OH. (Hearing site: Memphis, TN, or Little Rock, AR.)

MC 119777 (Sub-461F), filed February 11, 1980. Applicant: LIGON SPECIALIZED HAULER, INC., Highway 85—East, Madisonville, KY, 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY, 42431. Transporting *composition board*, from the facilities of Abitibi-Price Corporation in Wiles County, NC to points in the United States in and east of ND, SD, NE, CO, TX and NM. (Hearing site: Detroit, MI.)

MC 123476 (Sub-52F), filed January 30, 1980. Applicant: CURTIS TRANSPORT, INC., #23 Grandview Ind. Ct., Arnold, MO 63010. Representative: David G. Dimit (same address as applicant). Transporting *plastic, and expanded plastic products* (except in bulk in tank vehicles), from Stevens Point, WI, to points in the US on and east of US Hwy 85. (Hearing site: St. Louis, MO, or Chicago, IL.)

MC 124306 (Sub-80F), filed February 15, 1980. Applicant: KENAN TRANSPORT COMPANY, INCORPORATED, P.O. Box 2729, Chapel Hill, NC 27514. Representative: Richard A. Mehley, 1000 16th Street, NW, Washington, DC 20036. Transporting *synthetic plastic granules*, in bulk, in tank vehicles, from Darlington, S.C. to points in the United States (except AK and HI). (Hearing site: Charlotte, NC, or Washington, DC.)

MC 128837 (Sub-15F), filed February 15, 1980. Applicant: TRUCKING SERVICE, INC., P.O. Box 229, Carlinville, IL 62656. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. Transporting *lumber, lumber products and particle board*, from points in AL, AR, LA and MS to points in IA, IL, IN, MO, OH and KY. (Hearing site: Chicago, IL.)

MC 129387 (Sub-111F), filed February 15, 1980. Applicant: PAYNE TRANSPORTATION, INC., P.O. Box 1271, Huron, SD 57350. Representative: Charles E. Dye (same address as applicant). Transporting *bottles, glass beverage*, from points in IL and IN to points in SD. Hearing site: Chicago, IL, or Sioux Falls, SD.)

MC 134197 (Sub-9F), filed February 8, 1980. Applicant: JACKSON AND JOHNSON, INC., Box 327, Savannah, NY 13146. Representative: Raymond A. Richards, 35 Curtice Park, Webster, NY 14580. Transporting (1) *foodstuffs* (except in bulk), and (2) *materials, supplies and equipment* used in the distribution of commodities in (1) between points in NJ, PA, DE, MD, ME, VT, NH, MA, CT, RI, DC, and New York, NY, and Nassau, Suffolk, Westchester, and Rockland Counties, NY, on the one hand, and, on the other, the facilities of Seneca Foods Corporation, at Marion, Williamson, E. Williamson, Newark, Oaks Corners, Dundee, Himrod, and Penn Yan, NY. (Hearing site: Rochester or Buffalo, NY.)

Note.—Dual operations may be involved.

MC 134806 (Sub-65F), filed February 11, 1980. Applicant: B-D-R TRANSPORT, INC., P.O. Box 1277, Brattleboro, VT 05301. Representative: Francis J. Ortman, 7101 Wisconsin Avenue, Suite 605, Washington, DC 20014. Contract carrier, transporting: *footwear*, from Wilton, ME to points in CA, under continuing contract(s) with G. H. Bass & Company, of Wilton, ME. (Hearing site: Washington, DC.)

MC 135797 (Sub-201F), filed April 25, 1979, previously issued in the **Federal Register** issue of October 4, 1979, and republished this issue. Applicant: J. B. HUNT TRANSPORT, INC., P.O. Box 130, Lowell, AR 72745. Representative: Paul R. Bergant (same address as applicant). Transporting *such commodities* as are dealt in by wholesale and retail grocery houses (except commodities in bulk), from Byhalia, MS, and Rialto, CA, to points in the US (except AK and HI). (Hearing site: Washington, DC.)

Note.—The purpose of this republication is to reflect correctly the territorial description.

MC 136786 (Sub-202F), filed February 4, 1980. Applicant: ROBCO TRANSPORTATION, INC., 4475 N.E. 3rd Street, Des Moines, IA 50313. Representative: Stanley C. Olsen, Jr., 7400 Metro Boulevard, Suite 411, Edina, MN 55435. Transporting *meat, meat products, meat byproducts* and *articles distributed by meat packing houses* (except hides and commodities in bulk), as defined in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates*, 61 M.C.C. 209 and 766, from the facilities of Wilson Foods Corporation at Omaha, NE to points in DC, DE, GA, MD, NC, NJ, NY, PA, SC, VA, and WV, restricted to the transportation of traffic originating at the above named origins and destined to

the nearest destinations. (Hearing site: Dallas, TX, or Kansas City, MO.)

MC 136786 (Sub-209F), filed February 4, 1980. Applicant: ROBCO TRANSPORTATION, INC., P.O. Box 10375, Des Moines, IA 50306. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. Transporting (1) *Such commodities* as are dealt in by wholesale, retail, grocery and food business houses and feed businesses; *soy products; paste; flour products; dairy products* and (2) *materials, ingredients and supplies* used in the manufacture, distribution of commodities in (1) above (except commodities in bulk), between the facilities of Ralston Purina Company at or near Oklahoma City, OK, on the one hand, and, on the other, points in AR, LA, NM, TN, and TX. (Hearing site: Oklahoma City, OK.)

MC 136786 (Sub-210F), filed February 19, 1980. Applicant: ROBCO TRANSPORTATION, INC., 4475 N.E. 3rd Street, Des Moines, IA 50313. Representative: Stanley C. Olsen, Jr., 7400 Metro Boulevard, Suite 411, Edina, MN 55435. Transporting *meat, meat products, meat by-products, dairy products* and *articles distributed by meat packinghouses and commodities as are used by meat packers in the conduct of their business when destined to and for use by meat packers,* as described in Sections A, B, C and D 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), between the facilities of Lauridsen Foods, Inc., at or near Britt, IA and the facilities of Armour and Company located at Mason City, IA on the one hand, and, on the other, points in the U.S. in and east of AR, KS, LA, OK, ND, NE, and SD, restricted to the transportation of traffic originating at and/or destined to the facilities of Lauridsen Foods, Inc. and/or Armour and Company. (Hearing site: Minneapolis, MN, or Chicago, IL.)

MC 136786 (Sub-212F), filed February 15, 1980. Applicant: ROBCO TRANSPORTATION, INC., 4475 N.E. 3rd Street, Des Moines, IA 50313. Representative: Stanley C. Olsen, Jr., 7400 Metro Boulevard, Suite 411, Edina, MN 55435. Transporting (1) *cleaning and polishing compounds, textile softeners, lubricants, hypochlorite solutions, deodorants, disinfectants, paints, stains, varnishes, plastic bags* and *filters,* and (2) *supplies* and *equipment* used in the manufacture and distribution of the commodities named in (1) above (except commodities in bulk) between Joliet and Chicago, IL, on the one hand, and, on the other, points in the U.S. (except AK and HI), restricted to traffic originating at or destined to the facilities of Economics Laboratory, Inc. (Hearing site: Minneapolis, MN, or Chicago, IL.)

MC 138627 (Sub-90F), filed February 8, 1980. Applicant: SMITHWAY MOTOR XPRESS, INC., P.O. Box 404, Fort Dodge, IA 50501. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Road, Omaha, NE 68106. Transporting *iron and steel articles,* from Granite City, IL to points in MN, ND, SD, and WI. (Hearing site: St. Louis, MO, or Des Moines, IA.)

MC 139587 (Sub-13F), filed May 29, 1979, and previously noticed in the FR issue of January 8, 1980. Applicant: BROWN REFRIGERATED EXPRESS, INC., P.O. Box 603, 21st and Sidney, Fort Scott, KS 66701. Representative: Wilburn L. Williamson, Suite 615-East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. Transporting *steel storage and display racks,* from the facilities of Old Brazos Forge, Inc., at or near Brenham, TX, to those points in the United States in and west of NY, PA and MI). (Hearing site: Kansas City, MO.)

Note.—This republication is to reflect correctly the territorial description.

MC 139697 (Sub-4F), filed June 4, 1979, previously published in the FR issue of February 26, 1980, and republished this issue. Applicant: EDWARD BRUCE WAGONER, d.b.a. WAGONER TRANSPORTATION, 19562 Dice St., South Bend, IN 46614. Representative: Morton E. Kiel Suite 1832, 2 World Trade Center New York, NY 10048. *Contract carrier,* transporting (1) *foodstuffs,* and (2) *materials, equipment and supplies* used in the manufacture and distribution of foodstuffs, (1) between points in IN on the one hand, and, on the other points in AL, AZ, CA, CO, CT, DE, FL, GA, IL, IA, KS, KY, LA, MD, MA, MI, MN, MS, MO, NE NJ, NM, NY, NC, ND, OH, OK, PA, RI, SC, SD, TN, TX, VA, WV, WI, WY, and DC, and (2) from Cockeysville, MD to South Bend, IN, under continuing contract(s) with McCormick Company, Inc., of Cockeyville, MD. (Hearing site: Washington, DC.)

Note:—The purpose of this republication is to correctly reflect the territorial description in (1) above.

MC 139906 (Sub-100F), filed February 5, 1980. Applicant: INTERSTATE CONTRACT CARRIER CORPORATION, 2156 West 2200 South, P.O. Box 30303, Salt Lake City, UT 84127. Representative: Richard A. Peterson, 512 South 14th St., P.O. Box 81849, Lincoln, NE 68501. Transporting, *household products* (except in bulk), from the facilities of Blue Cross Laboratories, Inc., at or near North Hollywood, CA, to points in the US (except AK and HI). (Hearing site: Salt Lake City, UT, or Lincoln, NE.)

Note:—Dual operations may be involved.

MC 139906 (Sub-101F), filed February 6, 1980. Applicant: INTERSTATE CONTRACT CARRIER CORPORATION, 2156 West 2200 South, P.O. Box 30303, Salt Lake City, UT 84125. Representative: Richard A. Peterson, 521 South 14th St., P.O. Box 81849, Lincoln, NE 68501. Transporting (1) *medical and surgical equipment and supplies,* and (2) *materials and supplies* used in the manufacture and distribution of commodities in (1) above (except in bulk), (1) between the facilities of Automated Molding Company, at or near Pamona, CA and the facilities of Bard-Parker Division at Hancock, NY and Salt Lake City, UT, and (2) from the facilities in (1) above to Benecia, CA, Atlanta, GA, Itasca: IL, Fairfield, NJ, and Dallas, TX. (Hearing site: Lincoln, NE, or Salt Lake City, UT.)

Note.—Dual operations may be involved.

MC 143127 (Sub-69F), filed June 2, 1979. Applicant: K. J. TRANSPORTATION, INC., 6070 Collett Rd., Victor, NY 14568. Representative: Linda A. Calvo (same address as applicant). Transporting, *foodstuffs,* from the facilities of Campbell Soup Company at Napoleon, OH, to points in IL, IN, KY, NJ, NY, PA, and WV. (Hearing site: Buffalo, NY, or Cleveland, OH.)

Note.—Dual operations may be involved.

MC 143236 (Sub-48F), filed January 28, 1980. Applicant: WHITE TIGER TRANSPORTATION CO., INC., 40 Hackensack Avenue, S. Kearny, NJ 07032. Representative: John R. Sims, Jr., 915 Pennsylvania Bldg., 425 13th Street, NW., Washington, DC 20004. Transporting *swimming pool parts and accessories* between Elizabeth, NJ, on the one hand, and, on the other, points in the U.S. (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Hayward Manufacturing Company, Inc. (Hearing site: Washington, DC.)

MC 143236 (Sub-49F), filed February 11, 1980. Applicant: WHITE TIGER TRANSPORTATION CO., INC., 40 Hackensack Avenue, S. Kearny, NJ 07032. Representative: Elizabeth Murphy (same address as applicant). Transporting *paints and materials* used for the distribution of paint, between Union NJ, on the one hand, and, on the other, points in FL, LA, and TX, restricted to the transportation of traffic originating at or destined to the facilities of International Paint Company, Inc. (Hearing site: Newark, NJ.)

MC 143267 (Sub-104F), filed February 15, 1980. Applicant: CARLTON ENTERPRISES, INC., P.O. Box 520, Mantua, OH 44255. Representative: Neal A. Jackson, 1156 15th Street, NW., Washington, DC 20005. Transporting *building materials*, from Grand Rapids, MI, to points in IN, IL, KY and OH. (Hearing site: Cleveland, OH, or Washington, DC.)

MC 143436 (Sub-40F), filed February 5, 1980. Applicant: CONTROLLED TEMPERATURE TRANSIT, INC., 8328 Hill Gail Drive, P.O. Box 41228, Indianapolis, IN 46241. Representative: Stephen M. Gentry, 1500 Main St., Speedway, IN 46224. Transporting *such merchandise* as is dealt in by retail department stores, drug stores, and hardware stores and *materials and supplies* used in the manufacture and distribution of such merchandise between the facilities of Drackett Products Company at or near Urbana, OH on the one hand, and, on the other, points in IN and KY. (Hearing site: Indianapolis, IN.)

MC 148187 (Sub-2), filed February 6, 1980. Applicant: VIERON, INC., 5326 Wasena Ave., Baltimore, MD 21225. Representative: Walter T. Evans, 7961 Eastern Avenue, Silver Spring, MD 20910. Contract carrier, transporting *fuel oils and gasoline*, in bulk, (1) from Baltimore, MD, to points in VA, WV and DC, and (2) from Fairfax City and Newington, VA, to points in MD WV, and DC, under continuing contract(s) with Pedroni Fuel Oil of Vineland, NJ, and Waller Petroleum Company, of Towson, MD. (Hearing site: Baltimore, MD.)

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Decided: March 10, 1980.

By the Commission, Review Board Number 2, Members Eaton, Liberman and Jensen. Member Jensen not participating.

MC 35227 (Sub-13F), filed November 8, 1979. Applicant: EDSON EXPRESS, INC., P.O. Box 925, Longmont, CO 80501. Representative: Richard P. Kissinger, Steele Park, Suite 330, 50 South Steele St., Denver, CO 80209. Over regular routes, 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), between Denver, CO and Lander, WY, serving the intermediate point of Riverton, WY, and serving points in WY in the Gas Hills Uranium Mining District as off-route points, (1) from Denver over Interstate Hwy 25 to junction U.S. Hwy 26, then over U.S. Hwy 26 to Riverton, WY, then over WY Hwy 789 to Lander, and return over the same route; and (2) from Denver over U.S. Hwy 287 to junction Interstate Hwy 80, then over Interstate Hwy 80 to junction U.S. Hwy 287, then over U.S. Hwy 287 to Lander, WY, and return over the same route. (Hearing site: Lander, WY, or Denver, CO.)

MC 51146 (Sub-807F), filed January 24, 1980. Applicant: SCHNEIDER TRANSPORT, INC., P.O. Box 2298, Green Bay, WI 54306. Representative: Matthew J. Reid, Jr. (same address as applicant). Transporting *household appliances*, and *equipment, materials and supplies*, used in the manufacture and distribution of household appliances (except commodities 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 the Major Appliance Business Group of General Electric. (Hearing site: Chicago, IL.)

MC 51146 (Sub-815F), filed February 1, 1980. Applicant: SCHNEIDER TRANSPORT, INC., P.O. Box 2298, Green Bay, WI 54306. Representative: Matthew J. Reid, Jr. (same address as applicant). Transporting *such commodities* as are dealt in, or used by, manufacturers and distributors of beverages from points in the United States in and east of ND, SD, NE, KS, OK, and TX to the facilities of Tippecanoe Beverages, Inc., at points in IN. (Hearing site: Chicago, IL.)

MC 67156 (Sub-5F), filed February 4, 1980. Applicant: CONTAINER TRANSPORT COMPANY, DIVISION OF FIBREBOARD CORPORATION (a Delaware corporation), P.O. Box 1409, Antioch, CA 94509. Representative: P. W. Pollock (same adress as applicant). *Contract carrier*, transporting (1) *gypsum products, plaster and lime*, from points in Clark County, NV, to points in Los Angeles and Orange Counties, CA; and (2) *fibreboard, pulpboard, and lumber*, in the reverse direction, under continuing contract(s) in (1) and (2) with Louisiana-Pacific Corporation, of Portland, OR, and The Flintkote Company, of Los Angeles, CA. (Hearing site: Los Angeles or San Francisco, CA.)

MC 67156 (Sub-6F), filed February 8, 1980. Applicant: CONTAINER TRANSPORT COMPANY, DIVISION OF FIBREBOARD CORPORATION (a Delaware corporation), P.O. Box 1409, Antioch, CA 94509. Representative: P. W. Pollock (same adress as applicant). *Contract carrier*, transporting *paper, paper articles, and woodpulp*, in containers having a subsequent movement by water, from the facilities of Fibreboard Corporation, at Antioch, CA, to Oakland and San Francisco, CA; and (2) *containers*, in the reverse direction, under continuing contract(s) with Hanjin Container Lines, Ltd., of Oakland, CA. (Hearing site: Oakland or San Francisco, CA.)

MC 78687 (Sub-85F), filed November 1, 1979. Applicant: LOTT MOTOR LINES, INC., P.O. Box 751, Moravia, NY 13118. Representative: E. Stephen Heisley, 805 McLachlen Bank Bldg., 666 11th St., N.W., Washington, DC. 20001. Transporting *household cleaning products* (except commodities in bulk) from the facilities of Purex Corporation at Bristol, PA, to points in NY. (Hearing site: Philadelphia, PA.)

Note.—Dual operating may be invovled.

MC 108937 (Sub-62F), filed February 1, 1980. Applicant: MURPHY MOTOR FREIGHT LINES, INC., 2323 Terminal Rd., St. Paul, MN 55113. Representative: Jerry E. Hess, P.O. Box 43640, St. Paul, MN 55164. Over regular routes, 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), (1) between Hutchinson, MN and St. Paul, MN, over MN Hwy 7, (2) between Hutchinson, MN and Litchfield, MN, over MN Hwy 22 and (3) between Hutchinson, MN and Glenco, MN, over MN Hwy 22. (Hearing site: St. Paul, MN.)

MC 113666 (Sub-191F), filed December 6, 1979. Applicant: FREEPORT TRANSPORT, INC., Drawer "A" 1200 Butler Ro, Freeport, PA 16229. Representative: D. R. Smetanick (same address as applicant). Transporting (1) *abrasives materials and steel shot and* (2) *materials and supplies* used in the production of the commodities in (1) above, between Niagara Falls, NY, and those ports of entry on the international boundary line between the United States and Canada at points in NY and MI, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 114606 (Sub-13F), filed December 19, 1979. Applicant: S. F. DOUGLAS TRUCK LINE, INC., 587 S.W. 1st St., New Brigton, MN 55551. Representative: Samuel Rubenstein, P.O. Box 5, Minneapolis, MN 55440. Transporting *refined sugar*, in bulk, from the facilties used by North Central Sugar Marketing Cooperative, (a) at or near Wahpeton, ND, to points in MN, IA, WI, IL, MO, SD, and NE, and (b) at or near Renville, MN, to points in IA, WI, IL, MO, SD, and NE. (Hearing site: Minneapolis or St. Paul, MN.)

MC 115357 (Sub-15F), filed February 6, 1980. Applicant: TAT, INC., 800 Wyoming St., P.O. Box 4013, Kansas City, MO 64101. Representative: Raymond A. Greene, 100 Pine St., Suite 2550, San Francisco, CA 94111. Transporting *automobiles and trucks*, in secondary movements in truckaway service, between Kansas City, KS, on the one hand, and, on the other, points in MO, and those points in IL within the St. Louis, MO-East St. Louis, IL commercial zone. (Hearing site: Kansas City, MO.)

MC 115667 (Sub-17F), filed February 4, 1980. Applicant: ARROW TRANSPORTATION SYSTEMS, INC., 5658 West Marginal Way S.W., Seattle, WA 98106. Representative: Clyde H. MacIver, 1900 Peoples National Bank Bldg., Suite 1900, Seattle, WA 98171. Transporting, in foreign commerce only, *wood residuals*, from the port of entry on the international boundary line between the United States and Canada, at or near Oroville, WA, to points in WA. (Hearing site: Seattle, WA, or Portland, OR.)

MC 115826 (Sub-577F), filed February 6, 1980. Applicant: W. J. DIGBY, INC., 6015 East 58th Ave., Commerce City, CO 80022. Representative: Howard Gore (same address as applicant). Transporting (1) *fiberglass materials, fiberglass products, plastic materials, and plastic products*, and (2) *materials, equipment, and supplies* used in the manufacturing, packing, or installation of the commodities in (1) above, (except commodities in bulk), between the facilities of Owens-Corning Fiberglass Corporation, at or near Amarillo, TX, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Denver, CO.)

MC 115826 (Sub-578F), filed February 15, 1980. Applicant: W. J. DIGBY, INC., 6015 East 58th Ave., Commerce City, CO 80022. Representative: Howard Gore (same address as applicant). Transporting (1) *shampoo, toilet preparations, soap, and cosmetics*, and (2) *materials, equipment, and supplies* used in the manufacture of the commodities in (1) above, (a) between Friendship, NC, and those points in that part of the United States in and east of WI, IL, KY, TN, and MS; and (b) from Friendship, NC, to points in CA. (Hearing site: Denver, CO.)

MC 115826 (Sub-580F), filed February 11, 1980. Applicant: W. J. DIGBY, INC., 6015 East 58th Ave., Commerce City, CO 80022. Representative: Howard Gore (same address as applicant). Transporting *foodstuffs, pet foods and ingredients* used in the manufacture of pet foods (except commodities in bulk), between the facilities of McK, Limited, at or near Loveland, CO, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Denver, CO.)

MC 119777 (Sub-454F), filed February 4, 1980. Applicant: LIGON SPECIALIZED HAULER, INC., Hwy 85 East, Madisonville, KY, 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY, 42431. Transporting *timber and timber products*, from Lady Lake, FL to points in GA, AL, MS, LA, TN, VA, NC, SC, KY, IN, IL and WV. (Hearing site: Miami or Tampa, FL.)

MC 119777 (Sub-455F), filed February 4, 1980. Applicant: LIGON SPECIALIZED HAULER, INC., Hwy 85—East, Madisonville, KY 42431. Representative: Carl U. Hurst, P.O. Drawer, "L", Madisonville, KY 42431. Transporting *fencing and materials* used in the installation of fencing, from points in FL to points in TN, VA, NC, SC, GA, AL and MS. (Hearing site: Tampa or Jacksonville, FL.)

MC 119777 (Sub-456F), filed February 4, 1980. Applicant: LIGON SPECIALIZED HAULER, INC., Hwy 85—East, Madisonville, KY 42431. Representative: Carl U. Hurst, P.O. Drawer, "L", Madisonville, KY 42431. Transporting (1) *paper, paper products, cellulose products, vinyl book binders, vinyl book covers, and plastics*, and (2) *materials, equipment, and supplies* used in the manufacture, distribution, and sale of the commodities in (1) above, between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities used by Georgia Pacific Corporation. (Hearing site: Washington, DC.)

MC 136246 (Sub-39F), filed November 1, 1979. Applicant: GEORGE BROS., INC., P.O. Box 492, Sutton, NE 68979. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Rd., Omaha, NE 68106. Transporting *grease and tallow*, in bulk, from the facilities of Hastings Hide, Inc., at Hastings, NE, to points in IA, KS, and MO. (Hearing site: Omaha, NE.)

MC 142416 (Sub-6F), filed July 26, 1979. Applicant: HAMILTON TRANSFER, STORAGE & FEEDS, INC., Box H, Hwy 26 West, Torrington, WY 82240. Representative: James E. Ballenthin, 630 Osborn Bldg., St. Paul, MN 55102. Over regular routes, 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), (1) between Denver, CO and Cheyenne, WY, over U.S. Hwy 87 and Interstate Hwy 25, serving no intermediate points, (2) between Cheyenne, WY and Torrington, WY, from Cheyenne over Interstate Hwy 25 to junction U.S. Hwy 26, then over U.S. Hwy 26 to Torrington, (b) from Cheyenne over Interstate Hwy 25 to junction U.S. Hwy 85, then over U.S. Hwy 85 to Torrington, and (c) from Cheyenne over Interstate Hwy 80 to junction WY Hwy 215, then over WY Hwy 215 to junction WY Hwy 151, then over WY Hwy 151 to junction U.S. Hwy 85, then over U.S. Hwy 85 to Torrington, and (d) serving in (a), (b), and (c) all intermediate points, and points in Goshen County, WY, and points in Laramie County, WY east of Interstate Hwy 25 and the Missouri Basin Power Project in Platte County, WY as off-route points. (Hearing site: Torrington or Cheyenne, WY.)

MC 143396 (Sub-7F), filed February 4, 1980. Applicant: R. B. HUMPHREYS, INC., P.O. Box 736, Tibbitts Rd., New Hartford, NY 13413. Representative: S. Michael Richard, P.O. Box 225, Webster, NY 14580. Transporting *foodstuff* (except in bulk), in vehicles equipped with mechanical refrigeration, from points in FL, GA, KY, MD, NJ, NY, NC, OH, PA, SC, TN, VA, WV, and DC. (Hearing site: New York or Syracuse, NY.)

Note.—Dual operations may be involved.

MC 145036 (Sub-2F), filed December 17, 1979. Applicant: THOMAS O MARTINDALE, 1530 N. Sierra Bonita, Hollywood, CA 90046. Representative: Thomas O Martindale (same address as applicant). Transporting *automobiles*, between points in CA, AZ, NM, TN, LA, OR, NV, UT, CO, KS, OK, WA, ID, MT, WY, ND, SD, NE, MN, IA, IL, WI, MO, and AR. (Hearing site: Los Angeles, CA.)

MC 146117 (Sub-2F), filed December 26, 1979. Applicant: D. C., INC., 712 South York, Mechanicsburg, PA 17055. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Rd., N.E., Atlanta, GA 30326. *Contact carrier*, transporting *such commodities* as are used or dealt in by manufacturers of cosmetics, between Newark, DE, and York; PA, on the one hand, and, on the other, points in Adams, Berks, Chester, Cumberland, Dauphin, Franklin, Fulton, Huntingdon, Juniata, Lancaster, Lebanon, Mifflin, Perry and York Counties, PA, under continuing contract(s) with Avon Products, Inc. (Hearing site: Washington, DC.)

MC 146676 (Sub-2F), filed February 12, 1980. Applicant: BURKS TRUCKING, INC., P.O. Box 37, Old Fort, OH 44861. Representative: Richard H. Brandon, 220 West Bridge St., Dublin, OH 43017. Transporting (1) *stereo speakers*,

cabinets, wood fuel, and *insulation board* and (2) *materials, equipment, and supplies* used in the manufacture and sale of the commodities in (1) above (except commodities in bulk); between Tiffin, OH, on the one hand, and, on the other, points in the United States (except AL and HI). (Hearing site: Columbus, OH.)

MC 148456 (Sub-2F), filed February 4, 1980. Applicant: MICHAEL MASTEL, d.b.a. MASTEL TRANSFER, Hazelton, ND 58544. Representative: Charles E. Johnson, 418 East Rosser Ave., P.O. Box 1982, Bismarck, ND 58501. *Contact carrier,* transporting (1) *corrugated steel pipe, sheet piling, and guard rail,* and (2) *accessories* for the commodities in (1) above, from Minneapolis, MN and Topeka, KS, to points in ND, under continuing contract(s) with Basin Steel, Inc., of Bismarck, ND. (Hearing site: Bismarck, ND, or Minneapolis, MN.)

MC 148647 (Sub-1F), filed February 14, 1980. Applicant: HI-CUBE CONTRACT CARRIER CORP., 7005 South Pulaski Rd., Chicago, IL 60629. Representative: Arnold L. Burke, 180 North LaSalle St., Chicago, IL 60601. *Contact carrier,* transporting (1) *such commodities* as are dealt in by grocery, hardware and drug stores, (2) *cleaning and building maintenance materials and supplies,* (3) *swimming pool, spa and hot tub products,* (4) *chemicals,* and (5) *materials, equipment and supplies* used in the manufacture and distribution of the commodities in (1) through (4) above, between points in the United States (except AK and HI), restricted in (1) through (5) above against the transportation of commodities in bulk), under continuing contract(s) with Purex Corporation. (Hearing site: Los Angeles, CA.)

MC 149236 (Sub-2F), filed February 4, 1980. Applicant: CUNDIFF TRUCKING CO, a corporation, P.O. Box 253, Russell Springs, KY 42642. Representative: William L. Willis, 708 McClure, Frankfort, KY 40601. Transporting (1) *cheese and cheese products,* and (2) *materials, equipment, and supplies* used in the manufacture and distribution of cheese and cheese products, between the facilities of Cudahy Foods, at Harrodsburg, Russell Springs and Tompkinsville, KY, on the one hand, and, on the other, those points in the United States in and east of MN, IA, MO, AR, and LA. (Hearing site: Harrodsburg or Lexington, KY.)

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Decided: February 29, 1980.

By the Commission, Review Board Number 2, Members Eaton, Liberman and Jensen. Member Jensen not participating.

MC 5227 (Sub-61F), filed February 4, 1980. Applicant: ECKLEY TRUCKING, INC., P.O. Box 201, Mead, NE 68041. Representative: A. J. Swanson, P.O. Box 1103, 226 N. Phillips Ave., Sioux Falls, SD 57101. Transporting *construction materials,* from Wilmington and Chicago, IL to points in IA, MO, MS, NE, CO, and MN. (Hearing site: Tampa, FL, or Lincoln, NE.)

MC 11207 (Sub-522F), filed February 4, 1980. Applicant: DEATON, INC., 317 Ave. W, P.O. Box 938, Birmingham, AL 35201. Representative: Kim D. Mann, Suite 1010, 7101 Wisconsin Ave., Washington, DC 20014. Transporting *composition board,* from the facilities of Abitibi-Price Corporation, at points in (a) Lucas County, OH, and (b) Wilkes County, NC, to those points in the United States in and east of ND, NE, SD, CO, and NM. (Hearing site: Detroit, MI, or Washington, DC.)

MC 19227 (Sub-252F), filed February 1, 1980. Applicant: LEONARD BROS. TRUCKING CO., INC., 2515 N.W. 20th St., P.O. Box 523610, Miami, FL 33152. Representative: Robert F. McCaughey (same address as applicant). Transporting *torpedos,* between Keyport, WA, on the one hand, and, on the other, Seal Beach, CA, Travis Air Force Base, CA, New London, CT, Charleston, SC, and Yorktown, VA. (Hearing site: Washington, DC.)

MC 59557 (Sub-19F), filed January 10, 1980. Applicant: AUCLAIR TRANSPORTATION, INC., P.O. Box 5195, Manchester, NH 03108. Representative: Elliott Bunce, Suite 1301, 1600 Wilson Blvd., Arlington, VA 22209. 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), between Atlanta, GA, Chicago, IL, Dallas, Ft. Worth, Houston, TX, Los Angeles, Oakland, and San Francisco, CA, Jacksonville, Orlando, St. Petersburg, Miami, and Tampa, FL. (Hearing site: Boston, MA, or Concord, NH.)

MC 63417 (Sub-267F), filed February 1, 1980. Applicant: BLUE RIDGE TRANSFER COMPANY, INCORPORATED, P.O. Box 13447, Roanoke, VA 24034. Representative: William E. Bain (same address as applicant). Transporting (1) *such commodities* as are dealt in and distributed by grocery, hardware, and drug stores, (2) *cleaning and building maintenance materials and supplies,* (3) *swimming pool, spa, and hot tub products,* (4) *chemicals,* and (5) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) through (4) above, between points in the United States (except AK and HI), restricted (a) to the transportation of traffic originating at or destined to the facilities of Purex Corporation, and (b) against commodities in bulk. (Hearing site: Roanoke, VA.)

MC 69116 (Sub-261F), filed February 4, 1980. Applicant: SPECTOR INDUSTRIES, INC., d.b.a. SPECTOR FREIGHT SYSTEM, 1050 Kingery Hwy., Bensenville, IL 60106. Representative: Edward G. Bazelon, 39 South La Salle St., Chicago, IL 60603. 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), serving Midland, MI, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Midland, MI or Chicago, IL.)

Note.—Applicant proposes to tack the requested authority with its existing authority.

MC 102616 (Sub-1026F), filed January 8, 1980. Applicant: COASTAL TANK LINES, INC., 250 North Cleveland-Massillon Rd., Akron, OH 44313. Representative: David F. McAllister (same address as applicant). Transporting *corn product,* in bulk, from Muscatine, IA, to points in the United States (except AK and HI). (Hearing site: Des Moines, IA or Chicago IL.)

MC 107496 (Sub-1266F), filed January 8, 1980. Applicant: RUAN TRANSPORT CORPORATION, 666 Grand Ave., Des Moines, IA 50309. Representative: E. Check, P.O. Box 855, Des Moines, IA 50304. Transporting *fly ash,* in bulk, from Weston, MO, to points in IA, KS, and NE. (Hearing site: Kansas City, MO or Des Moines, IA.)

MC 107496 (Sub-1267F), filed January 8, 1980. Applicant: RUAN TRANSPORT CORPORATION, 666 Grand Ave., Des Moines, IA 50309. Representative: E. Check, P.O. Box 855, Des Moines, IA 50304. Transporting *asphalt and asphalt products,* in bulk, (1) from Janesville, WI, to points in IL and IA, and (2) from Nevada, MO, to points, in KS. (Hearing site: Chicago, IL or Des Moines, IA.)

MC 107496 (Sub-1268F), filed January 8, 1980. Applicant: RUAN TRANSPORT CORPORATION, 666 Grand Ave., Des Moines, IA 50309. Representative: E. Check, P.O. Box 855, Des Moines, IA 50304. Transporting *tallow,* in bulk, from the facilities of Iowa Beef Processors, Inc., at or near Holcomb, KS, to points in AZ, AR, CA, CO, IL, IN, IA, LA, MA, MN, MO, NE, NV, NJ, NM, OH, OK, OR, PA, TN, TX, UT, WA, WI, and WY.

(Hearing site: Omaha, NE, or Des Moines, IA.)

MC 107496 (Sub-1269F), filed January 8, 1980. Applicant: RUAN TRANSPORT CORPORATION, 666 Grand Ave., Des Moines, IA 50309. Representative: E. Check, P.O. Box 855, Des Moines, IA 50304. Transporting *liquefied petroleum gas,* in bulk, from the Dester LPG Terminal, at or near Dexter, MO, to points in AR, IL, KS, KY, OK, and TN. (Hearing site: St. Louis, MO, or Des Moines, IA.)

MC 109397 (Sub-488F), filed December 7, 1979. Applicant: TRI-STATE MOTOR TRANSIT CO. (a Delaware corporation), P.O. Box 113, Joplin, MO 64801. Representative: A. N. Jacobs (same address as appliant). Transporting (1) *machinery,* and (2) *parts and supplies* for machinery, from Arvada, CO, to points in the United States (except AK and HI). (Hearing site: Denver, CO.)

MC 109397 (Sub-498F), filed January 30, 1980. Appliant: TRI-STATE MOTOR TRANSIT CO. (a Delaware corporation), P.O. Box 113, Joplin, MO 64801. Representative: A. N. Jacobs (same address as applicant). Transporting *equipment, materials,* and *supplies* used in the mining and manufacturing of copper, (except commodities in bulk in tank vehicles), from the facilities of Kennecott Copper Corporation, at or near (a) Garfield, UT, and (b) Hurley, NM, to points in the United States (except AK and HI). (Hearing site: Salt Lake City, UT.)

MC 114457 (Sub-559F), filed February 4, 1980. Applicant: DART TRANSIT COMPANY, a corporation, 2102 University Ave., St. Paul, MN 55114. Representative: James H. Willis (same address as applicant). Transporting (1) *dental, hospital, hygenic, medical, and surgical supplies,* and (2) *materials, equipment, and supplies* used in the application and maintenance of the commodities in (1) above, (except commodities in bulk), from Argonne, IL, to points in MN. (Hearing site: Chicago, IL, or St. Paul, MN.)

MC 114457 (Sub-560F), filed February 4, 1980. Applicant: DART TRANSIT COMPANY, a corporation, 2102 University Ave., St. Paul, MN 55114. Representative: James H. Wills (same address as applicant). Transporting *corn products in bags* from Muscatine, IA to points in the United States (except AK and HI). (Hearing site: Des Moines, IA, or St. Paul, MN.)

MC 117786 (Sub-89F), filed February 11, 1980. Applicant: RILEY WHITTLE, INC., P.O. Box 19038, Phoenix, AZ 85005. Representative: A. Michael Bernstein, 1441 E. Thomas Rd., Phoenix, AZ 85015. Transporting *alcoholic beverages,* in vehicles equipped with mechanical refrigeration, from New York City, NY, Jersey City, NJ and Dayton, NJ, to points in AZ, CA, and NV. (Hearing site: Phoenix, AZ.)

MC 119656 (Sub-72F), filed January 8, 1980. Applicant: NORTH EXPRESS, INC., 219 Main St., Winamac, IN. Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46240. Transporting (1) *steel springs, wear plates,* and *parts* for tractor trailer machine tools, grading and road making equipment, and agricultural implements, between the facilities of Winamac Steel Products Division of Norris Industries, at Winamac, IN, on the one hand, and, on the other, points in the United States (except AK and HI); and (2) *iron and steel articles,* between Harrisburg, PA, on the one hand, and, on the other, points in MN, IL, IN, MI, KY, TN, OH, and WV. (Hearing site: Indianapolis, IN, or Washington, DC.)

MC 119777 (Sub-453F), filed February 4, 1980. Applicant: LIGON SPECIALIZED HAULER, INC., Hwy 85 East, Madisonville, KY 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY 42431. Transporting (1) *building materials, fiberglass, and fiberglass products,* and (2) *materials, equipment, and supplies* used in the manufacture of distribution of commodities in (1) above, between Ennis, TX, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Dallas, TX.)

MC 119777 (Sub-457F), filed February 4, 1980. Applicant: LIGON SPECIALIZED HAULER, INC., Hwy 83 East, Madisonville, KY 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY 42431. Transporting *iron and steel articles,* from points in LA, to points in the United States (except AK and HI). (Hearing site: Dallas, TX, or New Orleans, LA.)

MC 119777 (Sub-458F), filed Febrary 4, 1980. Applicant: LIGON SPECIALIZED HAULER, INC., Hwy 85-East, Madisonville, KY 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY 42431. Transporting (1) *non-ferrous metal articles,* and (2) *materials, equipment,* and *supplies* used in the production and mining of the commodities in (1) above, between points in Pima County, AZ, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Houston, TX.)

MC 125777 (Sub-270F), filed February 1, 1980. Applicant: JACK GRAY TRANSPORT, INC., 4600 East 15th Ave., Gary, IN 46406. Representative: Carl L. Steiner, 39 South LaSalle St., Chicago, IL 60603. Transporting *granulated slag* between the facilities of H. B. Reed Company at or near Moundsville, WV, on the one hand, and, on the other, points in DE, IN, KY, MO, NC, NJ, NY, OH, PA, SC, VA, and DC. (Hearing site: Indianapolis, IN, or Chicago, IL.)

MC 125777 (Sub-271F), filed February 1, 1980. Applicant: JACK GRAY TRANSPORT, INC., 4600 East 15th Ave., Gary, IN 46406. Representative: Carl L. Steiner, 39 South LaSalle St., Chicago, IL 60603. Transporting *alloys and chrome ore,* in dump vehicles, from Charleston, SC, to points in the United States (except AK and HI). (Hearing site: Charleston, SC, or Washington, DC.)

MC 126736 (Sub-123F), filed January 9, 1980. Applicant: FLORIDA ROCK AND TANK LINES, INC., 155 East 21st St., Jacksonville, FL 32206. Representative: L. H. Blow, P.O. Box 1559, Jacksonville, FL 32201. Transporting *granulated slag,* in bulk, from points in Charlton County, GA, to points in FL. (Hearing site: Jacksonville, FL.)

MC 128007 (Sub-150F), filed January 10, 1980. Applicant: HOFER, INC., 20th & 69 Bypass, P.O. Box 583, Pittsburg, KS 66762. Representative: Larry E. Gregg, 641 Harrison St., P.O. Box 1979, Topeka, KS 66601. Transporting *meats, meat products, and meat byproducts,* as defined in Section A of the Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766, in boxes, between Pittsburg, KS, on the one hand, and, on the other, points in AR, MO, OK, and TX. (Hearing site: Wichita, KS, or Kansas City, MO.)

MC 133676 (Sub-14F), filed January 10, 1980. Applicant: COMET TRUCK LINE, INC., P.O. Box 3175, Baton Rouge, LA 70821. Representative: Harold H. Mitchell, Jr., 120 South Poplar St. P.O. Box 1295, Greenville, MS 38701. Transporting (1) *paper, woodpulp, paper articles and chemicals* (except commodities in bulk), and (2) *materials, equipment,* and supplies used in the manufacture of the commodities in (1) above, (except commodities in bulk), between the facilities of Georgia Pacific Corporation, in East Baton Rouge Parish, LA, on the one hand, and, on the other, points in AL, AR, LA, MS and TX, restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Baton Rouge or St. Francisville, LA.)

MC 133676 (Sub-15F), filed February 4, 1980. Applicant: COMET TRUCK LINE, INC., P.O. Box 3175, Baton Rouge, LA 70821. Representative: Harold H. Mitchell, Jr., P.O. Box 1295, Greenville, MS 38701. 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), between Baton Rouge, LA and St. Francisville, LA, over U.S. Hwy 61, serving all intermediate and off-route points in East Baton Rouge Parish, LA. Condition: Applicant must request in writing the coincidental cancellation of its certificate of registration in MC 133676 (Sub-6F). (Hearing site: Baton Rouge or New Orleans, LA.).

MC 134477 (Sub-402F), filed February 4, 1980. Applicant: SCHANNO TRANSPORTATION, INC., 5 West Mendota Rd., West St. Paul, MN 55118. Representative: Thomas D. Fischbach, P.O. Box 43496, St. Paul, MN 55164. Transporting *automotive parts,* and *materials and supplies* used in the manufacture of automobiles (except commodities in bulk), from points in WI, to the facilities of Ford Motor Company, at or near St. Paul, MN. (Hearing site: St. Paul, MN.)

MC 135797 (Sub-305F), filed February 1, 1980. Applicant: J. B. HUNT TRANSPORT, INC., P.O. Box 130, Lowell, AR 72745. Representative: Paul R. Bergant, (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers and distributors of charcoal and hickory chips, and between points in the United States (except AK and HI), restricted to traffic originating at or destined to the facilities of the Kingsford Company. (Hearing site: Louisville, KY, or Washington, DC.).

MC 136786 (Sub-206F), filed February 4, 1980. Applicant: ROBCO TRANSPORTATION, INC., P.O. Box 10375, Des Moines, IA 50306. Representative: Larry D. Knox, 600 Hubbell Bldg., Des Moines, IA 50309. Transporting *foodstuffs, drugs, plastic articles, and rubber products* (except commodities in bulk), from Sturgis, MI, and Columbus, OH, to points in OR and WA. (Hearing site: Columbus, OH.).

MC 138157 (Sub-215F), filed January 10, 1980. Applicant: SOUTHWEST EQUIPMENT RENTAL, INC., d.b.a. SOUTHWEST MOTOR FREIGHT, 2931 S. Market St., Chattanooga, TN 37410. Representative: Patrick E. Quinn, P.O. Box 9596, Chattanooga, TN 37412. *Floor covering materials* and *materials, equipment and supplies* used in the manufacture and distribution of floor covering materials, from Whitehall, PA and Vailsgate, NY, to points in KY, VA and TN. (Hearing site: Knoxville, TN.)

Note.—Dual operations may be involved.

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Decided: March 5, 1980.

By the Commission, Review Board Number 2, Members Liberman, Eaton and Jensen. Member Jensen not participating.

MC 29866 (Sub-3F), filed February 11, 1980. Applicant: WHITE STAR TRUCKING LINES, INC., 521 Young St., Tonawanda, NY 14150. Representative: Peter Gregory Lordi, Jr., 4 Richard Court, Butler, NJ 07405. *Contract carrier,* transporting *foodstuffs and pet food* (except commodities in bulk, in tank vehicles), between Buffalo, NY, and Chicago, IL, under continuing contract(s) with Nabisco, Inc., of East Hanover, NJ. (Hearing site: Buffalo, NY, or Washington, DC.)

MC 35807 (Sub-112F), filed February 6, 1980. Applicant: WELLS FARGO ARMORED SERVICE CORPORATION, P.O. Box 4313, Atlanta, GA 30302. Representative: Francis J. Mulcahy (same address as applicant). *Contract carrier,* transporting *coin, currency, securities, jewelry, and articles of unusual value,* between Savannah, GA, on the one hand, and, on the other, points in Allendale County, SC, under continuing contract(s) with banks and banking institutions. (Hearing site: Savannah, GA.)

MC 126346 (Sub-33F), filed February 8, 1980. Applicant: HAUPT CONTRACT CARRIERS, INC., P.O. Box 1023, Wausau, WI 54401. Representative: Elaine M. Conway, 10 So. LaSalle St., Suite #1600, Chicago, IL 60603. *Contract carrier,* transporting *such commodities* as are dealt in or used by manufacturers of lawn and garden products and snow blowers, between the facilities of Ariens Company at (a) Des Moines, IA, and (b) Brillion, WI, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with Ariens Company. (Hearing site: Chicago, IL.)

MC 142126 (Sub-7F), filed February 15, 1980. Applicant: FOAM TRANSPORT, INC., 201 Ballardvale Street, Wilmington, MA 01887. Representative: Wesley S. Chused, 15 Court Square, Boston, MA 02108. *contract carrier,* transporting *plastic articles* (except in bulk), from Leola, PA, to points in CT, ME, MA, NH, NJ, NY, RI, and VT, under a continuing contract(s) with Dart Container Corporation of Pennsylvania, of Leola, PA. (Hearing site: Boston, MA, or Washington, DC.)

MC 142766 (Sub-12F), filed February 8, 1980. Applicant: WHITE TIGER TRANSPORTATION CO., INC., 40 Hackensack Ave., Kearny, NJ 07032. Representative: Elizabeth Murphy (same address as applicant). *Contract carrier,* transporting (1) *plastic articles, and school and office supplies,* and (2) *equipment and materials* used in the manufacture and sale of the commodities in (1) above (except commodities in bulk), between the facilities of Sterling Plastics, Division of Borden Chemical, at or near Mountainside, NJ, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with Sterling Plastics, Division of Borden Chemical. (Hearing site: Newark, NJ, or New York, NY.)

Note.—Dual operations may be involved.

MC 143387 (Sub-9F), filed February 8, 1980. Applicant: ASSOCIATED COURIERS, INC., 342 Fee Fee Rd., Maryland Heights, MO 63043. Representative: Daniel C. Sullivan, 10 S. LaSalle St., Suite 1600, Chicago, IL 60603 *Contract carrier,* transporting *radioactive pharmaceuticals, radioactive isotopes and medical testing kits,* between Maryland Heights, MO, on the one hand and on the other, points in CO, IA, KS, LA, MN, MO, MT, NB, ND, SD, OK, TX, WY, and MS, under continuing contract(s) with E. R. Squibb & Son, Inc. Condition: To the extent any permit issued in this proceeding authorizes the transportation of radioactive commodities it shall be limited, in point of time, to a period expiring 5 years from its date of issuance. (Hearing site: Chicago, IL, or St. Louis, MO.)

MC 143387 (Sub-10F), filed February 8, 1980. Applicant: ASSOCIATED COURIERS, INC., 342 Fee Fee Rd., Maryland Heights, MO 63043. Representative: Daniel C. Sullivan, 10 S. LaSalle St., Suite 1600, Chicago, IL 60603 *Contract carrier,* transporting *radioactive pharmaceuticals radioactive isotopes and medical testing kits,* between Maryland Heights, MO, on the one hand, and, on the other, points in Kentucky, Louisiana and New Mexico, under a continuing contract(s) with Mallinckrodt, Inc. Condition: To the extent any permit issued in this proceeding authorizes the transportation of radioactive commodities it shall be limited, in point of time, to a period expiring 5 years from its date of issue. (Hearing site: St. Louis, MO, or Chicago, IL.)

MC 143956 (Sub-9F), filed February 15, 1980. Applicant: GARDNER TRUCKING CO., INC., P.O. Drawer 493, Walterboro, SC 29488. Representative: Steven W. Gardner (same address as applicant). Transporting *lead and alloys,* between Manville, RI, on the one hand, and, on the other, Darien, WI, Los Angeles, CA, and points in PA and IN. (Hearing site: Providence, RI.)

Note.—Dual operations may be involved.

MC 144117 (Sub-63F), filed February 11, 1980. Applicant: T. L. C. LINES, INC., P.O. Box 1090, 1666 Fabick Dr., Fenton, MO 63026. Representative: Jack H. Blanshan, 205 West Touhy Ave., Suite 200, Park Ridge, IL 60068. Transporting *such commodities* as are dealt in or used by manufacturers of photographic products (except commodities in bulk) from the facilities of Eastman Kodak Company, at Rochester, NY, to Oak Brook, IL. (Hearing site: Chicago, IL, or Washington DC.)

MC 144407 (Sub-19F), filed February 11, 1980. Applicant: DECKER TRANSPORT COMPANY, INCORPORATED, 412 Route 23, Pompton Plains, NJ 07444. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. Transporting (1) *household appliances*, and (2) *materials, equipment, and supplies* used or useful in the manufacture and sale of household appliances (except commodities in bulk), between the facilities used or utilized by the Edison Products Co., Division of White-Westinghouse Corporation, located at or near Edison, NJ, on the one hand, and, on the other, points in the U.S. (except AK and HI). (Hearing site: New York, NY or Washington, DC.)

Note.—Dual operations may be involved.

MC 144667 (Sub-17F), filed February 8, 1980. Applicant: ARTHUR E. SMITH & SON TRUCKING, INC., P.O. Box 1054, Scottsbluff, NE 69361. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501. Transporting (1) (a) *prepared animal diets*, and (b) *meats, meat products, meat and byproducts and articles distributed by meat packing houses*, from the facilities of Central Nebraska Packing, Inc. at or near North Platte, NE, to points in the United States (except AK and HI), and (2) *materials, equipment, and supplies* used in the production and distribution of the commodities named in (1) above, in the reverse direction. (Hearing site: Lincoln, NE.)

MC 146856 (Sub-1F), filed January 24, 1980. Applicant: EUGENE P. SCHREINDL, d.b.a., AMERICAN INDEPENDENT EXPRESS, 40849 Sundale Dr., Fremont, CA 94538. Representative: Eugene P. Schreindl (same address as applicant). *Contract carrier*, transporting (1) *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 Armour and Company, at or near South San Francisco, CA, to Mesa, Phoenix, and Tempe, AZ, under continuing contract(s) with Armour and Company, and (2) *malt beverages* (except in bulk), from the facilities of Carling National Breweries, Inc., at or near Phoenix, AZ, to points in CA, under continuing contract(s) with Carling National Breweries, Inc. (Hearing site: San Francisco, CA.)

MC 147636 (Sub-8F), filed February 13, 1980. Applicant: LARRY E. HICKOX, d.b.a., LARRY E. HICKOX TRUCKING, Box 95, Casey, IL 62420. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. Transporting *welding equipment and supplies*, from Troy, OH, to points in AZ, CA, CO, ID, MT, NM, NV, OR, UT, WA, and WY. (Hearing site: Chicago, IL, or Cleveland, OH.)

Note.—Dual operations may be involved.

MC 147746 (Sub-1F), filed January 17, 1980. Applicant: TRI-UNION EXPRESS, INC., 3680 179th St., Suite D, Hammond, IN 46323. Representative: James R. Madler, 120 W. Madison St., Chicago, IL 60602. Transporting *iron and steel articles*, between Chicago, IL, on the one hand, and, on the other, points in IL, IN, MI, and WI. (Hearing site: Chicago, IL.)

MC 147947 (Sub-1F), filed December 17, 1979. Applicant: SANDERS CARTAGE COMPANY, INC., 117 Industrial Rd., P.O. Box 515, Cleburne, TX 76031. Representative: William Sheridan, 1025 Metker, P.O. Drawer 5049, Irving, TX 75062. 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), between points in Dallas and Tarrant Counties, TX, on the one hand, and, on the other, Cleburne, TX, restricted to traffic having a prior or subsequent movement by rail. (Hearing site: Fort Worth, TX, or Washington, DC.)

MC 148016 (Sub-6F), filed January 10, 1980. Applicant: MCWHORTER-GRAY ENTERPRISES, INC., 1010 Highway 15 North, Ripley, MS 38663. Representative: Robert H. Taylor, P.O. Box 864, Jackson, MS 39205. *Contract carrier*, transporting *new furniture*, from Dumas, MS, to points in the United States (except AK, AZ, CA, CO, HI, ID, MT, NV, NM, OR, UT, WA, and WY), under continuing contract(s) with Jerry Reno Manufacturing Company, of Dumas, MS. (Hearing site: Memphis, TN.)

Appendix D

MC 148356 (Sub-2F), filed December 18, 1979. Applicant: STAR MOTOR FREIGHT LINES, INC., 3110 No. Stone, Colorado Springs, CO 80907. Representative: Raymond M. Kelley, 450 Capitol Life Center, Denver, CO 80203. Over regular routes, 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), between Denver and Lamar, CO: from Denver over Interstate Hwy 25, U.S. Hwy 85, or U.S. Hwy 87 to Pueblo, CO, and then over U.S. Hwy 50 to Lamar, and return over the same route, serving all intermediate points. (Hearing site: Denver or Pueblo, CO.)

Note.—Applicant intends to interline at Denver, CO, and Colorado Springs, CO, and to tack at common points with existing for future regular-route authority.

MC 148636 (Sub-1F), filed February 1, 1980. Applicant: GOLDEN ARROW, INC., P.O. Box 726, Clifton, NJ 07015. Representative: Morton E. Kiel, Suite 1832, 2 World Trade Center, New York, NY 10048. *Contract carrier*, transporting *such commodities* as are dealt in or used by manufacturers of hardware (except commodities in bulk), between the facilities of Hardware Designers, Inc., at Mt. Kisco, NY, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with Hardware Designers, Inc., of Mt. Kisco, NY. (Hearing site: New York, NY.)

MC 148667 (Sub-1F), filed October 18, 1979. Applicant: BIG T TRUCK SERVICE, INC., 5878 Buford Hwy., Suite 5, Atlanta, GA 30360. Representative: Stephen J. Habash, 100 East 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 Department of Defense Depot, at Memphis, TN, to Eglin Air Force Base, in Oklaloosa County, FL, McCoy Air Force Base, in Orange County, FL, Fort Benjamin Harrison, in Marion County, IN, Fort Knox, in Hardin County, KY, Camp Grayline, in Crawford County, MI, Selfridge Air Force Base, in McComb County, MI, Wurtsmith Air Force Base, in Iosco County, MI, Rickenbacker Air Force Base, at or near Columbus, OH, and Wright-Patterson Air Force Base, at or near Fairborn, OH. (Hearing site: Columbus, OH, or Washington, DC.)

Note.—Dual operations may be involved.

MC 148996 (Sub-1F), filed January 17, 1980. Applicant: MERCHANTS' DELIVERY SERVICE, INC., P.O. Box 999, San Antonio, TX 78294.

Representative: Kenneth R. Hoffman, 801 Vaughn Bldg., Austin, TX 78701. 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), between San Antonio, TX, on the one hand, and, on the other, Laredo, TX, restricted to traffic having a prior or subsequent movement by rail. (Hearing site: Laredo, TX.)

MC 149207 (Sub-1F), filed January 17, 1980. Applicant: BLUE MT. EXPRESS, INC., Route 8, Box 43, Frederick, MD 21701. Representative: Hanna & Cullen, 2550 M St., N.W., Suite 475, Washington, DC 20037. *Contract carrier,* transporting *such commodities* as are dealt in by grocery and food business houses (except frozen commodities and commodities in bulk), between the facilities of The Clorox Company, at Frederick, MD on the one hand, and, on the other, points in PA, VA, and WV, under continuing contract(s) with The Clorox Company. (Hearing site: Washington, DC or Baltimore, MD.)

MC 149247 (Sub-1F), filed January 24, 1980. Applicant: JOHNNY M. JENKINS and ARTHUR L. JENKINS, d.b.a. KENTUCKY TENNESSEE GEORGIA EXPRESS, 304 Oothcaloga St., Calhoun, GA 30701. Representative: M. C. Ellis, 1001 Market St., Chattanooga, TN 37402. Transporting *floor coverings, and materials and supplies* used in the manufacture of floor coverings (except commodities in bulk), between points in Georgia and Hamilton Counties, TN, on the one hand, and, on the other, points in KY, and those in TN on and east of a line beginning at the KY–TN state line and extending along Interstate Hwy 75 to junction U.S. Hwy 129, and then over U.S. Hwy 129 to the TN–NC state line. (Hearing site: Chattanooga or Nashville, TN.)

MC 149296F, filed January 25, 1980. Applicant: LEVINGE CORPORATION, 6804 La Paseo, Houston, TX 77087 Representative: J. G. Dail, Jr., P.O. Box LL, McLean, VA 22101. *Contract carrier,* transporting (1) *equipment, materials, and supplies* used in, or in connection with, the discovery, development production, refining, manufacture, processing, storage, transmission, and distribution of natural gas and petroleum and their products and byproducts, (2) *equipment, materials, and supplies* used in, or in connection with, the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, including the stringing and picking up thereof, and (3)(a) *values, engines, generators, and switchgear,* and (b) *parts* for the commodities in (3)(a), between Houston, TX, on the one hand, and, on the other, points in LA, MS, and OK, under continuing contract(s) in (1), (2), and (3)(a) and (b), with WKM Valve Div., ACF Industries, Inc., FMC Corporation, NL Rig Equipment/NL Industries, Inc., Baylor Company, Stewart & Stevenson Services, Inc., Waukesha-Pearce Industries, Inc., and Cummins Marine Sales & Service, all of Houston, TX. (Hearing site: Houston, TX.)

MC 149297, filed January 17, 1980. Applicant: H. C. CROKER WRECKER SERVICE, INC., P.O. Box 403, Lavonia, GA 30553. Representative: Virgil H. Smith, Suite 12, 1587 Phoenix Blvd., Atlanta, GA 30349. Transporting *wrecked or disabled motor vehicles, and replacement vehicles* by use of wrecker equipment only, between points in GA, on the one hand, and, on the other, points in OH, IN, IL, MO, AR, LA, MS, FL, SC, NC, VA, WV, KY, and TN. (Hearing site: Atlanta, GA.)

MC 149307F, filed January 14, 1980. Applicant: FREIGHT EXPRESS, INC., 1 No. LaSalle St., Suite 2225, Chicago, IL 60602. Representative: David Kugler (same address as applicant). Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), between the facilities of National Brands, Inc., at Troy, MI, and Feather Lite Manufacturing Company, a Division of National Brands, Inc., at Hot Springs, AR, on the one hand, and, on the other, points in the United States, including AK but excluding HI. (Hearing site: Detroit, MI.)

MC 149356F, filed February 8, 1980. Applicant: CARE TRANSPORTATION, INC., 700 Woodward Ave., Chippewa Falls, WI 54729. Representative: Val M. Higgins, 1000 First National Bank Bldg., Minneapolis, MN 55402. *Contract carrier,* transporting *liquefied petroleum gas,* from Minneapolis, MN to points in Washburn, Polk, St. Croix, Pierce, Barron, Dunn, Pepin, Buffalo, Rusk, Chippewa, and Trempealeau Counties, WI, under continuing contract(s) with Farmers Union Central Exchange, Inc. (CENEX). Condition: Any permit issued in this proceeding shall be limited in point of time, to a period expiring 5 years from its date of issue. (Hearing site: Minneapolis, MN.)

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Decided: March 17, 1980.

By the Commission, Review Board Number 3, Members Parker, Fortier and Hill.

MC 24583 (Sub-36F), filed January 24, 1980. Applicant: FRED STEWART COMPANY, a corporation, P.O. Box 665, Magnolia, AR 71753. Representative: James M. Duckett, 927 Pyramid Life Bldg., Little Rock, AR 72201. Transporting *bromine,* in bulk, in shipper owned trailers, from the facilities of The Dow Chemical Company near Magnolia, AR, to those points in the US on and east of U.S. Hwy 85. (Hearing site: Little Rock or El Dorado, AR.)

MC 44783 (Sub-11F), filed February 8, 1980. Applicant: THE MAHONING EXPRESS COMPANY, a corporation, P.O. Box 557, Mineral Ridge, OH 44440. Representative: Earl N. Merwin, 85 East Gay St., Columbus, OH 43215. Transporting (1) *building materials and supplies* (except commodities in bulk; (2) *iron and steel articles* (except those in (1) above), and (3) *equipment, materials, and supplies* used in the manufacture of iron and steel articles (except commodities in bulk), between points in OH, PA, and Hancock Brooke, OH, and Marshall Counties, WV, on the one hand, and, on the other, points in DE, IL, IN, KY, MD, MI, NJ, NY, OH, PA, VA, WV, WI, TN, and NC. (Hearing site: Columbus, OH or Washington, DC.)

MC 52793 (Sub-57F), filed February 8, 1980. Applicant: BEKINS VAN LINES CO., a corporation, 3090 Via Mondo, Compton, CA 90221. Representative: Patricia M. Schnegg, 707 Wilshire Blvd., 1800 United California Bank Bldg., Los Angeles, CA 90017. Transporting *new furniture, furnishings, shelving, wall units, office partitions, filing cabinets, lighting fixtures, and tool boxes,* from points in AR and TX to points in the US (except AK and HI). (Hearing site: Los Angeles, CA.)

MC 61403 (Sub-282F), filed February 1, 1980. Applicant: THE MASON AND DIXON TANK LINES, INC., P.O. Box 969, Kingsport, TN 37662. Representative: W. C. Mitchell, Suite 1201, 370 Lexington Avenue, New York, NY 10017. Transporting *liquid chemicals,* in bulk, in tank vehicles, from the plant site of International Minerals & Chemical Corporation at Terre Haute, IN, to those points in the US in and east of ND, SD, NE, CO, OK, and TX. (Hearing site: Chicago, IL.)

MC 61403 (Sub-283F), filed February 1, 1980. Applicant: THE MASON AND DIXON TANK LINES, INC., P.O. Box 969, Kingsport, TN 37662. Representative: W. C. Mitchell, Suite 1201, 370 Lexington Avenue, New York, NY 10017. Transporting *chemicals,* in bulk, in tank vehicles, from plant site of Argus Chemical, Div. Witco Chemical Corp., Taft, LA, to those points in the US

in and east of MN, IA, MO, AK, and TX. (Hearing site: New Orleans, LA.)

MC 63562 (Sub-70F), filed February 11, 1980. Applicant: BN TRANSPORT, INC., P.O. Box 22694, 6775 East Evans Ave., Denver, CO 80222. Representative: Cecil L. Goettsch, 1100 Des Moines Bldg., Des Moines, IA 50307. Transporting *plastic pipe and aluminum pipe*, from Grand Island, NE to points in MN, ND, and SD. (Hearing site: Spokane, WA or Denver, CO.)

MC 71593 (Sub-57F), filed January 7, 1980. Applicant: FORWARDERS TRANSPORT, INC., 1608 East Second Street, Scotch Plains, NJ 07076. Representative: Ronald S. Potter, (same address as applicant). 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 special equipment) from the facilities of Southeastern Michigan Shippers Co-Operative in Michigan to Bridgeport, Hartford, CT; Boston, Natick, Worcester, MA; New York, NY; Philadelphia, PA; Chicago, IL; Baltimore, MD; and Atlanta, GA. (Hearing site: New York, NY.)

MC 71593 (Sub-58F), filed January 8, 1980. Applicant: FORWARDERS TRANSPORT, INC., 1608 East Second Street, Scotch Plains, NJ 07076. Representative: Ronald S. Potter (same address as applicant). Transporting *ground clay* in bags from Olmstead, IL; Bloomfield, MO; and Paris, TN, to points in the states of AL, AK, CT, DC, DE, FL, GA, IL (except from Olmstead, IL), IN, IA, KY, LA, ME, MD, MA, MI, MN, MS, MO (except from Bloomfield, MO), NH, NJ, NY, NC, OH, PA, RI, SC, TN (except from Paris, TN), VT, VA, WV, and WI. (Hearing site: Newark, NJ.)

MC 71652 (Sub-43F), filed February 11, 1980. Applicant: BYRNE TRUCKING, INC., P.O. Box 280–4669 Crater Lake Hwy, Medford, OR. Representative: David J. Stewart (same address as applicant). Transporting *building board*, from the facilities of Masonite Corporation, at or near Ukiah, CA, to points in AZ, CO, MT, NV, NM, UT, and WY. (Hearing site: Medford, OR or San Francisco, CA.)

MC 82063 (Sub-118F), filed February 15, 1980. Applicant: KLIPSCH HAULING CO., a corporation, 10795 Watson Rd., Sunset Hills, MO 63127. Representative: W. E. Klipsch, (same address as applicant). Transporting *bromine*, in bulk, in shipper owned trailers, from the facilities of The Dow Chemical Company, near Magnolia, AR, to those points in the US east of U.S. Highway 85. (Hearing site: Little Rock, AR or Memphis, TN.)

MC 87103 (Sub-43F), filed February 14, 1980. Applicant: MILLER TRANSFER AND RIGGING CO., a corporation, P.O. Box 322, Cuyahoga Falls, OH 44222. Representative: Edward Bocko (same address as applicant). Transporting *iron and steel articles*, from the facilities of Weirton Steel Company at (a) Weirton, WV, and (b) Stubenville, OH, to points in AL, AR, FL, GA, LA, MN, NC, SC, and TX, restricted to the transportation of traffic originating at the named origins. (Hearing site: Washington, DC or Pittsburgh, PA.)

Note.—Dual operations may be involved.

MC 96813 (Sub-5F), filed January 8, 1980. Applicant: FISK TRUCKING AND TRANSFER COMPANY, a corporation, 716 San Fernando Rd., Los Angeles, CA 90065. Representative: Glenn Fisk (same address as applicant). Transporting *tile, plastic sheets, and marble*, from points in Los Angeles and Orange County, CA, to points in Los Angeles, Orange, Riverside, San Bernardino, San Diego, Santa Barbara and Ventura Counties, CA. (Hearing site: Los Angeles or San Bernardino, CA.)

MC 104523 (Sub-77F), filed February 15, 1980. Applicant: HUSTON TRUCK LINE, INC., P.O. Box 427, Seward, NE 68434. Representative: Michael J. Ogborn, P.O. Box 82028, Lincoln, NE 68501. Transporting *drilling fluids* and *drilling mud* and *drilling fluid* and *drilling mud ingredients*, between points in AR, CO, FL, IA, KS, MN, MO, MT, NC, ND, NE, NM, NV, OK, SD, TN, TX, UT, WA, WV, and WY. (Hearing site: Kansas City, MO.)

MC 107012 (Sub-322F), filed February 15, 1980. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Hwy 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: Stephen C. Clifford (same address as applicant). Transporting *foam and plastic articles, artificial Christmas trees, holiday decorations, ornaments and novelty items, wading pools, swimming pool flotation chairs, toys and games, coin banks, and notebooks*, from the facilities of General Foam Plastics Corporation at or near (a) Lebanon, IN, (b) Scranton, PA, and (c) Norfolk, VA, to points in the U.S. (except AK and HI). (Hearing site: Norfolk, VA or Washington, DC.)

MC 107012 (Sub-476F), filed January 2, 1980. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Highway 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: David D. Bishop (same address as applicant). Transporting *carpet samples*, from points in GA and Chattanooga, TN, to Fort Wayne, IN. (Hearing sites: Chicago, IL or Washington, DC.)

MC 107012 (Sub-477F), filed January 7, 1980. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Highway 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: Bruce W. Boyarko (same address as applicant). Transporting *appliances*, from the facilities of Amana Refrigeration, Inc., at or near Amana, IA to points in CO, AZ and NV. (Hearing sites: Des Moine, IA or Chicago, IL).

MC 107012 (Sub-478F), filed January 8, 1980. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Highway 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: Bruce W. Boyarko (same address as applicant). Transporting (1) *toys, games, juvenile novelty items, and sporting goods*, and (2) *materials and supplies* used in the manufacture of the commodities in (1) (except commodities in bulk and commodities which because of size or weight require the use of special equipment), from points in NY, NJ, PA, MD and TN to points in the U.S. (except AK and HI). (Hearing sites: Philadelphia, PA or Washington, DC.)

MC 107323 (Sub-64F), filed February 4, 1980. Applicant: GILLILAND TRANSFER CO., a corporation, 7180 West 48th Street, Fremont, MI 49412. Representative: Donald B. Levine, 39 South LaSalle Street, Chicago, IL 60603. Transporting *such commodities* as are used by or dealt in by *manufacturers of baby foods and baby food products (except commmodities in bulk)*, from the facilities of Gerber Products Company at or near Fremont, MI, to points in PA and Cattaraugus, Chautauqua and Erie Counties, NY. (Hearing site: Chicago, IL.)

MC 107403 (Sub-1317F), filed January 30, 1980. Applicant: MATLACK, INC., Ten West Baltimore Ave., Lansdowne, PA 19050. Representative: Martin C. Hynes, Jr. (same address as applicant). Transporting *petroleum and petroleum products*, in bulk, in tank vehicles, between Carson City, MI, on the one hand, and, on the other, Cleveland and Toledo, OH, Chicago and Lemont, IL and Indianapolis, East Chicago, Ft. Wayne, and Hammond, IN. (Hearing site: Washington, DC.)

MC 107403 (Sub-1320F), filed January 14, 1980. Applicant: MATLACK, INC., Ten West Baltimore Ave., Lansdowne, PA 19050. Representative: Martin C. Hynes, Jr. (same address as applicant). Transporting *fertilizer*, in bulk, in tank vehicles, from the facilities of Cenex Soil Service Center, at or near Billings, MT, to points in WY and ND. (Hearing site: Washington, DC.)

MC 108053 (Sub-171F), filed January 17, 1980. Applicant: LITTLE AUDREY'S TRANSPORTATION CO., INC., P.O.

Box 129, Fremont, NE 68025. Representative: Arnold L. Burke, 180 N. LaSalle Street, Chicago, IL 60601. Transporting *alcoholic beverages, materials, equipment, and supplies* used in the manufacture and distribution of alcoholic beverages (except in bulk, in tank vehicles) (1) between Fort Smith, AR, on the one hand, and, on the other, points in AZ, CA, CO, ID, IL, IA, MN, NE, NV, NM, ND, SD, OR, UT, WA, WI, WY, and (2) between Plainfield, IL, on the one hand, and, on the other, points in CO, IA, MN, MT, NE, NM, ND, SD, and WY, restricted to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc. (Hearing site: Chicago, IL.)

MC 108053 (Sub-173F), filed January 21, 1980. Applicant: LITTLE AUDREY'S TRANSPORTATION CO., INC., P.O. Box 129, Fremont, NE 68025. Representative: Arnold L. Burke, 180 N. LaSalle Street, Chicago, IL 60601. Transporting *such merchandise as is dealt in by wholesale or retail food business houses* (except foodstuffs), and *materials, equipment and supplies* used in the conduct of such business, from Chicago, IL, to points in AZ, CA, ID, MT, NV, NM, OR, UT, WA, and WY. (Hearing site: Chicago, IL.)

MC 108223 (Sub-31F), filed January 14, 1980. Applicant: CENTURY-MERCURY MOTOR FREIGHT, P.O. Box 43050, St. Paul, MN 55164. Representative: Robert S. Lee, 1000 First National Bank Bldg., Minneapolis, MN 55402. Transporting: over regular routes, *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), (1) between Dickinson, ND, and Billings, MT, over Interstate Hwy 94, serving no intermediate points; (2) between Billings, MT, and Seattle, WA over Interstate Hwy 90, serving all intermediate points; (3) between Seattle, WA, and Portland, OR, over Interstate Hwy 5, serving all intermediate points; (4) between Spokane, WA, and Portland, OR; from Spokane, WA, over Interstate Hwy 90 to junction US Hwy 395, then over US Hwy 395 to junction Oregon Hwy 14, then over Oregon Hwy 14 to junction US Hwy 730 to junction Interstate Hwy 80 then over Interstate Hwy 80 to Portland, OR, and return over the same route, serving all intermediate points. (Hearing site: Applicant anticipates approximately 200 witnesses would testify taking approximately one week of hearing time. Because of the geography of the application applicant requests that the hearing be held in multiple locations including St. Paul, MN, Chicago, IL, Seattle, WA and Billings, MT.)

MC 110683 (Sub-165F), filed October 17, 1979. Applicant: SMITH'S TRANSFER CORPORATION, Box 1000, Staunton, VA 24401. Representative: Francis W. McInerny, Suite 502, 1000 16th St., NW, Washington, DC 20036. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over regular routes, transporting *general commodities* (except those of unusual value, household goods as defined by the Commission, classes A and B explosives, commodities in bulk, and those requiring special equipment), (1) between Charleston, SC, and Asheville, NC over Interstate Hwy 26, serving all intermediate points, and serving points in Charleston, Berkeley, Dorchester, Colleton, Richland, Lexington, Saluda, Fairfield, Newberry, Greenwood, Laurens, Union, Spartanburg, Anderson, Pickens, and Greenville Counties, SC, and Polk, Henderson, Transylvania, Buncombe, Yancey, Madison, Haywood, and Swain Counties, NC, as off-route points; (2) between Middlesboro, KY, and Elizabeth City, NC, serving all intermediate points, from Middlesboro over U.S. Hwy 25E, to junction U.S. Hwy 58, then over U.S. Hwy 58 to junction U.S. Hwy 501, then over U.S. Hwy 501 to junction VA Hwy 96, then over VA Hwy 96 to junction NC Hwy 96, then over NC Hwy 96 to Oxford, then over U.S. Hwy 158 to Elizabeth City, and return over the same route, serving points in Bell County, KY, Lee, Scott, Washington, Grayson, Carroll, Patrick, Henry, Pittsylvania, and Halifax Counties, VA, and Person, Granville, Vance, Warren, Nash, Wilson, Pitt, Edgecombe, Martin, Bertie, Halifax, Northampton, Washington, Hertford, Gates, Chowan, Perquimans, Pasquotank, Camden, and Currituck Counties, NC, as off-route points; (3) between Corbin, KY, and Augusta, GA, serving all intermediate points, from Corbin over U.S. Hwy 25E to junction U.S. Hwy 25, then over U.S. Hwy 25 to Augusta, and return over the same route, serving points in Laurel, Whitley, Knox, and Bell Counties, KY, Madison, Yancey, Haywood, Buncombe, Transylvania, Henderson, Polk Counties, NC, and Pickens, Greenville, Oconee, Anderson, Laurens, Abbeville, Greenwood, Saluda, McCormick, Edgefield, and Aiken Counties, SC, as off-route points; (4) between New Bern, NC, and Jellico, KY, serving all intermediate points, from New Bern over U.S. Hwy 70 to junction Interstate Hwy 40, then over Interstate Hwy 40 to junction Interstate Hwy 75, then over Interstate Hwy 75 to Jellico, and return over the same route, serving points in Carteret, Pamlico, Craven, Jones, Onslow, Beaufort, Greene, Lenoir, Duplin, Wayne, Johnston, Wake, Franklin, Durham, Orange, Alamance, Caswell, Guilford, Davidson, Forsyth, Davie, Rowan, Iredell, Lincoln, Catawba, Alexander, Burke, Caldwell, Rutherford, McDowell, Buncombe, Haywood, and Madison Counties, NC, and Whitley County, KY, as off-route points; (5) between Richlands and Charlotte, NC, over NC Hwy 24, serving all intermediate points and serving points in Jones, Onslow, Duplin, Sampson, Cumberland, Hoke, Harnett, Moore, Richmond, Randolph, Montgomery, Stanley, Union, Cabarrus, and Mecklenburg Counties, NC, as off-route points; (6) between Charlotte, NC, and Fair Play, SC, over Interstate Hwy 85, serving all intermediate points, and serving points in Mecklenburg, Gaston, Cleveland, and Polk Countes, NC, and York, Cherokee, Spartanburg, Greenville, Anderson, Pickens, and Oconee Counties, SC, as off-route points; (7) between Bristol, VA, and Wilmington, NC, over U.S. Hwy 421, serving all intermediate points, and serving points in Pender, Brunswick, New Hanover, Sampson, Johnston, Harnett, Chatham, Randolph, Alamance, Guilford, Forsyth, Stokes, Rockingham, Yadkin, Surry, Iredell, Alexander, Wilkes, Caldwell, Allegheny, Ashe, Wautauge, Mitchell, Bladen, Columbus, and Avery Counties, NC, as off-route points; (8) between Danville, VA, and Savannah, GA, serving all intermediate points, from Danville, over U.S. Hwy 29 to Charlotte, NC, then over U.S. Hwy 21 to junction U.S. Hwy 17, then over U.S. Hwy 17 to Savannah, and return over the same route, serving points in Pittsylvania County, VA, Rockingham, Caswell, Stokes, Guilford, Forsyth, Randolph, Davidson, Rowan, Davie, Cabarrus, Lincoln, Mecklenburg, Gaston, and Union Counties, NC, and York, Chester, Union, Lancaster, Newberry, Fairfield, Kershaw, Saluda, Lexington, Richland, Sumter, Calhoun, Orangeburg, Bamberg, Dorchester, Colleton, Allendale, Hampton, Jasper, Charleston, and Beaufort Counties, SC as off-route points; (9) between Lumberton, NC, and Yemassee, SC, over Interstate Hwy 95, serving all intermediate points, and serving points in Robeson, Bladen, and Columbus Counties, NC, and Dillon, Marlboro, Horry, Darlington, Marion, Florence, Sumter, Clarendon, Calhoun, Berkeley, Williamsburg, Dorchester, Bamber, Colleton, Jasper, and Beaufort Counties, SC, as off-route points; (10) between Charleston, SC, and Augusta, GA, over

U.S. Hwy 78, serving all intermediate points, and serving points in Charleston, Berkeley, Dorchester, Colleton, Orangeburg, Bamberg, Allendale, Hampton, Barnwell, Aiken, and Edgefield Counties, SC, as off-route points; (11) between Hillsville, VA, and Ocoee, TN, serving all intermediate points in NC and VA, from Hillsville over Interstate Hwy 77 to junction U.S. Hwy 64, then over U.S. Hwy 64 to Ocoee, and return over the same route, serving points in Surry, Allegheny, Stokes, Wilkes, Yadkins, Davie, Alexander, Iredell, Rowan, Lincoln, Catawba, Caldwell, Burke, Rutherford, McDowell, Cleveland, Polk, Henderson, Transylvania, Jackson, Haywood, Swain, Macon, Clay, Graham, and Cherokee Counties, NC, as off-route points; (12) between Wilmington, NC, and Point South, SC, over U.S. Hwy 17, serving all intermediate points, and serving points in New Hanover and Brunswick Counties, NC, and Horry, Williamsburg, Georgetown, Berkeley, Charleston, Colleton, Jasper, and Beaufort Counties, SC, as off-route points; (13) between Charlotte, NC, and Augusta, GA, serving all intermediate points, from Charlotte over U.S. Hwy 74 to junction U.S. Hwy 601, then over U.S. Hwy 601 to junction Interstate Hwy 20, then over Interstate Hwy 20 to Augusta, and return over the same route, serving points in Mecklenburg and Union Counties, NC, and York, Chester, Lancaster, Chesterfield, Fairfield, Kershaw, Lee Sumter, Richland, Lexington, Saluda, Aiken, McCormick, and Barnwell Counties, SC, as off-route points; (14) between Ranger, NC, and Tellico Plains, TN, serving all intermediate points, from Ranger over NC Hwy 294 to junction TN Hwy 123, then over TN Hwy 123 to junction TN Hwy 68, then over TN Hwy 68 to Tellico Plains, and return over the same route, serving points in Cherokee County, NC, as off-route points; (15) between Hillsville, VA, and Myrtle Beach, SC, serving all intermediate points, from Hillsville, over U.S. Hwy 52 to junction U.S. Hwy 76, then over U.S. Hwy 76 to junction U.S. Hwy 501, then over U.S. Hwy 501 to Myrtle Beach, SC, and return over the same route, serving points in Carroll County, VA, Surry, Stokes, Yadkin, Forsyth, Guilford, Davie, Davidson, Rowan, Cabarrus, Montgomery, Stanly, Union, Anson, Richmond, and Scotland Counties, NC, and Chesterfield, Marlboro, Darlington, Lee, Florence, Marion, Dillon, and Horry Counties, SC, as off-route; (16) between Gate City, Va, and Columbia, SC, serving all intermediate points, from Gate City over U.S. Hwy 23 to junction U.S. Hwy 321, then over U.S. Hwy 321 to Columbia and return over the same route, serving points in Wataugh, Ashe, Avery, Caldwell, Alexander, Burke, Catawba, Lincoln, Gaston, Union, and Mecklenburg Counties, NC, and Cherokee, York, Union, Chester, Lancaster, Newberry, Fairfield, and Richland Counties, SC, as off-route points; (17) between Florence and Camden, SC, serving all intermediate points, from Florence over U.S. Hwy 301 to junction Interstate Hwy 20, then over Interstate Hwy 20 to Camden, and return over the same route, serving points in Florence, Darlington, Lee, Kershaw, and Sumter Counties, SC, as off-route points; (18) between Jonesville, VA, and junction U.S. Hwy 25 and NC Hwy 208, serving all intermediate points, from Jonesville over VA Hwy 70 to junction TN Hwy 70, then over TN Hwy 70 to junction NC Hwy 208, then over NC Hwy 208 to junction U.S. Hwy 25, and return over the same route, serving points in Madison, Yancey, Mitchell, and Haywood Counties, NC, as off-route points; and (19) between Rosman, NC, and Greenville, SC, serving all imtermediate points, from Rosman over U.S. Hwy 178 to junction SC Hwy 8, then over SC Hwy 8 to junction U.S. Hwy 123, then over U.S. Hwy 123 to Greenville, and return over the same route, serving joints in Transylvania, Jackson, Henderson Counties, NC, and Oconee, Pickens, Anderson, and Greenville Counties, SC, as off-route points. Conditions: (1) The regular-route authority granted in this proceeding shall not be severable, by sale or otherwise, from applicant's retained pertinent irregular-route authority. (2) Applicant must file a statement providing specific references, by docket and sub-no., to the irregular-route authority it seeks here to convert and must request, in writing, the imposition of restriction on its underlying irregular-route authority precluding service between any two points authorized to be served here pursuant to regular-route authority. The purpose of this application is to convert irregular-route authority to regular route and to eliminate gateways. (Hearing site: Washington, DC; Charlotte, NC.)

Note.—Applicant proposes to tack sought authority with existing authority at common points.

MC 112223 (Sub-131F), filed February 5, 1980. Applicant: QUICKIE TRANSPORT COMPANY, a corporation, 1700 New Brighton Blvd., Minneapolis, MN 55413. Representative: Earl Hacking (same address as applicant). Transporting *dry edible sugar*, in bulk, in tank vehicles, from Chaska, Crookston, Moorhead, and Renville, MN, and Wahpeton, ND to Battle Creek, MI, Evansville, IN, Lafayette, IN, Chicago and Kankakee, IL. (Hearing site: St. Paul, MN.)

MC 112822 (Sub-481F), filed February 5, 1980. Applicant: BRAY LINES INCORPORATED, P.O. Box 1191, 1401 N. Little St., Cushing, OK 74023. Representative: Dudley G. Sherrill (same address as applicant). Transporting *alcoholic liquors* and *materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors (exept in bulk, in tank vehicles), (1) between Ft. Smith, AR, on the one hand, and, on the other, points in the US (except AK and HI), and (2) between Plainfield, Il, on the one hand, and, on the other, points in WI, IN, MN, MO, KS, OK, CO, and TX, restricted to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc. (Hearing site: St. Louis, MO or Chicago, IL.)

MC 112893 (Sub-61F), filed January 30, 1980. Applicant: BULK TRANSPORT COMPANY, a corporation, 100 Waukegan Road, P.O. Box 1000, Lake Bluff, IL 60044. Representative: John R. Sims, Jr., 915 Pennsylvania Bldg., 425 13th Street NW., Washington, DC 20004. Transporting *asphalt and asphalt products, in bulk, in tank vehicles*, from Janesville, WI to points in IL on and north to U.S. Highway 136. (Hearing site: Chicago, IL.)

MC 113843 (Sub-279F), filed February 4, 1980. Applicant: REFRIGERATED FOOD EXPRESS, INC., 316 Summer Street, Boston, MA 02210. Representative: Lawrence T. Shells (same address as applicant). Transporting *staples, stapling machines and stapling machine parts*, from East Greenwich, RI, Indianapolis, IN, Lexington, KY, Detroit, Farmington, and Grand Rapids, MI, Minnepolis, MN, Kansas City, Maryland Heights, and St. Louis, MO, and Middleburgh Heights, and Cleveland, OH, restricted to the transportation of traffic originating at the facilities of Bostitch, Division of Textron. (Hearing site: Boston, MA.)

MC 113843 (Sub-280F), filed February 4, 1980. Applicant: REFRIGERATED FOOD EXPRESS, INC., 316 Summer Street, Boston, MA 02210. Representative: Lawrence T. Shells (same address as applicant). Transporting *such commodities* as are dealt in by retail wholesale and food business houses (except commodities in bulk, in tank vehicles), from the facilities of Lever Bros. Co., at or near Chicago, IL, and Hammond, IN, to points in MD, NJ, NY, PA, and RI. (Hearing site: Chicago, IL.)

MC 114273 (Sub-698F), filed January 28, 1980. Applicant: CRST, INC., P.O. Box 68, Cedar Rapids, IA 52406. Representative: Kenneth L. Core (same address as applicant). Transporting *foodstuffs*, except in bulk, in tank vehicles from Richmond, VA, to points in PA, MI, NJ, IN, and NY. (Hearing site: Chicago, IL or Washington, DC.)

Note.—Common control may be involved.

MC 114552 (Sub-248F), filed January 8, 1980. Applicant: SENN TRUCKING COMPANY, A Corporation, P.O. Drawer 220, Newberry, SC 29108. Representative: Frank A. Graham, Jr., 707 Security Federal Building, Columbia, SC 29201. Transporting *nails and wire* between points in Lexington County, SC on the one hand, and, on the other, points in AL, AR, FL, GA, IL, IN, KY, LA, MD, MS, MO, NE, OH, SC, TN, VA, and WV. (Hearing site: Columbia, SC, Atlanta, GA or Washington, DC.)

MC 114552 (Sub-249F), filed January 4, 1980. Applicant: SENN TRUCKING COMPANY, Post Office Drawer 220, Newberry, SC 29108. Representative: William P. Jackson, Jr., 3426 N. Washington Boulevard, Post Office Box 1240, Arlington, VA 22210. Transporting *general commodities* (except those of unusual value, Classes A and B explosives, and household goods as defined by the Commission between port cities in AL, FL, GA, MD, NC, SC, and VA, on the one hand, and, on the other, points in the US (except AK and HI). (Hearing site: Charleston, SC, Savannah, GA, or Jacksonville, FL.)

MC 114632 (Sub-272F), filed January 2, 1980. Applicant: APPLE LINES, INC., P.O. Box 287, Madison, SD 57042. Representative: David E. Peterson (same address as applicant). Transporting *paper and paper products*, and *commodities* used in the manufacture and distribution of paper and paper products (except commodities in bulk), between points in AR, IA, KS, MN, MO, NE, OH, OK, TX, and WI, restricted to transportation of traffic originating at or destined to the facilities of Champion International Corporation. (Hearing site: Cincinnati, OH or Chicago, IL.)

MC 114632 (Sub-273F), filed January 4, 1980. Applicant: APPLE LINES, INC., P.O. Box 287, Madison, SD 57042. Representative: David E. Peterson (same address as applicant). Transporting *aluminum and aluminum articles*, and *zinc alloy ingots*, from the facilities of Aluminum Smelting & Refining Co., Inc. and Certified Alloys Company at Maple Heights, OH to points in IL, IN, IA, KS, LA, MI, MN, MS, MO, NE, ND, OK, SD, TX and WI. (Hearing site: Cleveland, OH or Washington, DC.)

MC 114632 (Sub-274F), filed January 4, 1980. Applicant: APPLE LINES, INC., P.O. Box 287, Madison, SD 57042. Representative: David E. Peterson (same address as applicant). Transporting *advertising matter, periodicals, and equipment, materials and supplies* used in the printing and publishing business, from the facilities of Dayton Press, Inc., at Dayton, OH to points in PA, D.C., MD, CT, MA, NY, NJ, RI, VA, MN, ND, SD, KS, MO, IA, NE and WI. (Hearing site: Dayton, or Columbus, OH.)

MC 114632 (Sub-275F), filed January 4, 1980. Applicant: APPLE LINES, INC., P.O. Box 287, Madison, SD 57042. Representative: David E. Peterson (same address as applicant). Transporting *aluminum and aluminum articles, and materials, equipment, and supplies* used in the manufacture and distribution of aluminum and aluminum articles, between points in Yankton County, SD, on the one hand, and, on the other, points in CO, GA, IL, IN, IA, KS, MN, MO, MT, NE, ND, TN, TX, OK, WI and WY. (Hearing site: Sioux Falls, SD or Minneapolis, MN.)

MC116063 (Sub-163F), filed January 2, 1980. Applicant: WESTERN-COMMERCIAL TRANSPORT, INC., P.O. Box 270, Fort Worth, TX 76101. Representative: W. H. Cole (same address as applicant). Transporting *soybean oil*, in bulk, in tank vehicles, from Dallas, TX, to Port Ivory (Staten Island), NY. (Hearing site: Fort Worth or Dallas, TX.)

MC 116763 (Sub-645F), filed February 13, 1980. Applicant: CARL SUBLER TRUCKING, INC., North West Street, Versailles, OH 45380. Representative: Gary J. Jira (same address as applicant). Transporting *general commodities* (except commodities in bulk, in tank vehicles, used house furniture, commodities the transportation of which because of size or weight requires the use of special equipment, automobiles, trucks and buses as described in the report in *Descriptions in Motor Carrier Certificates*, 61, MCC 209 and 766, and explosives), between those points in the US in and east of MN, IA, MO, OK and TX, restricted to the transportation of traffic originating at or destined to the facilities used by Allied Foods, Inc. (Hearing site: Atlanta, GA.)

MC 118202 (Sub-150F), filed February 8, 1980. Applicant: SCHULTZ TRANSIT, INC., P.O. Box 406, 323 Bridge Street, Winona, MN 55987. Representative: Robert S. Lee, 1000 First National Bank Bldg., Minneapolis, MN 55402. Transporting *empty plastic containers*, (1) from Port Clinton, OH to points in IL, IN, IA, KY, MI, MN, MO, NY, ND, PA, SD, TN, and WI; (2) from St. Paul, MN, to Port Clinton, OH. (Hearing site: Minneapolis, MN or Chicago, IL.)

MC 119493 (Sub-356F), filed February 8, 1980. Applicant: MONKEM COMPANY, INC., P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone (same address as applicant). Transporting *iron and steel articles and materials and supplies* used in the manufacture and distribution of iron and steel articles (except commodities in bulk), between Sioux City, IA on the one hand, and, on the other, points in IA, IL, IN, KS, MN, and MO. (Hearing site: Sioux City, IA or Omaha, NE.)

MC 119543 (Sub-11F), filed February 15, 1980. Applicant: RICHARD J. MULLANEY, 66 Helena Street, Leominster, MA 01453. Representative: David M. Marshall, 101 State Street Suite 304, Springfield, MA 01103. Transporting *coke*, in bulk, between Swedeland, PA on the one hand, and, on the other, points in ME, NH, VT, MA, CT and RI. (Hearing site: Washington, DC.)

MC 119843 (Sub-10F), filed February 11, 1980. Applicant: ROESCH LINES, INC., 844 E. Ninth Street, San Bernardino, CA 92402. Representative: Fred H. Mackensen, 9454 Wilshire Blvd., Suite 400, Beverly Hills, CA 90212. Transporting *passengers and their baggage* in round-trip charter operations, beginning and ending at points in Los Angeles and San Diego Counties, CA, and extending to points in the US (including AK, but excluding CA and HI). (Hearing site: Los Angeles, CA.)

MC 121473 (Sub-3F), filed January 22, 1980. Applicant: VENCO TRUCKING INC., R. D. #3, Emlenton, PA 16373. Representative: Guy W. Shoup (same address as applicant). Transporting *petroleum products*, in packages, and *empty containers*, between Rouseville, and Reno, PA, on the one hand, and, on the other, points in OH and NY. (Hearing site: Pittsburg, PA.)

MC 123993 (Sub-71F), filed January 24, 1980. Applicant: FOGLEMAN TRUCK LINE, INC., P.O. Box 1504, Crowley, LA 70526. Representative: Austin L. Hatchell, P.O. Box 2165, Austin, TX 78768. Transporting *such commodities* as are dealt in by grocery and drug stores (except in bulk), between the facilities of Colgate-Palmolive at or near Kansas City, KS, on the one hand, and, on the other, points in LA. (Hearing site: New Orleans, LA or Dallas, TX.)

Note.—Dual operations may be involved.

MC 124692 (Sub-328F), filed February 8, 1980. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59806. Representative: J. David Douglas (same address as applicant). Transporting

lumber and wood products, from the facilities of Potlatch Corporation at or near Couer d'Alene, Jaype, Kamiah, Lewiston, Post Falls, Potlatch, St. Maries, and Santa, ID to points in CA, restricted to the transportation of traffic originating at the named origins. (Hearing site: Boise, ID.)

MC 124813 (Sub-224F), filed February 15, 1980. Applicant: UMTHUN TRUCKING CO., a corporation, 910 South Jackson Street, Eagle Grove, IA 50533. Representative: Thomas E. Leahy, Jr., 1980 Financial Center, Des Moines, IA 50309. Transporting *spring steel,* from Detroit, MI, to Omaha, NE. (Hearing site: Omaha, NE or Washington, DC.)

Note.—Dual operations may be involved.

MC 125433 (Sub-375F), filed February 4, 1980. Applicant: F–B TRUCK LINE COMPANY, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: John B. Anderson (same as applicant). Transporting (1) *building and construction materials* (except in bulk), and (2) *materials* and *supplies* used in the manufacture and distribution of construction materials (except in bulk), between the facilities of The Celotex Corporation a Jim Walter Company at or near Tracy, CA, on the one hand, and, on the other, points in the United States in and west of MN, IA, MO, AR and LA. (Hearing site: Chicago, IL.)

MC 125433 (Sub-376F), filed February 4, 1980. Applicant: F–B TRUCK LINE COMPANY, a corporation, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: John B. Anderson (same as applicant). Transporting *salt, sand, and fertilizer spreaders,* from the facilities of Highway Equipment Company at or near (a) Cedar Rapids, IA, (b) Lebanon, TN and (c) Oneonta, NY to points in the US (except AK and HI). (Hearing site: Chicago, IL.)

MC 125433 (Sub-380F), filed February 8, 1980. Applicant: F–B TRUCK LINE COMPANY, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: John B. Anderson (same as applicant). Transporting *plastic film and sheeting,* from points in Los Angeles and Orange Counties, CA, to points in the United States (except AK and HI). (Hearing site: Los Angeles, CA.)

MC 125433 (Sub-381F), filed February 11, 1980. Applicant: F–B TRUCK LINE COMPANY, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: John B. Anderson (same as applicant). Transporting *paints, resins, adhesives, and paint material* (except in bulk), from Riverside, CA, to points in the United States (except AK and HI), restricted to the Transportation of traffic originating at the facilities utilized by Devoe & Raynolds Company. (Hearing: Los Angeles, CA.)

MC 125433 (Sub-382F), filed February 11, 1980. Applicant: F–B TRUCK LINE COMPANY, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: John B. Anderson (same as applicant). Transporting (1) *prefabricated buildings,* knocked down, or in sections, and (2) *equipment, supplies* and *parts* used in the construction, erection and completion of prefabricated buildings (except in bulk in tank vehicles), from Ft. Collins, CO, to points in TX, LA, AR and OK. (Hearing: Denver, CO.)

MC 125433 (Sub-384F), filed February 14, 1980. Applicant: F–B TRUCK LINE COMPANY, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: John B. Anderson (same as applicant). Transporting *outdoor recreational equipment and heating and air conditioning apparatuses* between the facilities of the Coleman Company at or near Wichita, KS, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing: Chicago, IL.)

MC 135953 (Sub-16F), filed January 25, 1980. Applicant: CHEROKEE LINES, INC., P.O. Box 152, Cushing, OK 74023. Representative: Donald L. Stern, Suite 610, 7171 Mercy Rd., Omaha, NE 68106. Transporting *meats, meat products, meat byproducts, and articles distributed by meat-packing houses* (except hides and commodities in bulk), 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, from the facilities of Wilson Foods Corporation at (1) Albert Lea, MN and (2) Marshall, MO, to points in CT, DE, VA, ME, MD, MA, NH, NJ, NY, PA, RI, VT, and DC, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Dallas, TX or Kansas City, MO.)

Note.—Dual operations may be involved.

MC 136343 (Sub-212F), filed January 28, 1980. Applicant: MILTON TRANSPORTATION, INC., P.O. Box 355, Milton, PA 17847. Representative: Herbert R. Nurick P.O. Box 1166, Harrisburg, PA 17108. Transporting *paper and paper products* from Hamilton and West Carrollton, OH, to points in CT, DE, ME, MD, NA, NH, NJ, NY, NC, PA, RI, VT, VA, WV and DC. (Hearing site: Columbus, OH or Washington, DC.)

Note.—Dual operations may be involved.

MC 136343 (Sub-213F), filed February 8, 1980. Applicant: MILTON TRANSPORTATION, INC., P.O. Box 355, Milton, PA 17847. Representative: Herbert R. Nurick, Esq., McNees, Wallace & Nurick, P.O. Box 1166, Harrisburg, PA 17108. Transporting *paper, paper products, and plastic articles,* and *materials, equipment,* and *supplies* used in the manufacture and distribution of all the foregoing commodities (except commodities in bulk in tank vehicles), between points in the United States in and east of MN, IA, MO, AR, and LA, on the one hand, and, on the other, the facilities of James River Corporation in VA, DE, NJ, MA, ME, and MI, restricted to the transportation of traffic originating at or destined to the facilities of James River Corporation. (Hearing site: Richmond, VA; Washington, DC.)

Note.—Dual operations may be involved.

MC 136553 (Sub-101F), filed February 5, 1980. Applicant: ART PAPE TRANSFER, INC., 1080 East 12th Street, Dubuque, IA 52001. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. Transporting *liquid fertilizer,* from Clinton, IA, to points in IL and WI. (Hearing site: Chicago, IL or Des Moines, IA.)

MC 136773 (Sub-8F), filed February 4, 1980. Applicant: S.T.S. MOTOR FREIGHT, INC., 107 Evergreen Rd., Stratford, NJ 08084. Representative: Alan Kahn, 100 South Broad St., Philadelphia, PA 19110. 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), between points in PA on and east of U.S. Hwy 15 and on and south of Interstate Hwy 80, points in DE and NJ. (Hearing site: Phildelphia, PA.)

MC 138703 (Sub-5F), filed January 28, 1980. Applicant: BOESDORFER TRUCKING, INC., 117 Church St., Pleasant Plains, IL 62677. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. Transporting *clay,* in bulk, in dump vehicles, from Springfield, IL, to Muscatine, IA. (Hearing site: St. Louis, MO; Chicago, IL.)

MC 139482 (Sub-172F), filed February 13, 1980. Applicant: NEW ULM FREIGHT LINES, INC., P.O. Box 877, New Ulm, MN 56073. Representative: James E. Ballenthin, 630 Osborn Building, St. Paul, MN 55102. Transporting *televisions, video tape recorders, microwave ovens and parts* and *accessories* for the foregoing commodities, from Franklin Park, IL, to Denver, CO. (Hearing site: Chicago, IL.)

MC 139973 (Sub-81F), filed January 21, 1980. Applicant: J. H. WARE TRUCKING CO., a corporation, P.O. Box 398, Fulton, MO 65251. Representative: Larry D. Knox, 600 Hubbell Building, Des Moines, IA 50309. Transporting (1) *electrical applicances,* (2) *equipment and parts* for electrical appliances, and (3) *poleline hardware,* between Greenville, NC and Lumberton, MS, on the one hand, and, on the other, points in the US (except AK and HI). (Hearing site: Chicago, IL.)

MC 140243 (Sub-11F), filed February 15, 1980. Applicant: APPLE HOUSE, INC., 3726 Birney Avenue, Scranton, PA 18505. Representative: Joseph F. Hoary, 121 South Main Street, Taylor, PA 18517. Transporting (1) animal and poultry feed, from Limeridge, PA, to Miami, FL, and (2) plastic film sheeting and plastic bags, from Pottsville, PA to points in NC, FL, and GA. (Hearing site: Philadelphia, PA.)

MC 140612 (Sub-81F), filed February 8, 1980. Applicant: ROBERT F. KAZIMOUR, P.O. Box 2207, Cedar Rapids, IA 52406. Representative: J. L. Kazimour (same as applicant). Transporting over irregular routes, *general commodities,* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk in tank vehicles, and those requiring special equipment), between the facilities utilized by the Ardan Co. at points in the United States (except AK and HI). (Hearing site: Des Moines, IA.)

MC 141443 (Sub-57F), filed January 17, 1980. Applicant: JOHN LONG TRUCKING, INC., 1030 East Denton, Sapulpa, OK 74066. Representative: Wilburn L. Williamson, Suite 615-East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. Transporting *such commodities as are dealt in by wholesale, retail and chain grocery and food business houses,* and *equipment, materials* and *supplies* used in the conduct of such business (except in bulk), between points in AZ, AR, CA, CO, ID, IA, KS, LA, MN, MO, MT, NE, NV, NM, OK, OR, TX, UT, WA, WI and WY, restricted to the transportation of traffic originating at or destined to the facilities utilized by Safeway Stores, Inc. (Hearing site: San Francisco, CA.)

Note.—Dual operations may be involved.

MC 141443 (Sub-58F), filed January 17, 1980. Applicant: JOHN LONG TRUCKING, INC., 1030 East Denton, Sapulpa, OK 74066. Representative: Wilburn L. Williamson, Suite 615-East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. Transporting *petroleum products and fuel additives,* (except in bulk), from the facilities of Majestic Lubricating Company at or near Tulsa, OK, to points in AZ, AR, CA, CO, ID, KS, LA, MO, MT, NV, NM, OR, TX, UT, WA, and WY. (Hearing site: Tulsa, OK.)

Note.—Dual operations may be involved.

MC 141443 (Sub-59F), filed February 11, 1980. Applicant: JOHN LONG TRUCKING, INC., 1030 East Denton, Sapulpa, OK 74066. Representative: Wilburn L. Williamson, Suite 615-East, The Oil Center, 2601 Northwest Expressway, Oklahoma City, OK 73112. Transporting *cheese, cheese products* and *synthetic cheese,* from the facilities of L. D. Schreiber Cheese Co. at or near Logan, UT, to points in CO, ID, MT, OR and WA. (Hearing site: Dallas, TX.)

Note.—Dual operations may be involved.

MC 141533 (Sub-14F), filed February 4, 1980. Applicant: LYN TRANSPORT, INC., 37 North Central Avenue, Elmsford NY 10532. Representative: Bruce J. Robbins, 118–21 Queens Boulevard, Forest Hills, NY 11375. Transporting *frozen meats,* from Port Newark, NJ and Philadelphia, PA, to points in IL, IN, WI, MI and Louisville, KY. (Hearing site: New York, NY.)

MC 141742 (Sub-12F), filed February 1, 1980. Applicant: FLOWERS TRANSPORTATION, INC., P.O. Box B, Station A, Auburn, CA 95603. Representative: Walter H. Walker, III, 100 Pine Street, Suite 2550, San Francisco, CA 94111. Transporting *lumber and lumber products,* (a) from points in OR, to points in CA and NV; and (b) from points in CA, to points in NV, restricted in (a) and (b) above to the transportation of traffic from the facilities of Bendix Forest Products. (Hearing site: San Francisco, CA.)

MC 142703 (Sub-27F), filed February 15, 1980. Applicant: INTERMODAL TRANSPORTATION SERVICES, INC., 750 West Third Street, Post Office Box 14072, Cincinnati OH 45214. Representative: Michael Spurlock, 275 East State Street, 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) between Alexandria, VA on the one hand, and, on the other, points in CT, DE, MD, MA, NJ, NY, PA, RI, VA and DC. Restricted to the transportation of traffic having a prior or subsequent movement by rail or water. (Hearing site: Columbus, OH.)

Note.—Dual operations may be involved.

MC 142743 (Sub-21F), filed February 15, 1980. Applicant: FAST FREIGHT SYSTEMS, INC., P.O. Box 132C, Tupelo, MS 38801. Representative: Martin J. Leavitt, 22375 Haggerty Road, P.O. Box 400, Northville, MI 48167. Transporting *building and roofing materials, and materials, equipment and supplies* used in or incidental to the manufacture, installation and distribution of the foregoing commodities (except commodities in bulk), between points in the United States in and east of ND, SD, NE, KS, OK and TX, restricted to the transportation of traffic originating at or destined to the facilities of GAF Corporation. (Hearing site: Washington, D.C., Atlanta, GA, or Chicago, IL.)

MC 144622 (Sub-142F), filed February 1, 1980. Applicant: GLENN BROS. TRUCKING, INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Phillip G. Glenn (same address as applicant) and Attorney: Robert D. Gisvold, 1000 First National Bank Bldg., Minneapolis, MN 55402. Transporting *food stuffs* from the facilities of Land O' Frost at Searcy, AR, to points in AL, AZ, CA, CO, FL, GA, KS, LA, MD, MI, NC, OK, OR, SC, TN, TX, UT, VA, WA, and WV. (Hearing site: Little Rock, AR.)

Note.—Dual operations may be involved.

MC 144622 (Sub-146F), filed February 13, 1980. Applicant: GLENN BROS. TRUCKING, INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Phillip G. Glenn (same address as applicant). Transporting (1) *cigarette lighters,* (2) *lighter fuels and accessories* for the commodities in (1) above, and (3) *electric applicances,* between Woodbridge, NJ, on the one hand, and, on the other, Reno and Sparks, NV, and points in CA. (Hearing site: Little Rock, AR.)

Note.—Dual operations may be involved.

MC 146293 (Sub-52F), filed February 11, 1980. Applicant: REGAL TRUCKING CO., INC., P.O. Box 829, Lawrenceville, GA 30246. Representative: Richard M. Tettelbaum, Serby & Mitchell, P. C., Fifth Floor, Lenox Towers S, 3390 Peachtree Road, N.E., Atlanta, GA 30326. Transporting (1) *such merchandise as is dealt in by wholesale, retail, chain grocery stores, food business houses, and agricultural feed business houses, soy products, dry flour paste,* and *dairy products;* (2) *materials, equipment, ingredients and supplies* used in the development, manufacture, distribution, and sale of the commodities in (1), (except commodities 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 Ralston Purina Company). (Hearing site: St. Louis, MO.)

Note.—Dual operations may be involved.

MC 146753 (Sub-7F), filed February 8, 1980. Applicant: SAM YOUNG, INC., P.O. Box 337, Wolcott, IN 47995.

Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46240. Transporting *dessert and beverage preparations,* from the facilities of Gel-Sert Company at West Chicago, IL, to points in the United States (except AK and HI). (Hearing site: Chicago, IL, or Washington, DC.)

MC 148743 (Sub-2F), filed January 14, 1980. Applicant: JOEY CRAWFORD TRUCKING COMPANY, Rt. 1, Box 366D, Farmington, MO 63640. Representative: Joey Crawford (same address as applicant). Transporting (1) *lime,* in bulk, in dump vehicles, from St. Genevieve, MO, to Carleton, MI, and (2) *dolomite,* in dump vehicles, from Gibsonburg, OH, to Flat River, MO. (Hearing site: St. Louis, MO, or Detroit, MI.)

MC 149353 F filed February 13, 1980. Applicant: D. D.H., INC., P.O. Box 459, Middleburg, FL 32068. Representative: Sol H. Proctor, 1101 Blackstone Bldg., Jacksonville, FL 32202. Transporting: *lumber,* from Lake Butler, FL, to points in GA and FL. (Hearing site: Jacksonville, FL.)

MC 149043 (Sub-1F), filed January 31, 1980. Applicant: EASTERN TANK LINES, INC., 5536 Brentlinger Drive, Dayton, OH 45414. Representative: Andrew Jay Burkholder, Beery & Spurlock Co., L.P.A., 275 East State Street, Columbus, OH 43215. Transporting *sugar, corn syrup,* and *fructose, in bulk, in tank vehicles,* between points in NY, NJ, MI, IN, OH, IL and PA. (Hearing site: Columbus, OH.)

MC 149362 F filed February 8, 1980. Applicant: EUREKA VAN & STORAGE COMPANY, INC., P.O. Box 17383, Dulles International Airport, Washington, D.C. 20041. Representative: Dean N. Wolfe, Suite 145, 4 Professional Drive, Gaithersburg, MD 20760. Transporting *household goods as defined by the Commission,* between points in MD, VA, and DC, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC.).

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Decided: March 28, 1980.

By the Commission, Review Board Number 3, Members Parker, Fortier and Hill.

(1) MC 7840 (Sub-26F). Applicant: ST. LAWRENCE FREIGHTWAYS, INC., 650 Cooper St., Watertown, NY 13601.

(2) MC 48441 (Sub-54F). Applicant: R.M.E. INC., P.O. Box 418, Streator, IL 61364.

(3) MC 73688 (Sub-110F). Applicant: SOUTHERN TRUCKING CORPORATION, 1500 Orenda Ave., P.O. Box 7195, Memphis, TN 38107.

(4) MC 78687 (Sub-88F *). Applicant: LOTT MOTOR LINES, INC., West Cayuga St., P.O. Box 751, Moravia, NY 13118.

(5) MC 106920 (Sub-87F). Applicant: RIGGS FOOD EXPRESS, INC., West Monroe St., P.O. Box 26, New Bremen, OH 45869.

(6) MC 115331 (Sub-525F). Applicant: TRUCK TRANSPORT, INCORPORATED, 11040 Manchester Rd., St. Louis, MO 63122.

(7) MC 119349 (Sub-34F *). Applicant: STARLING TRANSPORT LINES, INC., P.O. Box 1733, Fort Pierce, FL 33450.

(8) MC 127303 (Sub-68F). Applicant: ZELLMER TRUCK LINES, INC., P.O. Box 343, Granville, IL 61326.

(9) MC 136161 (Sub-26F). Applicant: ORBIT TRANSPORT, INC., P.O. Box 163, Spring Valley, IL 61362.

(10) MC 136511 (Sub-96F). Applicant: VIRGINIA APPALACHIAN LUMBER CORPORATION, 9640 Timberlake Rd., Lynchburg, VA 23502.

(11) MC 141914 (Sub-66F). Applicant: FRANKS & SON, INC., Route 1, Box 1 8A, Big Cabin, OK 74332.

(12) MC 142873 (Sub-2F *). Applicant: DEWEY L. WILFONG, d.b.a. D & W TRUCK LINES, 209 First St., Parsons, WV 26287.

(13) MC 144676 (Sub-4F *). Applicant: M & S TRANSPORT LINES, INC., P.O. Box 417, Sultana, CA 93666.

(14) MC 145950 (Sub-71F *). Applicant: BAYWOOD TRANSPORT, INC., Route 6, P.O. Box 2611, Waco, TX 76706.

(15) MC 146573 (Sub-9F). Applicant: LA SALLE TRUCKING, INC., P.O. Box 46, Peru, IL 61354.

(16) MC 146890 (Sub-17F *). Applicant: C & E TRANSPORT, INC., d.b.a. C. E. ZUMSTEIN CO., P.O. Box 27, Lewisburg, OH 45338.

(17) MC 147451 (Sub-1F *). Applicant: RAY J. FORNEY, INC., P.O. Box 207, Ashton, IL 61006.

(18) MC 148600 (Sub-1F *). Applicant: TRANSHIELD TRUCKING, INC., 1470 N. Farnsworth Ave., P.O. Box 1617, Aurora, IL 60507.

(19) MC 147452 (Sub-1F *). Applicant: W. D. W. TRUCKING, INC., 2620 S.W. 66th Terrace, Miramar, FL 33023.

(20) MC 148573 (Sub-2F *). Applicant: SHEA/RUSTIN TRANSPORT CO., a corporation, P.O. Box 93567, Martech Station, Atlanta, GA 30318.

Representative for all applicants above: E. Stephen Heisley, 805 McLachlen Bank Bldg., 666 Eleventh St., NW, Washington, DC 20001. By applications filed October 26, 1979, the 20 above-named carriers are granted authority to transport (1) *glass products, metal products, plastic products, clay and clay products, feld-spar, and talc,* (except commodities in bulk), (2) *molds and machinery* used in the manufacture of glass products, (3) *bottle coating systems,* (4) *parts and accessories* for the commodities in (2) and (3) above, (except commodities in bulk), and (5) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1), (2), (3), and (4) above, (except commodities in bulk), between the facilities of Wheaton Industries, at or near Centralia, IL, on the one hand, and, on the other, points in the US (except AK and HI). (Hearing site: Washington, DC).

Note.—* Dual operations may be involved.

MC 133085 (Sub-15F), filed November 8, 1979. Applicant: TRENCO, INCORPORATED, 2109 Marydale Ave., P.O. Box 697, Williamsport, PA 17701. Representative: E. Stephen Heisley, 805 McLachlen Bank Bldg., 666 Eleventh St., NW., Washington, DC 20001. Transporting (1) *glass products, metal products, plastic products, clay and clay products, feldspar, and talc,* (except commodities in bulk), (2) *molds and machinery* used in the manufacture of glass products, (3) *bottle coating systems,* (4) *parts and accessories* for the commodities in (2) and (3) above, (except commodities in bulk), and (5) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1), (2), (3), and (4) above, (except commodities in bulk), between the facilities of Wheaton Industries, at or near Centralia, IL, on the one hand, and, on the other, points in the US (except AK and HI). (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 148655 (Sub-1F), filed November 8, 1979. Applicant: ERIEVIEW CARTAGE, INC., 100 Erieview Plaza, P.O. Box 6977, Cleveland, OH 44114. Representative: E. Stephen Heisley, 805 McLachlen Bank Bldg., 666 Eleventh St., NW., Washington, DC 20001. Transporting (1) *glass products, metal products, plastic products, clay and clay products, feldspar, and talc,* (except commodities in bulk), (2) *molds and machinery* used in the manufacture of glass products, (3) *bottle coating systems,* (4) *parts and accessories* for the commodities in (2) and (3) above, (except commodities in bulk), and (5) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1), (2), (3), and (4) above, (except commodities in bulk), between the facilities of Wheaton Industries, at or near Centralia, IL, on the one hand, and, on the other, points in the US (except AK and HI). (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

Volume No. 137

Decided: April 7, 1980.

By the Commission, Review Board Number 1, Members Carleton, Joyce and Jones.

MC8973 (Sub-61F) (correction), filed July 17, 1979, published in the **Federal Register**, issue of February 12, 1980, and republished, as corrected, this issue. Applicant: METROPOLITAN TRUCKING, INC., 2424 95th Avenue, North Bergen, NJ 07047. Representative: Morton E. Kiel, Suite 1832, 2 World Trade Center, New York, NY 10048. Transporting (1) *containers; and materials; supplies and equipment* used in the manufacture and distribution of containers (except in bulk) between points in the United States (except AK and HI). (Hearing site: New York, NY.) The purpose of this republication is to correct the commodity and territorial description in part (1). The remainder of the authority remains as previously published.

MC119632 (Sub-105F) (correction), filed August 3, 1979, published in the **Federal Register**, issue of March 5, 1980, and republished as corrected this issue. Applicant: REED, INC., 634 Ralston Ave., Defiance, OH 43512. Representative: Wayne C. Pence (same address as applicant). Transporting *foodstuffs* (except in bulk), from the facilities of Ragu Foods, Inc., at Rochester and Manchester, NY, to Milwaukee, WI, and points in IL, MI, OH and PA. (Hearing site: Rochester or Buffalo, NY.) The purpose of this republication is to correctly identify "Milwaukee, MI" as "Milwaukee, WI" which was previously published in error.

MC139482 (Sub-144F) (correction), filed August 6, 1979, published in the **Federal Register**, issue of March 5, 1980, and republished, as corrected, this issue. Applicant: NEW ULM FREIGHT LINES, INC., P.O. Box 877, New Ulm, MN 56073. Representative: Samuel Rubenstein, 301 North Fifth Street, Minneapolis, MN 55403. Transporting (1) *mechanical construction forms,* and (2) *equipment and supplies* used in the manufacture of the commodities in (1) above, between points in WI, MN, ND, SD and IA. (Hearing site: Minneapolis or St. Paul, MN.) The purpose of this republication is to correct the territorial description.

MC145433 (Sub-1F) (correction), filed August 27, 1979, published in the **Federal Register**, issue of February 28, 1980, and republished, as corrected, this issue. Applicant: COLORADO STEEL & WIRE TRANSPORTATION CO., INC., Route 1, Box 161C, Eaton, CO 80615. Representative: Truman A. Stockton, Jr., The 1650 Grant St. Bldg., Denver, CO 80203. *Contract carrier,* transporting (1) *steel fence posts, rebars, barbed bailing wire, angles, smooth bars, T-bar stock, fence, nails and welded fabric,* from the facilities of Colorado Steel and Wire Company, at or near Loveland, CO, to points in IN and MO, and (2) materials used in the manufacture of the commodities named in (1) above, in the reverse direction, under continuing contract(s) with Colorado Steel and Wire Company, of Loveland, CO. Condition: Issuance of a permit in this proceeding is subject to the prior or coincidental cancellation, at the written request of applicant and the other partners owning Transport Steel, of permit MC140517. (Hearing site: Denver, CO.) The purpose of this republication is to correct the commodity description in Part (1) above.

MC146643 (Sub-12F), filed August 6, 1979, and published in the **Federal Register**, issue of March 5, 1980, as (Sub-1F) and republished as corrected this issue. Applicant: DAVID GREECH TRANSPORTATION SYSTEMS, INC., 3202 State Street, South Chicago Heights, IL 60411. Representative: Donald B. Levine, 39 South LaSalle Street, Chicago, IL 60603. The purpose of this republication is to correctly identify the correct Sub No. assigned to this application which is (Sub-12F) in lieu of (Sub-1F) which was previously published in error. The request of authority remains the same as published.

MC 146953 (Sub-1F), filed May 23, 1979, and published in **Federal Register** issue of December 6, 1979, and republished as corrected this issue. Applicant: MONROE FUGATE, d.b.a. H & M CARTAGE, 17151 South Overhill, Tinley Park, IL 60477. Representative: William D. Brejcha, 10 S. LaSalle St., Suite 1600, Chicago, IL 60603. *Contract carrier* transporting (1) *plastic articles and chemicals* (except in bulk), from the facilities of Arco-Polymers, Inc., at or near (a) Chicago, IL, (b) Port Arthur, TX, (c) Beaver Valley, PA, and (d) Youngstown, OH, to points in AR, IA, IL, IN, KY, MI, MO, OH, PA, TX, and WI, and (2) *materials, equipment, and supplies* used in the manufacture of the commodities in (1) above (except commodities in bulk), in the reverse direction, under continuing contract(s) with Arco-Polymers, Inc., of Chicago, IL. (Hearing site: Chicago, IL.) The purpose of this republication is to show (1) "contract carrier authority" in lieu of "common carrier authority", and (2) the correct commodity description in part (1).

Volume No. 138

Decided: April 7, 1980.

By the Commission, Review Board No. 3, Members Parker, Fortier and Hill.

MC 133233 (Sub-73F), filed September 12, 1979, and published in the **Federal Register** issue of March 11, 1980 as (Sub-4F), and republished as corrected this issue. Applicant: CLARENCE L. WERNER, d.b.a. WERNER ENTERPRISES, P.O. Box 37308, I–80 and Highway 50, Omaha, NE 68137. Representative: J. F. Crosby, P.O. Box 37205, Omaha, NE 63137. The purpose of this republication is to correctly identify the Correct Sub. No. assigned to this application which is (Sub-73F) in lieu of (Sub-4F) which was previously published in error. The request of authority remains the same as published.

MC 139482 (Sub-150F), filed August 2, 1979, and published in the **Federal Register** issue of March 5, 1980, and republished as corrected this issue. Applicant: NEW ULM FREIGHT LINES, INC., P.O. Box 877, New Ulm, MN 56073. Representative: Samuel Rubenstein, 301 North Fifth St., Minneapolis, MN 55403. Transporting *bakery products* (except frozen), from Marietta, OK, to points in (a) Fresno, Sacramento, and Vacabille, CA; (b) Hartford, CT; (c) Denver, CO; (d) Cedar Rapids, IA; (e) Boise and Pocatello, ID; (f) Lawrence, MA; (g) Baltimore, MD; (h) Minneapolis, MN, and its commercial zone; (i) Winston Salem, NC; (j) Fargo and Minot, ND; (k) Grand Island, NE; (l) Akron and Cleveland, OH; (m) Pittsburgh, PA; (n) Pawtucket, RI; (o) Bristol and Richmond, VA; (p) Salt Lake City, UT; (q) Tacoma, WA; and (r) Milwaukee, WI. (Hearing site: Minneapolis or St. Paul, MN.) The purpose of this republication is to show the correct destination to read "(d) Cedar Rapids, IA" in lieu of "(d) Cedar Rapids, LA" published in error.

MC 141532 (Sub-46F) (correction), filed September 24, 1979, published in the **Federal Register**, issue of March 18, 1980 and republished, as corrected this issue. Applicant: PACIFIC STATES TRANSPORT, INC., 3328 East Valley Road, Renton, WA 98055. Representative: Henry C. Winters, 525 Evergreen Building, Renton, WA 98055. Transporting (1) *aluminum and aluminum products,* from the facilities of Kaiser Aluminum & Chemical Corp., at or near Ravenswood, WV to points in AZ, CA, CO, KS, OR, TX, and WA; and (2)(a) *titanium and titanium products,* and (2)(b) *materials and supplies* used in the production of the commodities in (2)(a) above (except commodities in bulk), between Toronto, OH, and Henderson, NV, restricted to the transportation of traffic originating at or destined to facilities of Titanium Metals

Corp. of America. (Hearing site: Las Vegas, NV.)

Note.—The purpose of this republication is to correct the commodity description and territorial description.

MC 144672 (Sub-18F) (correction), filed August 27, 1979, published in the **Federal Register**, issue of March 5, 1980, and republished, as corrected, this issue. Applicant: VICTORY EXPRESS, INC., P.O. Box 26189, Trotwood, OH 45426. Representative: Richard H. Schaefer (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers and converters of paper, paper products, pulp and plastic products (except in bulk), between Kalamazoo, MI, Edgely, PA, and Berlin and Gorham, NH, on the one hand and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Brown Company. (Hearing site: Kalamazoo, MI.) The purpose of this republication is to correct the territorial description and the restriction.

Note.—Dual operations may be involved.

MC 147463F (correction), filed June 20, 1979, published in the **Federal Register**, issue of January 15, 1980, and republished, as corrected, this issue. Applicant: R. M. GUINTHER, INC., R.D. No. 3, Box 81, Boyertown, PA 19512. Representative: John W. Dry, Esquire, 541 Penn Street, Reading, PA 19601. Transporting *specialty chemicals and metals*, between the facilities of Kawecki-Berylco Industries, a division of Cabot Corporation, in Colebrookdale Township, Berks County, and Douglas Township, Montomery County, PA, and in CT, DE, IN, MD, NJ, NY and OH. (Hearing site: Philadelphia, PA or Washington, DC.) The purpose of this republication is to correct the territorial description.

MC 147983 (Sub-2F) (correction), filed August 30, 1979, published in the **Federal Register**, issue of March 5, 1980, and republished, as corrected, this issue. Applicant: MIAMI TRUCKING, INC., 585 East Fifth Street, Peru, IN 46970. Representative: Warren C. Moberly, 320 North Meridian Street, Indianapolis, IN 46204. Transporting (1) *raw materials for processing or mixing into dry fertilizer*, and (2) *fertilizer*, dry, between points in IN on the one hand, and, on the other, points in OH on and west of U.S. Hwy 75, and between points in IN and points in IL in Cook, Will, Kankakee, Iroquois, Vermilion, Edgar, Clark, Crawford, Lawrence, Wabash, Edwards, White and Gallatin Counties. (Hearing site: Chicago, IL or Washington, DC.) The purpose of this republication is to correct the authority by removing the restriction "restricted to service for Kaiser Agricultural Chemicals, Division of Kaiser Aluminum & Chemical Sales, Inc."

Volume No. 141

Decided: April 7, 1980.

By the Commission, Review Board Number 2, Members Eaton, Liberman and Jensen.

MC 72423 (Sub-9F) (correction), filed September 6, 1979, published in the **Federal Register** issue of March 5, 1980, and republished as corrected this issue. Applicant: PLATTE VALLEY FREIGHTWAYS, INC., 111 East Chestnut St., Sterling, CO 80751. Representative: Raymone M. Kelley, 450 Capitol Life Center, Denver, CO 80203. To operate as a *common carrier*, by motor vehicle, in interstate or foreign commerce, over *regular routes*, transporting *general commodities* (except classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Sterling, CO and Ogallala, NE, from Sterling over U.S. Hwy 6, to Holyoke, CO, then over CO Hwy 176 to junction NE Hwy 23, then over NE Hwy 23 to Grant, NE, and then over NE Hwy 61 to Ogallala, and return over the same route, serving all intermediate points. (Hearing site: Denver, CO or Ogallala, NE.) The purpose of this republication is to add applicant's intention to tack and interline.

Note.—Applicant indicates intention to tack with existing authority, and interline with other carriers at Sterling and Holyoke, CO, and Ogallala, NE.

MC 107162 (Sub-55F) (correction), filed August 13, 1979, published in the **Federal Register**, issue of February 26, 1980, and republished, as corrected, this issue. Applicant: NOBLE GRAHAM TRANSPORT, INC., Rural Route No. 1, Brimley, MI 49715. Representative: John Duncan Varda, 121 South Pinckney Street, Madison, WI 53703. Transporting (1) *lumber and lumber products*, from Bangor, WI, to points in Nassau County, NY, (2) *lumber* from Camden, NJ, Norfolk, VA, Charleston, SC, ar.d New Orleans, LA to points in IA, IL, IN, MI, MN, OH and WI, and (3) *building and insulating materials* (except iron and steel articles and commodities in bulk) from the facilities of the CertainTeed Corporation in Scott County, MN, to points in WI and the Upper Peninsula of MI. (Hearing site: Chicago, IL or Detroit, MI.) The purpose of this republication is to correct the commodity description in Part (3). The remainder of the authority remains as previously published.QQ02

Note.—Dual operations may be involved.

MC 121332 (Sub-3F), filed September 17, 1979, and published in the **Federal Register** issue of March 5, 1980, as MC 121322 (Sub-3F), and republished as corrected this issue. Applicant: STEVE J. DUNNE CARTAGE, INC., 1800 South Wolf Road, Des Plaines, IL 60018. Representative: William H. Towle, 180 North LaSalle St., Chicago, IL 60601. The purpose of this republication is to correctly identify the applicant's MC number to read MC 121332 in lieu of MC 121322 which was previously published in error. The request of authority remains the same as published.

MC 139482 (Sub-145F) (correction), filed August 20, 1979, published in the **Federal Register**, issue of February 26, 1980, and republished, as corrected, this issue. Applicant: NEW ULM FREIGHT LINES, INC., P.O. Box 877 New Ulm, MN 56073. Representative: James E. Ballenthin, 630 Osborn Building, St. Paul, MN 55102. Transporting (1) *such commodities* as is dealt in by grocery and food business houses and agricultural feed business houses; soy products; paste, flour products; dairy based products and (2) *materials, ingredients, equipment and supplies* used in the manufacture, distribution and sale of the products in (1) above (except commodities in bulk), between points in the US (except AK and HI), restricted to shipments originating at or destined to facilities used by Ralston Purina Company. (Hearing site: St. Louis, MO.) The purpose of this republication is to correct the commodity in part (1).

MC 141652 (Sub-36F), filed September 13, 1979, and published as MC 141652 Sub 361F in the FR issue of March 18, 1980, and republished as corrected this issue. Applicant: ZIP TRUCKING, INC., P.O. Box 5717, Jackson, MS 39207. Representative: K. Edward Wolcott, P.O. Box 56387, Atlanta, GA 30343. The purpose of this republication is to correctly identify the correct Sub No. assigned to this application which is Sub 36F in lieu of Sub 361F previously published in error. The request of authority remains the same as published.

MC 143032 (Sub-29F), filed September 18, 1979, and published as MC 143032 Sub 279F in the FR issue of March 5, 1980, and republished as corrected this issue. Applicant: THOMAS J. WALCZYNSKI, d.b.a. WALCO TRANSPORT, 3112 Truck Center Drive, Duluth, MN 55806. Representative: William J. Gambucci, 414 Gate City Building, P.O. Box 1680, Fargo, ND 58107. The purpose of this republication is to correctly identify the correct Sub No. assigned to this application which is

Sub 29F in lieu of Sub 297F previously published in error. The request of authority remains the same as published.

MC 147423F, filed May 24, 1979, and published in the FR issue of October 23, 1979, and republished as amended this issue. Applicant: BOND TRANSFER, INC., 1831 Mills Avenue, P.O. Box 10756, El Paso, TX 79997. Representative: Kenneth R. Hoffman, 801 Vaughn Bldg., 807 Brazos Street, Austin, TX 78701. 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), between El Paso, TX, on the one hand, and, on the other, points in Grant, Hidalgo, Luna, Dona Ana, Otero, Lincoln, Chaves, Eddy, and Lea Counties, NM. (Hearing site: El Paso, TX.) The purpose of this republication is to remove the restriction which was previously published.

Agatha L. Mergenovich,

Secretary.

[FR Doc. 80-11112 Filed 4-14-80; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

Federal Committee on Apprenticeship; Public Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act (Pub. L. 92-463; 5 U.S.C. App. 1) of October 6, 1972, notice is hereby given of an open meeting of the Subcommittee on Equal Apprenticeship Opportunity to be held on April 29, 1980, at the Department of Labor Building, Room N-5437, 200 Constitution Avenue, NW, Washington, D.C. The meeting will be in session from 1:30 p.m. until 3:30 p.m. approximately.

The agenda for the meeting includes:

1. a. BAT Overview of the regulations on "Nondiscrimination on the Basis of Handicap"

b. The Handicap Issue and Affirmative Action—BAT/Women's Bureau Report

2. Establish liaison procedure to review all related regulations in advance so that the Committee will be in a preactor rather than reactor position to coordinate this information and set up guidelines.

3. Status Report on Promotional Activity—The Public Service Announcement Campaign.

Members of the public are invited to attend the proceedings. Any member of the public who wishes to file written data, views or arguments pertaining to the agenda may do so by furnishing it to the Executive Secretary at any time prior to the meeting. Thirty duplicate copies are needed for the members and for inclusion in the minutes of the meeting.

If time permits, members may be permitted to address the Subcommittee on the above issues.

Any member of the public who wishes to speak at this meeting should so indicate in a written statement, also the nature of intended presentation and amount of time needed. The Chairperson will announce at the beginning of the meeting the extent to which time will permit the granting of such requests.

Communications to the Executive Secretary shoud be addressed as follows: Mrs. M. M. Winters, Bureau of Apprenticeship and Training, ETA, U.S. Dept. of Labor, 601 D Street, N.W. (Room 5434), Washington, D.C. 20213.

Signed at Washington, D.C., this 10th day of April 1980.

Ernest G. Green,

Assistant Secretary for Employment and Training Administration.

[FR Doc. 80-11348 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-30-M

Mine Safety and Health Administration

[Docket No. M-80-32-M]

Grand Rapids Gypsum Co.; Petition for Modification of Application of Mandatory Safety Standard

Grand Rapids Gypsum Company, P.O. Box 2475, Grand Rapids, Michigan 49501, has filed a petition to modify the application of 30 CFR 57.4-52 (underground use of gasoline) to its mine located in Kent County, Michigan. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

The substance of the petition follows:

1. Petitioner's mine is non-gaseous and incline entries are concrete lined, with alternate access at mid point 50 feet above lower level and 50 feet below portal level.

2. Petitioner is operating a pickup truck using non-leaded gasoline with an E.P.A. approved catalytic convertor for access to the mine shop, to and from the mine and for occasional engineering use.

3. Petitioner's mine has only one mine opening that will accommodate this truck.

4. Petitioner states that a modification of the standard to allow the use of only this one mine opening will not result in a diminution of safety for the miners affected because:

a. Loading and unloading as well as engineering work will be performed with the engine off,

b. Noxious fume emissions are eliminated because of the use of no-lead fuel and the catalytic converter,

c. The fuel tank is well protected from any possible contact from wall abrasion, and

d. The mine is all horizontal except for a 25% grade incline access which is the mine ventilation exhaust portal. Any rollover chances are minimal.

5. Further, petitioner states that in the event of a mine emergency, immediate access by this highway-type vehicle would greatly improve medical response or other needed assistance.

6. For the reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments on or before May 15, 1980. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: April 4, 1980.

Frank A. White,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 80-11349 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-80-35-M]

Rio Blanco Oil Shale Co.; Petition for Modification of Application of Mandatory Safety Standard

Rio Blanco Oil Shale Company, 9725 East Hampden Avenue, Denver, Colorado 80231 has filed a petition to modify the application of 30 CFR 57.21-78 (permissible equipment) to its mine located in Rio Blanco County, Colorado. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statement follows:

1. Under normal operating conditions, the mine is ventilated by an 8-foot diameter, 300 HP main fan. A standby fan will be installed at the surface.

2. As an alternative to installation of a permissible standby fan, petitioner proposes to install a 200 HP Jetair Model P-4150-B, two-state axial fan, which is driven by an inline totally enclosed motor (460V, 3 phase). This fan will be installed at the surface, and will be protected by a methane monitor in the ventilation air exhaust stream. The

monitor would shut down the fan in the event dangerous quantities (1.0 percent or more) of methane are present in the air current.

3. Because of the relatively limited extent of the planned mine, as well as the very localized and low concentrations of methane encountered in its mine development, petitioner maintains that even the lower air capacity of the proposed standby fan will exceed the requirements for methane dilution.

4. In the event the standby fan stops, the petitioner would promptly de-energize all electrical power to the mine.

5. The petitioner states that this alternative method of operation will provide the same measure of protection to the miners affected as that provided by the standard.

Request for Comments

Persons interested in this petition may furnish written comments on or before May 15, 1980. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: April 4, 1980.

Frank A. White,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 80-11350 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-80-23-M]

Rio Blanco Oil Shale Co.; Petition for Modification of Application of Mandatory Safety Standard

Rio Blanco Oil Shale Company, 9725 East Hampden Avenue, Denver, Colorado 80231 has filed a petition to modify the application of 30 CFR 57.6-142 (explosives loading) to its mine located in Rio Blanco County, Colorado. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. Petitioner wishes to place approximately 1,000 pounds of water gel explosives at the bottom of several deep blastholes in order to fragment oil shale by a method similar to vertical crater retreat blasting.

2. The blastholes will be approximately 10 inches in diameter, 400 to 800 feet deep, and will be drilled from the surface.

3. As an alternative method, petitioner proposes to load these explosives through a wireline dump boiler, a cannister of approximately the capacity of the charge, the lower end of which opens on set-down to release the charge.

4. In the event the explosive is not discharged from the cannister at the bottom of the blasthole, that fact would be immediately apparent from the weight of the wireline. Attempts to activate the cannister dump could then be repeated. If such attempts failed, the charge could be raised to the surface in the cannister with no greater hazard than that initially associated with lowering it into position.

5. With the cannister being suspended by wireline, no opportunity exists for forced rotation to build up heat.

6. Petitioner contends that the alternative method proposed is the safest one that can be devised for the emplacement of these quantities of explosives at the bottom of deep vertical blastholes.

Request for Comments

Persons interested in this petition may furnish written comments on or before May 15, 1980. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: April 4, 1980.

Frank A. White,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 80-11351 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-80-22-M]

Rio Blanco Oil Shale Co.; Petition for Modification of Appliction of Mandatory Safety Standard

Rio Blanco Oil Shale Company, 9725 East Hampden Avenue, Denver, Colorado 80231 has filed a petition to modify the application of 30 CFR 57.21-24 (ventilation failure or stoppage) to its mine located in Rio Blanco County, Colorado. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. Under normal operating conditions, the mine is ventilated by an eight foot diameter, 300 HP main fan.

2. As an alternative method which will at all times guarantee the safety of the miners affected, petitioner proposes to:

a. Install a smaller 200 HP standby fan to be operated on the surface in compliance with applicable gassy mine standards in the event of stoppage of the main fan,

b. Withdraw all persons from the affected active workings and/or the mine in the event the main fan stops,

c. Leave electrical power to the mine pumps, which are located upstream with respect to the direction of mine air flow. This is to prevent the mine from flooding in the event the main fan stops while the standby fan is started, even though a methane excursion above 1.0 percent may occur downstream of the pumps.

d. Deenergize all electrical power to the mine if a 1.0 percent concentration of methane in the air is measured at the pumps.

e. Resume work in the mine after ventilation has been reestablished by the standby fan only in areas where a detailed ventilation survey shows that methane concentration is below 1.0 percent.

3. For these reasons, petitioner requests a modification of the standard.

Request for Comments

Persons interested in this petition may furnish written comments on or before May 15, 1980. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: April 4, 1980.

Frank A. White,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 80-11352 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-80-35-C]

T & H Coal Co., Inc.; Petition for Modification of Application of Mandatory Safety Standard

T & H Coal Company, Inc., Route 1, Box 88, Jackhorn, Kentucky 41825 has filed a petition to modify the application of 30 CFR 75.1719 (illumination) to its No. 2 Mine located in Knott County, Kentucky. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. Petitioner is mining a coal seam ranging from 28" to 36" in height.

2. The installation of lighting fixtures to the miner's equipment would result in a diminution of safety for the miners affected because:

a. The height of the coal seam keeps the miners bent to such a position that

the light from this equipment would shine directly in the miners' eyes, causing temporary blindness; and,

b. The equipment was not originally built for the installation of lights.

3. For these reasons, petitioner requests a modification of the standard for the mine.

Request for Comments

Persons interested in this petition may furnish written comments on or before May 15, 1980. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: April 4, 1980.

Frank A. White,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 80-11353 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-80-15-C]

P-G & H, Inc.; Petition for Modification of Application of Mandatory Safety Standard

P-G and H, Inc., P.O. Box 39, Dry Branch, West Virginia 25061, has filed a petition to modify the application of 30 CFR 75.1719 (illumination) to its No. 5 Mine located in Kanawha County, West Virginia. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. Petitioner is mining a coal seam ranging from 31 to 45 inches thick, with fragile roof, soft bottom and sharp localized undulations.

2. Petitioner states use of currently available illumination equipment for its electric face equipment would result in a diminution of safety to miners for the following reasons:

a. Illumination equipment would be sheared off the tops and sides of the mine's face machines because of the low seam height and narrow entries.

b. Glare problems from illumination equipment prevents the use of the miners' cap lamps for communications and control of the face activities.

c. Small changes in working height cause glare and increase fatigue to the miners.

3. For these reasons, petitioner requests a modification from application of the standard to its mine.

Request for Comments

Persons interested in this petition may furnish written comments on or before May 15, 1980. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Dated: April 14, 1980.

Frank A. White,

Director, Office of Standards Regulations and Variances.

[FR Doc. 80-11354 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-80-39-M]

Exxon Minerals Co., U.S.A.; Petition for Modification of Application of Mandatory Safety Standard

Exxon Minerals Company, U.S.A., P.O. Box 3020, Casper, Wyoming 82602, has filed a petition to modify the application of 30 CFR 57.11-55 (emergency hoisting facility) to its Highland Uranium Operation, Buffalo Shaft, located in Converse County, Wyoming. The petition is filed under section 101(c) of the Federal Mine Safety and Health Act of 1977.

A summary of the petitioner's statements follows:

1. There is a secondary escape hoist system permanently located at the ventilation intake shaft from which the employees would be hoisted from the mine.

2. Petitioner proposes to construct an additional means of escape in the form of a portable hoisting system that will be designed to hoist employees through any of the four exhaust ventilation boreholes connecting with the underground working.

3. This proposed emergency escape system will be used for hoisting employees only in the event of a disaster and during required monthly tests.

4. Petitioner states that this proposed emergency escape system would decrease the possibilities of employees becoming trapped in the mine should a disaster block access to the other two escape systems.

5. Petitioner states that this proposed hoisting system would increase the safety of the underground workers beyond that required by the standard.

Request for Comments

Persons interested in this petition may furnish written comments on or before May 15, 1980. Comments must be filed with the Office of Standards, Regulations and Variances, Mine Safety and Health Administration, Room 627, 4015 Wilson Boulevard, Arlington, Virginia 22203. Copies of the petition are available for inspection at that address.

Frank A. White,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 80-11355 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-43-M

[Docket No. M-79-30-M]

Riverside Cement Co.; Petition for Modification of Application of Mandatory Safety Standard; Correction

In 45 FR 8755 (February 8, 1980) the Mine Safety and Health Administration published notice that the Riverside Cement Company had submitted a petition for modification of 30 CFR 55.13-20 for its Crestmore mine located at Riverside, California.

In that notice, the Riverside Cement Company's Oro Grande mine located at Oro Grande, California was omitted. This notice is to add that mine as a location at which the company has applied for a modification.

Frank A. White,

Director, Office of Standards, Regulations and Variances.

[FR Doc. 80-11356 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-43-M

Office of the Secretary

Affirmative Determinations 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 summaries or certifications of eligibility to apply for worker adjustment assistance issued during the period March 31-April 4th, 1980.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

In the following cases it has been concluded that all of the criteria have been met.

TA-W-6912; Berman's, the Leather Experts, Leather Goods Factory, Minneapolis, Minnesota

The investigation was initiated on February 5, 1980 in response to a petition which was filed on behalf of workers at Berman's, The Leather Experts, Leather Goods Factory, Minneapolis, Minnesota. The workers produced men's and women's leather apparel and leather accessories.

U.S. imports of leather apparel increased absolutely in each year from 1975 through 1978 before decreasing in 1979. U.S. imports of flat goods including leather accessories increased absolutely in 1979 compared to 1978.

Company imports of leather apparel increased significantly in 1979 compared to 1978. Berman's, The Leather Experts permanently closed its Leather Goods Factory at the end of December 1979.

In this case, therefore, the certifying officer has determined that:

All workers at Berman's, The Leather Experts, Leather Goods Factory, Minneapolis, Minnesota who became totally or partially separated from employment on or after April 1, 1979 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA–W–7186; Chrysler Corporation, Dayton Plant I, Dayton, Ohio

The investigation was initiated on February 25, 1980 in response to a petition which was filed on behalf of workers at the Dayton Plant I of Chrysler Corporation, Dayton, Ohio. The workers produce heaters and air conditioner components for cars and trucks.

In order to determine if increased imports contributed importantly to production and employment declines at the petitioning auxiliary plants of Chrysler Corporation, the Department sought to determine the degree to which each auxiliary plant was integrated into the production of Chrysler car and/or truck lines which have been subject to import injury. Where it was established that an auxiliary plant was substantially integrated into the production of trade-impacted Chrysler car or truck lines, the Department considered imports of like or directly competitive cars and trucks in determining import injury to workers at the auxiliary plant.

The Department determined that the Dayton Plant I of Chrysler Corporation was substantially integrated into the production of one or more of the Chrysler car and truck lines which have been subject to import injury. A significant proportion of the total output of the Dayton Plant I was ultimately used in the production of trade-impacted Chrysler cars and trucks during the MY 1978–MY 1979 period.

In this case, therefore, the certifying officer has determined that:

All workers of the Dayton Plant I of Chrysler Corporation, Dayton, Ohio, who became totally or partially separated from employment on or after February 6, 1979 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA–W–6891; Connie Sportswear, Incorporated; Elizabeth, New Jersey

The investigation was initiated on January 30, 1980 in response to a petition which was filed on behalf of workers at Connie Sportswear, Incorporated of Elizabeth, New Jersey. The workers produce men's leather coats.

U.S. imports of men's and boys' leather coats and jackets increased in the January-September period of 1979 compared with same period of 1978.

Connie Sportswear, Incorporated is a garment contractor producing men's leather coats for manufacturers. A survey of the manufacturers of Connie Sportswear revealed that these manufacturers decreased their purchases from Connie Sportswear in 1979 compared with 1978 and had decreasing sales of men's leather coats. A survey of customers of the manufacturers revealed that several customers decreased purchases from the manufacturers and increased purchases of imported leather coats in 1979 compared with 1978.

In this case, therefore, the certifying officer has determined that "All workers of Connie Sportswear, Incorporated, Elizabeth, New Jersey who became totally or partially separated from employment on or after July 2, 1979 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974."

(TA–W–6904); Kolo, Incorporated, North Bergen, New Jersey

(TA–W–6904–A); Sally Gee, Incorporated, Ridgefield, New Jersey

The investigation was initiated on February 1, 1980 in response to a petition which was filed on behalf of workers at Kolo, Incorporated, North Bergen, New Jersey. The investigation was subsequently expanded to include workers at Sally Gee, Incorporated, Ridgefield, New Jersey. The workers at both firms produce women's sportswear.

Kolo, Incorporated is a prime contractor for Sally Gee, Incorporated.

In a survey conducted by the Department of Commerce, customers accounting for a significant portion of Sally Gee, Incorporated's sales declines indicated that they had decreased purchases from Sally Gee, Incorporated and increased purchases of imports. The Department of Commerce on September 7, 1979 certified Sally Gee, Incorporated, and Kolo, Incorporated eligible to apply for firm adjustment assistance.

In this case, therefore, the certifying officer has determined that:

All workers of Kolo, Incorporated, North Bergen, New Jersey (TA–W–6904) and Sally Gee, Incorporated, Ridgefield, New Jersey (TA–W–6904–A) who became totally or partially separated from employment on or after May 30, 1979 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA–W–6893; Northland Dodge Sales, Incorporated, St. Louis, Missouri

The investigation was initiated on January 30, 1980 in response to a petition which was filed on behalf of workers at Northland Dodge Sales, Incorporated, St. Louis, Missouri. The workers were engaged in the sale and servicing of Dodge cars and trucks.

In order to determine if increased imports contributed importantly to production and employment declines at the petitioning auxiliary plants of Chrysler Corporation, the Department sought to determine the degree to which each auxiliary plant was integrated into the production of Chrysler car and/or truck lines which have been subject to import injury. Where it was established that an auxiliary plant was substantially integrated into the production of trade-impacted Chrysler car or truck lines, the Department considered imports of like or directly competitive cars and trucks in determining import injury to workers at the auxiliary plant.

The Department determined that Northland Dodge Sales, Incorporated, a wholly-owned subsidiary of Chrysler Corporation, was substantially integrated into the production of one or more of the Chrysler car and truck lines which have been subject to import injury. Northland Dodge Sales, Incorporated was exclusively engaged in the sale and servicing of Dodge cars and trucks during the 1978–1979 period. Sales of trade-impacted cars and trucks accounted for a significant proportion of the total sales of Northland Dodge Sales, Incorporated in both 1978 and 1979. Production of trade-impacted Dodge cars and trucks at seven Chrysler Corporation assembly plants declined significantly from MY 1978 to MY 1979. Certifications were issued on behalf of workers at all seven of these plants on November 6, 1979 (TA–W–5979–83, 6037–38). In this case, therefore, the certifying officer was determined that:

All workers of Northland Dodge Sales, Incorporated, St. Louis, Missouri, who became totally or partially separated from employment on or after October 1, 1979 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA–W–6906; Seiberling Tire and Rubber Company, Barberton, Ohio

The investigation was initiated on February 1, 1980 in response to a petition which was filed by the United Rubber, Cork, Linoleum and Plastic Workers of America on behalf of

workers at the Barberton, Ohio plant of the Seiberling Tire and Rubber Company. The workers at the Barberton plant produce passenger car and truck tires.

U.S. imports of both passenger car and truck tires increased absolutely and relative to domestic production in 1979 compared with 1978.

The Department surveyed major customers and a random sample of the smaller customers of Seiberling. The survey revealed that some customers increased purchases of imported passenger car or truck tires and decreased purchases from Seiberling in 1979 compared with 1978. The survey further indicated that the reliance on imports by customers of Seiberling was substantially above the industry-wide level and had increased for both passenger car and truck tires in 1978 and 1979.

In this case, therefore, the certifying officer has determined that "All workers of the Barberton, Ohio plant of the Seiberling Tire and Rubber Company who became totally or partially separated from employment on or after May 20, 1979 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974."

TA-W-6808; Shutzer Manufacturing Company, Incorporated, Lawrence, Massachusetts

The investigation was initiated on January 18, 1980 in response to a petition which was filed on behalf of workers at the Lawrence, Massachusetts plant of Shutzer Manufacturing Company, Incorporated. The workers produce men's leather coats.

U.S. imports of men's and boys' leather coats and jackets increased absolutely in the first three quarters of 1979 compared with the same period of 1978.

A Department survey revealed that several customers of Shutzer, accounting for a significant proportion of company sales, reduced purchases from the company in 1979 from 1978 and increased their purchases of imported leather coats.

In this case, therefore, the certifying officer has determined that "All workers of Shutzer Manufacturing Company, Incorporated, Lawrence, Massachusetts who became totally or partially separated from employment on or after February 21, 1980 are eligible to apply for adjustment assistance under section 223 of the Trade Act of 1974."

TA-W-6810; Star Sportswear Manufacturing Corporation, Lynn, Massachusetts

The investigation was initiated on January 18, 1980 in response to a petition which was filed on behalf of workers at Star Sportswear Manufacturing Corporation, Lynn, Massachusetts. The workers produce men's leather coats.

U.S. imports of leather coats and jackets increased absolutely and relative to domestic production in 1978 compared to 1977. The ratio of imports to domestic production has been over 50 percent in each year from 1975 through 1979.

A Department survey revealed that customers representing a significant percentage of total company sales in 1978 reduced their purchases of men's leather costs from the subject firm in 1979 compared to 1978 while increasing their reliance on men's leather coats from foreign sources. As a percentage of total demand for leather coats by the responding customers, imports increased from 1978 to 1979.

In this case, therefore, the certifying officer has determined that "All workers of Star Sportswear Manufacturing Corporation, who became totally or partially separated from employment on or after September 15, 1979 are eligible to apply for adjustment assistance under Section 223 of the Trade Act of 1974."

I hereby certify that determinations were issued with respect to all of the aforementioned cases during the week of March 31–April 4th, 1980.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

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Negative Determinations 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 summaries of negative determinations regarding eligibility to apply for worker adjustment assistance issued during the period March 31–April 4th, 1980.

In order for an affirmative determination to be made and a certification of eligibility to apply for adjustment assistance to be issued, each of the group eligibility requirements of Section 222 of the Act must be met.

(1) That a significant number or proportion of workers in the worker's firm, or an appropriate subdivision thereof, have become totally or partially separated, or are threatened to become totally or partially separated.

(2) That sales or production, or both, of the firm or subdivision have decreased absolutely.

(3) 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.

In each of the following cases it has been concluded that at least one of the above criteria has not been met.

TA-W-7245; Adriana Coat, Incorporated, Jersey City, New Jersey

The investigation was initiated on March 3, 1980, in response to a petition which was filed by the International Ladies' Garment Workers' Union on behalf of workers at Adriana Coat, Incorporated, Jersey City, New Jersey. The workers produced ladies' coats.

The investigation revealed that criterion (3) has not been met.

U.S. imports of women's, misses', and children's coats and jackets decreased absolutely in 1979 compared with 1978.

Manufacturers for whom Adriana Coat, Incorporated, performed contract work in 1979 did not import ladies' wool coats in 1979. Gross sales by the manufacturers increased in January–October 1979 compared to the like period in 1978. The manufacturers increased their orders of ladies' wool coats with Adriana Coat, Incorporated in 1979 compared with 1978.

In this case, therefore, the certifying officer has determined that all workers at Adriana Coat, Incorporated, Jersey City, New Jersey, are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6911; Allied Products Corporation, South Bend Stamping Division, South Bend, Indiana

The investigation was initiated on February 5, 1980 in response to a petition which was filed on behalf of workers at the South Bend Stamping Division, South Bend, Indiana, of Allied Products Corporation. Workers at the plant produce automotive body stampings.

The investigation revealed that criterion (3) has not been met.

According to industry sources, U.S. imports of motor vehicle body stampings are negligible, both absolutely and by comparison to the domestic market.

After careful review, I determine that all workers of the South Bend Stamping Division, South Bend, Indiana, of Allied Products Corporation are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7153; Bohme and Blinkmann, Inc., Cleveland, Ohio

The investigation was initiated on February 19, 1980, in response to a petition which was filed by the Cleveland Typographical Union on behalf of workers at Bohme and Blinkmann, Inc., Cleveland, Ohio. The workers at Bohme and Blinkmann, Inc. are engaged in typesetting operations.

The investigation revealed that workers of Bohme and Blinkmann, Inc. 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 Bohme and Blinkmann, Inc. 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.

Bohme and Blinkmann, Inc. 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 typesetting operations at Bohme and Blinkmann, Inc. are employed by that firm. All personnel actions and payroll transactions are controlled by Bohme and Blinkmann, Inc. all employee benefits are provided and maintained by Bohme and Blinkmann, Inc. Workers are not, at any time, under employment or supervison by customers of Bohme and Blinkmann, Inc. Thus, Bohme and Blinkmann, Inc. and not any of its customers, must be considered to be the "workers' firm".

In this case, therefore, the certifying officer has determined that all workers of Bohme and Blinkmann, Inc., Cleveland, Ohio are denied eligiblity to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7251; The Cementation Company of America, Incorporated, Eccles, West Virginia

The investigation was initiated on March 3, 1980, in response to a petition which was filed by the United Mine Workers or America on behalf of workers at The Cementation Company of America, Incorporated, Eccles, West Virginia. The workers at the Cementation Company of America, Incorporated are engaged in providing the service of shaft and slope construction for coal companies.

The investigation revealed that workers of The Cementation Company of America, Incorporated 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 The Cementation Company of America, Incorporated 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. The Cementation Company of America, Incorporated and its customers have no controlling interest in one another. The subject firm is not corporately affiliated with any other company producing an article.

All workers engaged in shaft and slope construction work at The Cementation Company of America, Incorporated are employed by that firm. All personnel actions and payroll transaction are controlled by The Cementation Company of America, Incorporated. All employee benefits are provided and maintained by The Cementation Company of America, Incorporated. Workers are not, at any time, under employment or supervision by customers of The Cementation Company of America, Incorporated. Thus, The Cementation Company of America, Incorporated and not any of its customers, must be considered to be the "workers' firm".

In this case, therefore, the certifying officer has determined that all workers of The Cementation Company of America, Incorporated, Eccles, West Virginia are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7106; Charisse Fashions, Incorporated, New Hyde Park, New York

The investigation was initiated on February 13, 1980 in response to a petition which was filed by the International Ladies' Garment Workers' Union on behalf of workers at Charisse Fashions, Incorporated, New Hyde Park, New York. The workers produce women's coats and jackets.

The investigation revealed that criterion (3) has not been met.

U.S. imports of women's coats and jackets declined absolutely in 1979 compared with 1978.

Sales of women's coats and jackets by Charisse Fashions, Incorporated, New Hyde Park, New York increased in 1978 compared with 1977 and in 1979 compared with 1978. Sales increased in each quarter of 1979 compared to the like quarter of 1978. Monthly and quarterly declines within the period were the result of normal seasonal business fluctuations.

In this case, therefore, the certifying officer has determined that all workers of Charisse Fashions, Incorporated, New Hyde Park, New York are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7126; Commercial Carriers, Incorporated, Atlanta, Georgia

The investigation was initiated on February 19, 1980 in response to a worker petition which was filed on behalf of workers at Commercial Carriers, Inc., Atlanta, Georgia. The workers at Commercial Carriers, Inc. are engaged in providing the service of transporting automobiles and trucks.

The investigation revealed that workers of Commercial Carriers, Inc. 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 Commercial Carriers, Inc. 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.

Commercial Carriers, Inc. and its customers have no controlling interest in one another. The subject firm is not corporately affiliated with another company producing automobiles or trucks.

All workers engaged in transporting automobiles and trucks at Commercial Carriers, Inc. are employed by that firm. All personnel actions and payroll transactions are controlled by Commercial Carriers, Inc. Workers are not, at any time, under employment or supervision by customers of Commercial Carriers, Inc. Thus, Commercial Carriers, Inc. and not any of its customers, must be considered to be the "workers' firm".

In this case, therefore, the certifying officer has determine that all workers of Commercial Carriers, Inc. are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6872; Dowling Bag Company, Incorporated; Valdosta, Georgia

The investigation was initiated on January 30, 1980 in response to a petition which was filed on behalf of workers at the Valdosta, Georgia plant of Dowling Bag Company, Incorporated. The workers at the Valdosta plant produce paper, burlap, open mesh and woven polypropylene fabric bags.

The investigation revealed that with respect to workers engaged in employment related to paper bag production, criterion (2) has not been met.

Sales and production of paper bags at the Valdosta, Georgia plant of Dowling Bag Company increased in 1979 compared to 1978 and in January 1980 compared to January 1979.

With respect to workers engaged in employment related to textile bag production (burlap, open mesh and woven polypropylene), criterion (3) has not been met.

The decline in textile bag sales at Dowling in 1979 compared to 1978 was attributable to declining burlap and woven polypropylene bag sales. Open mesh bag sales increased from 1978 to 1979 and in January 1980 compared to January 1979.

Industry sources reported that in the second half of 1979 there was a shortage of the principle raw material used in woven polypropylene bag production. This shortage was caused by a temporary reduction in production capacity in a plant of the raw material producer.

Woven polypropylene fabric bags are included in the category of bags of man made fibers. U.S. imports of bags of man made fibers declined both absolutely and relative to domestic production in 1979 compared to 1978. The ratio of U.S. imports of bags of man made fibers to domestic production was one percent or less in every year from 1975 through 1979. U.S. exports of bags of man made fibers were more than twice as much as imports in every year from 1975 through 1979.

U.S. imports of burlap bags declined absolutely in 1979 compared to 1978.

The Office of Trade Adjustment Assistance conducted a survey of Dowling's burlap bag customers. None of the customers responding to the survey purchased imported burlap bags in 1979 or January 1980.

In this case, therefore, the certifying officer has determined that all workers of the Valdosta, Georgia plant of Dowling Bag Company are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7271; Falcon Air, Incorporated, Flint, Michigan

The investigation was inititated on February 26, 1980 in response to a petition which was filed on behalf of workers at Falcon Air, Incorporated, Flint, Michigan. The workers at Falcon Air, Incorporated, Flint, Michigan are engaged in providing the service of transporting auto parts by air on a nationwide basis.

The investigation revealed that workers of Falcon Air, Incorporated 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 Falcon Air, Incorporated 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.

Falcon Air, Incorporated and its customers have no controlling interest in one another. The subject firm shares common ownership with another firm engaged in air transport services.

All workers engaged in transporting auto products at Falcon Air, Incorporated are employed by that firm. All personnel actions and payroll transactions are controlled by Falcon Air, Incorporated. All employee benefits are provided and maintained by Falcon Air, Incorporated. Workers are not, at any time, under employment or supervision by customers of Falcon Air, Incorporated. Thus, Falcon Air, Incorporated, and not any of its customers, must be considered to be the "workers' firm".

In this case, therefore, the certifying officer has determined that all workers of Falcon Air, Incorporated, Flint, Michigan are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6860; Federal Screw Works, Detroit, Michigan; Romulus, Michigan

The investigation was initiated on January 28, 1980 in response to a petition which was filed by the United Auto Workers on behalf of workers at the Detroit, Michigan (Plant #1) and Romulus, Michigan plants (Plants #3 and #4) of Federal Screw Works. Workers at the Detroit, Michigan and Romulus, Michigan plants of Federal Screw Works produce specialty nuts and bolts and steel stock for nuts and bolts.

Investigation revealed that criterion 3 has not been met.

U.S. imports of specialty fasteners, including specialty nuts and bolts, were negligible in 1978 and 1979. Total U.S. imports of nuts and bolts and large screws decreased both absolutely and relative to domestic production in 1979 compared to 1978.

The Department's survey of customers representing over 95 percent of the subject firm's sales in 1978 and 1979 indicated that these customers' purchases of imported specialty nuts and bolts represented less than one-half of one percent of total purchases in 1978 and 1979.

In this case, therefore, the certifying officer has determined that all workers of the Detroit, Michigan (Plant #1) and Romulus, Michigan plants (Plants #3 and #4) of Federal Screw Works are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6873; FMC Corporation, Industrial Chemical Group, South Charleston, West Virginia

The investigation was initiated on January 30, 1980 in response to a petition which was filed by the United Steel Workers of American on behalf of workers at FMC Corporation, Industrial Chemical Group, South Charleston, West Virginia. The workers produce primarily chlorine, caustic soda, hydrogen peroxide, carbon bisulfide, and carbon tetrachloride.

The investigation revealed that criterion (3) has not been met.

U.S. imports of chlorine, carbon bisulfide and carbon tetrachloride have been less than 1.9 percent of domestic production in the years 1977 through 1978. Imports of caustic soda decreased in 1979 compared to 1978. Imports of carbon tetrachloride decreased absolutely in 1979 compared to 1978.

Combined sales and production, in quantity, of all chemicals produced at the South Charleston facilities increased in 1979 compared to 1978.

In this case, therefore, the certifying officer has determined that all workers of the South Charleston, West Virginia plants of FMC Corporation, Industrial Chemcial Group are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7262; Fred A. Groves Motor Company, Cape Girardeau, Missouri

The investigation was initiated on March 3, 1980, in response to a petition filed on behalf of workers at Fred A. Groves Motor Company, Incorporated, Cape Girardeau, Missouri. The workers at Fred A. Groves Motor Company,

Incorporated are engaged in providing the service of selling new and used cars.

The investigation revealed that workers of Fred A. Groves Motor Company, Incorporated 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 Fred A. Groves Motor Company, Incorporated 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.

Fred A. Groves Motor Company Company, Incorporated and its suppliers have no controlling interest in one another. The subject firm is not corporately affiliated with any other company.

All workers engaged in selling new and used automobiles at Fred A. Groves Motor Company, Incorporated are employed by that firm. All personnel actions and payroll transactions are controlled by Fred A. Groves Motor Company, Incorporated. All employee benefits are provided and maintained by Fred A. Groves Motor Company, Incorporated. Workers are not, at any time, under employment or supervision by suppliers of Fred A. Groves Motor Company, Incorporated. Thus, Fred A. Groves Motor Company, Incorporated, and not any of its suppliers, must be considered to be the "workers' firm".

In this case, therefore, the certifying officer has determined that all workers of Fred A. Groves Motor Company, Incorporated are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7250; Gibson Electric Company, Incorporated, Beckley, West Virginia

The investigation was initiated on March 3, 1980, in response to a petition which was filed by the United Mine Workers of America on behalf of workers at Gibson Electric Company, Incorporated, Beckley, West Virginia. The workers at Gibson Electric Company, Incorporated are engaged in providing the service of electrical construction of coal preparation plants.

The investigation revealed that workers of Gibson Electric Company, Incorporated 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 Gibson Electric Company, Incorporated, 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.

Gibson Electric Company, Incorporated 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 electrical construction at Gibson Electric Company, Incorporated are employed by that firm. All personnel actions and payroll transactions are controlled by Gibson Electric Company, Incorporated. All employee benefits are provided and maintained by Gibson Electric Company, Incorporated. Workers are not, at any time, under employment or supervision by customers of Gibson Electric Company, Incorporated. Thus, Gibson Electric Company, Incorporated and not any of its customers, must be considered to be the "workers' firm".

In this case, therefore, the certifying officer has determined that all workers of Gibson Electric Company, Incorporated, Beckley, West Virginia are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6820; Goodyear Tire and Rubber Company, Jackson, Michigan

The investigation was initiated on January 21, 1980 in response to a worker petition which was filed by the United Rubber, Cork, Linoleum and Plastic Workers of America on behalf of workers and former workers at the Jackson, Michigan plant of Goodyear Tire and Rubber Company. Workers at the Jackson plant produce truck tires and passenger car tires.

The investigation revealed that criterion (3) has not been met.

A Department survey of major customers and a random sample of customers purchasing passenger car tires from Goodyear revealed that most customers either do not import or decreased purchases of imported passenger car tires in 1979 compared with 1978. The reliance on imports by the customers of Goodyear buying passenger car tires was substantially below the industry-wide levels in 1978 and 1979.

The decline in production of truck tires was primarily due to a decreased demand for tires by truck manufacturers, reflecting decreased vehicle production in 1979 compared with 1978. In addition, a survey of major truck tire customers indicated that most customers either did not import tires or increased purchases from Goodyear. The customer that increased imports and decreased purchases from Goodyear was not significant in terms of Goodyear's total truck tire sales.

In this case, therefore, the certifying officer has determined that all workers of the Jackson, Michigan plant of the Goodyear Tire and Rubber Company are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7191; Gorgas & Associates, Incorporated, Claymont, Delaware

The investigation was initiated on February 25, 1980, in response to a petition which was filed on behalf of workers at Gorgas & Associates, Incorporated, Claymont, Delaware. The workers at Gorgas & Associates, Incorporated were engaged as the exclusive sales agents in six states for a manufacturer of personal care products.

The investigation revealed that workers at Gorgas & Associates, Incorporated 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 Gorgas & Associates, Incorporated 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 critieria for certification and that reduction must directly relate to the product impacted by imports.

Gorgas & Associates, Incorporated 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 sales operations at Gorgas & Associates, Incorporated are employed by that firm. All personnel actions and payroll transactions are controlled by Gorgas & Associates, Incorporated. All employee benefits are provided and maintained by Gorgas & Associates, Incorporated. Workers are not, at any time, under employment or supervision by customers of Gorgas & Associates, Incorporated. Thus, Gorgas & Associates, Incorporated, and not any of its customers, must be considered to be the "workers' firm".

In this case, therefore, the certifying officer has determined that all workers of Gorgas & Associates, Incorporated, Claymont, Delaware are denied eligibility to apply for adjustment

assistance under Section 223 of the Trade Act of 1974.

TA-W-6796; Louis Roth Clothes, Incorporated, Los Angeles, California

The investigation was initiated on January 9, 1980 in response to a petition which was filed on behalf of workers at Louis Roth Clothes, Incorporated, Los Angeles, California. The workers produce men's clothing.

Surveyed customers who decreased purchases from Louis Roth did not increase purchases of imported men's clothing. Most customers that did purchase imports also increased purchases from other domestic suppliers.

In this case, therefore, the certifying officer has determined that all workers of Louis Roth Clothes, Incorporated, Los Angeles, California are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6880, Pierce Garment Company, Incorporated; New Bedford, Massachusetts

The investigation was initiated on January 30, 1980 in response to a petition which was filed on behalf of workers at Pierce Garment Company, Incorporated; New Bedford, Massachusetts. The workers produce ladies' skirts, pants, robes, knit tops and blazers.

The investigation revealed that criterion (3) has not been met.

Pierce Garment Company, Incorporated produced primarily ladies' sportswear (skirts, pants, knit tops and blazers); sportswear accounted for all Pierce's 1979 sales decline.

U.S. imports of women's, misses', and children's skirts, slacks, blouses and shirts declined absolutely in the January-September period of 1979 compared to the same period of 1978.

A Departmental survey was conducted with the manufacturers who decreased contracts with Pierce Garment Company, Incorporated for ladies' sportswear in 1979 compared to 1978. Those manufacturers did not import ladies' sportswear nor did they use overseas contractors in 1978 or 1979. Furthermore, each of those manufacturers showed an increase in sales in 1979 compared to 1978.

In this case, therefore, the certifying officer has determined that all workers of Pierce Garment Company, Incorporated; New Bedford, Massachusetts are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6925, 6926, 6934, 6935, 6941; Ship 'n Shore; Charleston, South Carolina; Burlington, New Jersey; Baxley, Georgia; Ephrata (II), Pennsylvania

The investigation was initiated on February 5, 1980 in response to a petition which was filed on behalf of workers at the Charleston, South Carolina; Burlington, New Jersey, Baxley, Georgia and Ephrata, Pennsylvania (II) locations of Ship 'n Shore. The workers are engaged in employment related to the production of ladies' blouses, shirts, tops, skirts, pants, blazers and vests.

The investigation revealed that criterion (2) has not been met with respect to workers at the Charleston, South Carolina and Ephrata, Pennsylvania (II) locations of Ship 'n Shore.

The Charleston, South Carolina location of Ship'n Shore is a factory outlet store. Sales increased in quantity and value in 1979 compared to 1978 and in the January and February period of 1980 compared to the same period of 1979.

The Ephrata, Pennsylvania (II) plant opened in October 1979. From October, 1979 through February, 1980, production and employment has increased in each month compared to the previous month, except for the month of December 1979. Production and sales at the Ephrata II plant are equal.

With respect to workers at the Burlington, New Jersey facility and at the Baxley, Georgia plants of Ship 'n Shore, the investigation revealed that criterion (3) has not been met.

The Burlington, New Jersey location of Ship 'n Shore is a factory outlet store which opened in September 1979. Sales and employment have remained relatively constant except for some monthly fluctuations over the six months the store has been open. Due to the short term of operations, it is not possible to discount the seasonal influence on these monthly fluctuations, and therefore it cannot be considered that imports contributed importantly to monthly sales declines.

Workers at the Baxley plants produce ladies' sportswear. A Departmental survey was conducted with customers representing a substantial portion of total company sales by Ship 'n Shore in 1978 and 1979. The survey revealed that, in the aggregate, customers responding to the survey decreased their purchases of ladies' sportswear (including tops, skirts, pants, blazers, and vests) from Ship 'n Shore and also decreased their reliance on imported ladies' sportswear in 1979 compared to 1978.

U.S. imports of ladies' pants, blazers and vests decreased absolutely in 1979 compared to 1978.

Workers at the Baxley, Georgia plants of Ship 'n Shore are not separately identifiable by product line. Ladies' blouses (tops) account for a relatively small percentage of the sportswear. Any import influence on this product line could not have contributed importantly to overall employment declines at these plants.

In this case, therefore, the certifying officer has determined that all workers of the Charleston, South Carolina; Burlington, New Jersey; Baxley, Georgia; and Ephrata (II), Pennsylvania locations of Ship 'n Shore are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6909; Spectator Casuals, Incorporated; New York, New York

The investigation was initiated on February 1, 1980 in response to a petition which was filed by the International Ladies' Garment Workers' Union on behalf of workers at Spectator Casuals, Incorporated, New York, New York. The workers produced ladies' dresses and suits.

The investigation revealed that criterion (3) has not been met.

U.S. imports of women's and misses' dresses and women's, misses' and children's suits decreased absolutely in 1979 compared to 1978.

The Office of Trade Adjustment Assistance conducted a survey of major customers of Spectator Casuals, Incorporated. Most customers responding to the survey reported that they either reduced purchases of imported ladies' dresses and suits in 1979 compared to 1978 or did not purchase any imported ladies' dresses or suits in 1978 or 1979. Those customers who reduced purchases from Spectator from 1978 to 1979 and increased purchases of imported ladies' dresses and suits during this time period represented an insignificant proportion of Spectator's sales decline from 1978 to 1979.

In this case, therefore, the certifying officer has determined that all workers of Spectator Casuals, Incorporated, New York, New York are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6884; Tami Sportswear, Incorporated, San Francisco, California

The investigation was initiated on January 30, 1980 in response to a petition which was filed on behalf of workers at Tami Sportswear, Incorporated, San Francisco, California. The workers

produced ladies' sportswear (skirts, jackets, pants and vests).

The investigation revealed that criterion (3) has not been met.

U.S. imports of Women's Misses' and Children's skirts; Slacks and Shorts; and Coats and Jackets decreased in absolute terms in 1979 compared to 1978.

A Departmental survey among customers of Tami Sportswear, Incorporated revealed that most customers which reduced their purchases of ladies' sportswear (skirts, pants, jackets and vests) from Tami Sportswear, in 1978 compared to 1977 and in 1979 compared to 1978, increased their purchases to a greater extent with other domestic sources than with foreign sources. Those customers which increased their purchases of imported sportswear and which decreased purchases from Tami and from other domestic sources were an insignificant proportion of Tami's sales. In aggregate, imported sportswear as a percent of total sportswear demand remained constant from 1978 to 1979.

In this case, therefore, the certifying officer has determined that all workers of Tami Sportswear, Incorporated, San Francisco, California are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6867; Textile Prints Corporation, Branford, Connecticut

The investigation was initiated on January 28, 1980 in response to a petition which was filed on behalf of workers at Textile Prints Corporation, Branford, Connecticut. Workers at the subject firm produce finished printed fabric.

The investigation revealed that criterion (3) has not been met.

Textile Prints Corporation produced finished fabric for the apparel industry. The petitioners allege that increased imports of finished garments contributed importantly to the decline in sales or production and to the separation of workers at Textile Prints Corporation. Imported wearing apparel cannot be considered like or directly competitive with finished fabric. Imports of all types of finished fabric must be considered in determining import injury to workers producing finished fabric at Textile Prints Corporation, Branford, Connecticut.

Imports of all finished fabric into the United States decreased during the period January through September 1979 as compared to the same period in 1978. The ratio of imports to domestic production was 2.1 percent in 1978.

Both company sales and employment increased on an annual basis in 1979 as compared to 1978. Any quarterly decreases in sales or employment were attributable to seasonal market conditions affecting their manufacturing/converter customers.

In this case, therefore, the certifying officer has determined that all workers of Textile Prints Corporation, Branford, Connecticut are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7242; West End Cartage, Incorporated, Melvindale, Michigan

The investigation was initiated on March 3, 1980, in response to a petition which was filed on behalf of workers at West End Cartage, Incorporated, Melvindale, Michigan. The workers at West End Cartage, Incorporated are engaged in providing the service of transporting auto parts within the Detroit, Michigan commercial zone.

The investigation revealed that workers of West End Cartage, Incorporated 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 West End Cartage, Incorporated 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.

West End Cartage, Incorporated and its customers have no controlling interest in one another. The subject firm is not corporately affiliated with any other company producing an article.

All workers engaged in transporting auto parts at West End Cartage, Incorporated are employed by that firm. All personnel actions and payroll transactions are controlled by West End Cartage, Incorporated. All employee benefits are provided and maintained by West End Cartage, Incorporated. Workers are not, at any time, under employment or supervision by customers of West End Cartage, Incorporated. Thus, West End Cartage, Incorporated, and not any of its customers, must be considered to be the "workers' firm".

In this case, therefore, the certifying officer has determined that all workers of West End Cartage, Incorporated, Melvindale, Michigan are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-7263; Yellow Freight System, Incorporated, Kokomo, Indiana

The investigation was initiated on February 22, 1980, in response to a petition which was filed on behalf of workers at Yellow Freight System, Incorporated, Kokomo, Indiana. The workers at Yellow Freight System, Incorporated are engaged in providing the service of transporting general commodities with special exceptions.

The investigation revealed that workers of Yellow Freight System, Incorporated 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 Yellow Freight System, Incorporated 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.

Yellow Freight System, Incorporated and its customers have no controlling interest in one another. The subject firm has a subsidiary which is engaged in petroleum exploration.

All workers engaged in transporting general commodities at Yellow Freight System, Incorporated are employed by that firm. All personnel actions and payroll transactions are controlled by Yellow Freight System, Incorporated. All employee benefits are provided and maintained by Yellow Freight System, Incorporated. Workers are not, at any time, under employment or supervision by customers of Yellow Freight System, Incorporated. Thus, Yellow Freight System, Incorporated and not any of its customers, must be considered to be the "workers' firm".

In this case, therefore, the certifying officer has determined that all workers of Yellow Freight System, Incorporated, Kokomo, Indiana are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

TA-W-6454; Youngstown Sheet and Tube Company, Indiana Harbor Works, East Chicago, Indiana

The investigation was initiated on November 27, 1979 in response to a petition which was filed by the United Steelworkers of America on behalf of workers at the Indiana Harbor Works of the Youngstown Sheet and Tube Company, East Chicago, Indiana. Workers at the Indiana Harbor Works produce coke, tin mill products, hot and cold rolled steel and strip, galvanized

steel sheet, steel plate an steel pipe and tubing. Youngstown Sheet and Tube Company operates under the management of the Jones and Laughlin Steel Corporation.

All employees at the Indiana Harbor Works engaged in employment related to the production of coke and tin mill products are currently eligible to apply for adjustment assistance under an existing certification.

For the products listed below, the investigation revealed that criterion (3) has not been met.

Hot and Cold Rolled Sheet and Strip. U.S. imports of hot and cold rolled sheet and strip decreased absolutely and relative to domestic shipments in 1978 compared with 1977 and in 1979 compared with 1978.

Galvanized Sheet. U.S. imports of galvanized steel sheet decreased absolutely and relative to domestic shipments in 1979 compared with 1978.

Surveyed customers indicated that they did not decrease purchases of galvanized sheet from Jones and Laughlin and increase purchases of imported galvanized sheet in 1979 compared with 1978. Respondents which increased purchases of imports also reported purchases of imports also reported increased purchases from Jones and Laughlin.

Plate and Pipe and Tubing. U.S. imports of carbon steel plate and seamless carbon steel pipe and tubing decreased absolutely and relative to domestic production in 1979 compared with 1978.

Sales and production of carbon steel plate at the Indiana Harbor Works increased in 1978 compared with 1977 before declining in the first eleven months of 1979 compared with the same period of 1978.

In this case, therefore, the certifying officer has determined that:

All workers of the Indiana Harbor Works of the Youngstown Sheet and Tube Company, East Chicago, Illinois are denied eligibility to apply for adjustment assistance under Section 223 of the Trade Act of 1974.

I hereby Certify that determinations were issued with respect to all of the aformentioned cases during the week of March 31–April 4, 1980.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

[FR Doc. 80-11118 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6629]

Mercer Rubber Company, Inc., Trenton, N.J.; Negative Determination Regarding Application for Reconsideration

By letter of March 24, 1980, the petitioner 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 Mercer Rubber Company, Inc., Trenton, New Jersey. The determination was published in the Federal Register on March 4, 1980, (45 FR 14164).

Pursuant to 29 CFR 90.18(c), reconsideration may be granted under the following circumstances:

(1) if it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) if it appears that the determination complained of was based on a mistake in the determination of facts previously considered; or

(3) if, in the opinion of the Certifying Officer, a misinterpretation of facts or of the law justifies reconsideration of the decision.

The petitioner claims that foreign competition in conveyor belting and expansion joints caused the layoffs at the Mercer Rubber Company's Trenton, New Jersey, plant and that the Department's denial was based on current performance and not on what Mercer Rubber could do if it were not for imports.

The Department's review indicated that workers at Mercer Rubber were denied eligibility because they did not meet the "contributed importantly" test of the Trade Act of 1974. The Department's survey which represented a substantial portion of Mercer Rubber's 1978 and 1979 conveyor belt sales indicated that the few customers which decreased their purchases of conveyor belting from Mercer and increased their imports also increased their purchases of domestically-produced conveyor belting. The Department's survey further showed that customers which decreased their purchases from Mercer and increased their purchases of imported expansion joints accounted for an insignificant portion of the firm's decline in sales of that product. None of the survey respondents indicated that they anticipated decreased purchases of belting and expansion joints from domestic sources and incresed purchases of imports.

Mercer Rubber's sales and production of rubber hose increased in quantity and value in 1978 compared to 1977 and in 1979 compared to 1978. The Department does not consider the petitioner's claim of unrealized business opportunities as relevant sicnce the Act does not address itself to such potential business losses but addresses itself instead to actual declines in production and/or sales and worker separations.

Conclusion

After review of the application and the investigative file, I conclude that there has been no error or misinterpretation of fact or misinterpretation of the law which would justify reconsideration of the Department of Labor's prior decision. The application is, therefore, denied.

Signed at Washington, D.C., this 8th day of April 1980.

C. Michael Aho,

Director, Office of Foreign Economic Research.

[FR Doc. 80-11119 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-28-M

[TA-W-6699, 6700 and 6701]

Timex Corp., Little Rock, Ark.; Adams Field Plant, et al.; Determinations Regarding Eligibility To Apply for Worker Adjustment Assistance: Correction

In the matter of Timex Corporation, Little Rock, Arkansas; Adams Field Plant, Murray Street Plant, East Roosevelt Plant.

In FR Doc. 80-7464 appearing at page 15732 in the Federal Register of March 11, 1980 the 8th line from the bottom of the 1st column on pg. 15733 is corrected by omitting the word "Timex".

Signed at Washington, D.C., this 8th day of April 1980.

C. Michael Aho,

Director, Office of Foreign Economic Research.

[FR Doc. 80-11211 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-28-M

LIBRARY OF CONGRESS

Special Amplifier—Risk of Injury From Improper or Unauthorized Use; Policies and Procedures for Distribution

The National Library Service for the Blind and Physically handicapped (NLS) has available special amplifiers for free loan to blind and physically handicapped people who have been certified as eligible for the NLS library program. These amplifiers may be attached to NLS headsets for use with

playback equipment by persons with hearing loss.

The NLS amplifier-headset combination has a maximum output capability of 130 dB sound pressure level as determined by audiology studies. In the opinion of qualified persons consulted by NLS, such high intensity amplification can permanently damage hearing wihout causing warning pain or discomfort. Further, the audio plugs with which the special amplifier is equipped are compatible with those found in domestic commercial audio systems; therefore, persons with normal hearing may risk injury by improper and unauthorized use of the special amplifier.

As a precautionary measure, these policies and procedures are being published in the Federal Register to inform the public concerning the rules and regulations governing the distribution of the special amplifier. As a basis for these rules and regulations, NLS has adopted the precedent established by the U.S. Food and Drug Administration governing the distribution of hearing aids Federal Register, Vol. 42, No. 31, February 15, 1977, pages 9286–9296; 21 CFR 801.420). Therefore, efective immediately:

(1) The special amplifier will be issued only to those eligible borrowers of the recording playback equipment provided by NLS who have obtained a certification in writing by a physician or licensed audiologist which states that the applicant's hearing loss has been evaluated within the last six months, and that the special amplifier is appropriate.

The certification, a copy of which will be supplied to the applicant, will contain a warning concerning the possible hazardous effect if the device receives improper use.

(2) For persons over the age of 18 years the hearing loss evaluation may be waived in writing; however, such a waiver is strongly discouraged. In the case of a minor. i.e., a person under the age of 18 years, no waiver of the hearing loss evaluation will be permitted.

(3) Applications may be sent directly to the following address: National Library Service for the Blind and Physically Handicapped, Library of Congress, Equipment Control Officer, Washington, D.C. 20542 or to the cooperating regional library serving the area in which the applicant resides. The application will then be forwarded to NLS. The special amplifiers will be distributed only by authorized NLS personnel in Washington, D.C.

In a further effort to prevent the risk of injury resulting from improper or unauthorized use, all special amplifiers will be packaged with the following:

(1) A warning statement label permanently affixed to the special amplifier,

(2) An instruction booklet describing in detail the special amplifier's operating characteristics, and

(3) Information sheets, in both large print and braille reflecting the warning statement contained in the booklet.

For the Librarian of Congress.

Edmond L. Applebaum,

Associate Librarian for Management Library of Congress.

April 7, 1980.

[FR Doc. 80-11412 Filed 4-14-80; 8:45 am]

BILLING CODE 1410-01-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice 80-28]

NASA Advisory Council (NAC); Space Systems and Technology Advisory Committee (SSTAC); Meeting

The Informal Advisory Subcommittee on Chemical Propulsion of the NAC SSTAC will meet May 1–2, 1980, in Room 647, Federal Office Building 10B, NASA Headquarters, 600 Independence Avenue, SW, Washington, DC. The meeting will be open to the public up to the seating capacity of the room (approximately 25 persons including Subcommittee members and participants).

The Subcommittee was established to assist the NASA in identifying and examining chemical propulsion technology requirements for future mission requirements, and to recommend program additions, deletions, or changes in scope or emphasis which may be found necessary to support the overall NASA Space research and technology objectives. The Chairperson is Mr. Gerard W. Elverum, Jr., and there are seven members of the Subcommittee. The following is the approved agenda for the meeting:

Agenda

May 1, 1980

8:30 a.m.—Introductory Remarks.
9:00 a.m.—Review of Projected Future Space Missions, Vehicle Needs and Requirements.
10:30 a.m.—Review of Projected Chemical Propulsion Needs to Meets Future Vehicle Requirements.
11:30 a.m.—Review of Current NASA Chemical Propulsion Program and Long Range Plan.
2:00 p.m.—Committee Discussion on NASA Chemical Propulsion Technology Program Appropriateness and Adequacy.

May 2, 1980

8:30 a.m.—Committee Formulation of Recommendations.
12:30 p.m. Adjourn.

For further information contact Dr. Raymond S. Colladay, Executive Secretary of the Subcommittee, Code RTP–6, NASA Headquarters, Washington, DC 20546. Telephone 202/755–3273.

Russell Ritchie,

Deputy Associate Administrator for External Relations.

April 9, 1980.

[FR Doc. 80-11255 Filed 4-14-80; 8:45 am]

BILLING CODE 7510-01-M

[Notice 80-29]

NASA Advisory Council (NAC); Meeting

The NASA Advisory Council's Informal *Ad Hoc* Task Group on Handling Unconventional Ideas will meet on May 5, 1980, in room 6004, Federal Building 6, 400 Maryland Avenue, SW, Washington, DC 20546. The meeting will be open to the public up to the seating capacity of the room (about 30 persons, including task group members and other participants).

The Informal *Ad Hoc* Task Group on Handling Unconventional Ideas was established under the NASA Advisory Council to determine the approaches employed by NASA in handling unconventional, often innovative, ideas and to recommend on additional ways that such ideas can be stimulated, evaluated, and supported by NASA. The task group will report its findings to the Council. The chairperson of the task group is Mr. Willis M. Hawkins and the task group is composed of three other members of the Council. For further information, contact the executive secretary, Mr. Carl Praktish, NASA Headquarters, Code D, Washington, DC A/C 202 755–3572.

AGENDA

May 5, 1980

1:00 p.m.—Introductory Remarks.
1:10 p.m.—Round Table Discussion of Present NASA Approaches.
3:00 p.m.—Discussion and Report Preparation.
5:00 p.m.—Adjourn.

Russell Ritchie,

Deputy Associate Administrator for External Relations.

April 9, 1980.

[FR Doc. 80-11256 Filed 4-14-80; 8:45 am]

BILLING CODE 7510-01-M

NATIONAL SCIENCE FOUNDATION

Advisory Council; Meeting

In accordance with the Federal Advisory Committee Act, Pub. L. 92–463, the National Science Foundation announces the following meeting:

Name: NSF Advisory Council.
Place: Room 540, National Science Foundation, 1800 G Street, N.W., Washington, D.C. 20550.
Date: Thursday, May 1, and Friday, May 2, 1980.
Time: 9:00 a.m. until 5:00 p.m., both days.
Type of Meeting: Open.
Contact Person: Mr. Bruce Darling, Executive Secretary, NSF Advisory Council, National Science Foundation, Room 518, 1800 G Street, N.W., Washington, D.C. 20550. Telephone (202) 632–4384.
Purpose of Advisory Council: The purpose of the NSF Advisory Council is to provide advice and counsel to the NSF Director and principal members of his staff on Foundation-wide issues which require the expertise of the many and varied disciplines and program interests represented in the Foundation.
Summary Minutes: May be obtained from the contact person at above stated address.
Agenda: To review progress by the four task groups of the NSF Advisory Council and to meet with the Director and Deputy Director and NSF staff.

Dated: April 9, 1980.

M. Rebecca Winkler,

Committee Management Coordinator.

[FR Doc. 80-11291 Filed 4-14-80; 8:45 am]

BILLING CODE 7555-01-M

Availability of Advisory Committee Reports

The National Science Foundation has filed with the Library of Congress reports of six NSF advisory committees.

The reports were filed as required by the Federal Advisory Committee Act and are available for public inspection and use at the Library of Congress, Room 256, Rare Book Division, Washington, DC, and at the Committee Management Office, National Science Foundation, Room 247, Washington DC.

The names and titles of the committee submitting reports are:

(1) Advisory Committee for Atmospheric Sciences
Atmospheric Sciences into the 1980's
(2) Advisory Committee for Environmental Biology
Report of the Oversight Review Committee of the Population Biology and Physiological Ecology Programs
(3) Advisory Committee for Physics
Gravitational Radiation Dectector Projects Report
Report of the NSF Subcommittee to Review NSF-Supported Nuclear Science Laboratories
Report of the Advisory Committee on the Review of Gravitational Physics
(4) Advisory Committee on Post-International Phase of Ocean Drilling (IPOD) Science
The Merits and Potential of a Proposed Ocean Drilling Program for the 1980's
(5) DOE/NSF Nuclear Science Advisory Committee
Recommendations for FY 1981 Facility Construction
The 1978 Census of Basic Nuclear Scientists in the USA
A Long Range Plan for Nuclear Science
(6) National Science Foundation Advisory Council
Equipment Needs and Utilization Accountability in Research

M. Rebecca Winkler,

Committee Management Coordinator.

April 10, 1980.

[FR Doc. 80-11290 Filed 4-14-80; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

[Docket No. PRM-51-6]

Catherine Quigg; Filing of Petition for Rulemaking

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Publication of petition for rulemaking by Catherine Quigg.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing for public comment a petition for rulemaking filed by Catherine Quigg, Research Director, Pollution and Environmental Problems, Inc. The petition, which has been assigned Docket No. PRM–51–6, requests the NRC to amend 10 CFR Part 51, "Licensing and Regulatory Policy and Procedures for Environmental Protection," to require the preparation of a generic environmental impact statement for high burnup nuclear fuel as used in commercial nuclear reactors, stored in spent fuel pools or cooling racks, or potentially as processed in reprocessing plants or disposed of in permanent sites.

DATE: Comment period expires June 16, 1980.

ADDRESSES: A copy of the petition for rulemaking is available for public inspection in the Commission's Public Document Room, 1717 H Street, N.W., Washington, DC. A copy of the petition may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

All persons who desire to submit written comments or suggestions concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docket and Service Branch.

FOR FURTHER INFORMATION CONTACT: Joseph M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC, 20555, Telephone: 301–492–7211.

SUPPLEMENTARY INFORMATION: The petitioner states that with the decision not to reprocess, the Federal government and the utilities want to use more uranium in existing nuclear fuel in light water reactors across the country. To that end, the U.S. Department of Energy (DOE) has initiated cost-shared high burnup projects with Duke Power Company and Arkansas Power & Light. The DOE is also supporting two pellet clad interaction (p.c.i.) projects with Consumers Power Company and Commonwealth Edison Company.

The petition also states that on March 7, 1979 the NRC issued a permit to the Commonwealth Edison Company allowing the irradiation of four Zion fuel assemblies to extend burnups in Zion 2, up to about 55,000 MWD/MTU. Zion's Technical Specifications previously provided for a burnup limit of 38,000 MWD/MTU. The petitioner indicates that there has been no experience with fuel size fuel assemblies irradiated to these burnups, but nonetheless the NRC issued a Negative Declaration stating the higher burnups would have no appreciable environmental impact.

The petitioner states that these experiments and others are being conducted without an Environmental Impact Statement, even though they could cause significant and widespread long and short term effects on the human environment. The petitioner says that her major concern is the nationwide program of high burnup fuel in nuclear reactors that is sure to follow these fairly limited experiments. She requests, therefore, that 10 CFR Part 51 be amended to require that a full Environmental Impact Statement be prepared covering the generic environmental impacts of high burnup nuclear fuel as used in commercial nuclear reactors, stored in spent fuel pools or cooling racks, and potentially as processed in reprocessing plants or disposed of in permanent sites.

The petitioner concludes that the use of high burnup fuel could have the following significant effects upon the human environment:

1. Greater fission gas releases from nuclear reactors.

2. Increased fission gas releases from spent fuel pools.

3. Production of inferior grade nuclear spent fuel which can lead to long term environmental hazards.

4. Potential for greater radiological impact in reactor and spent fuel pool accidents.

5. Increased radioactive releases during reprocessing.

The petitioner's arguments with respect to each of the above potential effects are set forth in the petition.

Dated at Washington, D.C., this 8th day of April 1980.

For the Nuclear Regulatory Commission.

Samuel J. Chik,

Secretary of the Commission.

[FR Doc. 80-11224 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

Privacy Act of 1974; Notices of System of Records, Proposed Minor Amendments

AGENCY: United States Nuclear Regulatory Commission.

ACTION: Proposed Minor Amendments of Systems of Records.

SUMMARY: The Nuclear Regulatory Commission is proposing minor amendments to the NRC Systems of Records, NRC-22. The amendments clarify and update the information contained in the NRC Systems of Records, necessitated by the division of the Personnel Performance Appraisals Systems into two sections. The additional section will incorporate the new Senior Executive Service into the System and establish a separate System location.

COMMENT DATE: Comments are due on or before May 15, 1980.

ADDRESS: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT: Sarah N. Wigginton, FOI/PA Branch, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Phone: (301) 492-8133.

SUPPLEMENTARY INFORMATION: In accordance with the Privacy Act of 1974, the Nuclear Regulatory Commission has published notices of those systems of records maintained by the NRC which contain personal information about individuals and from which such information can be retrieved by an individual identifier. The notices were published as a document subject to publication in the annual compilation of Privacy Act documents.

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and sections 552 and 552a of Title 5 of the United States Code, as amended, notice is hereby given that adoption of the following amendments to the NRC System of Records is contemplated. All interested persons who desire to submit written comments or suggestions for consideration in connection with the purposed amendments should send them to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch by May 15, 1980. Copies of comments on the proposed amendments may be examined at the Commission's Public Document Room at 1717 H Street, N.W., Washington, DC.

1. System of Records NRC-22, "Personnel Performance Appraisals—NRC," is amended to read as follows:

NRC-22

SYSTEM NAME:

Personnel Performance Appraisals—NRC: Part A, GG-15 employees and below; Part B, Senior Executive Service and equivalent employees.

SYSTEM LOCATION:

Part A: Division of Organization and Personnel, Office of Administration, NRC, 7910 Woodmont Avenue, Bethesda, Maryland.

Part B: Chairman, Performance Review Board, 7735 Old Georgetown Road, Bethesda, Maryland.

Duplicate system—duplicate systems exist, in whole or in part, at the locations listed in Addendum I, Parts 1 and 2.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

NRC employees.

CATEGORIES OF RECORDS IN THE SYSTEM:

This system of records contains evaluations of employees, evaluation criteria and methods, supervisory appraisals of performance and career development potential, and other related records.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

a. Section 161(d), Atomic Energy Act of 1954, as amended, 42 U.S.C. 2201(d)(1976);

b. 5 U.S.C. 4311, et seq.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The records may be used for any of the routine uses specified in the Prefatory Statement.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Maintained on paper in the folders.

RETRIEVABILITY:

Records are accessed by name.

SAFEGUARDS:

Maintained in locked file cabinets. Access to and use of these records are limited to those persons whose official duties require such access.

RETENTION AND DISPOSAL:

Part A: Retained 1 year, or until subsequent rating is prepared, whichever is later.

Part B: Retained for 5 years, or until the fifth annual appraisal is completed, whichever is later.

SYSTEM MANAGER(S) AND ADDRESS:

Part A: Chief, Personnel Operations Branch Division of Organization and Personnel Office of Administration U.S. Nuclear Regulatory Commission Washington, DC 20555

Part B: Chairman, Performance Review Board U.S. Nuclear Regulatory Commission Washington, DC 20555

NOTIFICATION PROCEDURE:

Director, Office of Administration U.S. Nuclear Regulatory Commission Washington, DC 20555

RECORD ACCESS PROCEDURES.

Same as "Notification procedure" for each part.

CONTESTING RECORD PROCEDURES:

Same as "Notification procedure" for each part.

RECORD SOURCE CATEGORIES:

Part A: Individual to whom record pertains and employee's supervisor.

Part B: Individual to whom record pertains and employee's supervisors: any documents and sources used to develop critical elements and performance standards for that Senior Executive Service position.

Dated at Bethesda, Maryland this 4th day of April, 1980.

For the Nuclear Regulatory Commission.

William J. Dircks,

Acting Executive Director for Operations.

[FR Doc. 80-11236 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

Advisory Committee on Reactor Safeguards, Subcommittee on Reliability and Probabilistic Assessment; Meeting

The ACRS Subcommittee on Reliability and Probabilistic Assessment

will hold a meeting on April 30, 1980 in Room 1046, 1717 H St., NW., Washington, DC 20555 to continue its evaluation of the need to develop quantitative safety goals for nuclear power plants and consideration of the actual form these goals may take and what they should accomplish. The Subcommittee will also discuss some general items related to the Probabilistic Analyses Staff's ongoing programs and budget. Notice of this meeting was published March 19, 1980.

In accordance with the procedures outlined in the Federal Register on October 1, 1979, (44 FR 56408), oral or written statements may be presented by members of the public, recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the Designated Federal Employee as far in advance as practicable so that appropriate arrangements can be made to allow the necessary time during the meeting for such statements.

The agenda for subject meeting shall be as follows:

Wednesday, April 30, 1980

8:30 a.m. until the conclusion of business.

The Subcommittee may meet in Executive Session, with any of its consultants who may be present, to explore and exchange their preliminary opinions regarding matters which should be considered during the meeting.

At the conclusion of the Executive Session, the Subcommittee will hear presentations by and hold discussions with representatives of the NRC Staff, the consultants, and other interested persons.

In addition, it may be necessary for the Subcommittee to hold one or more closed sessions for the purpose of exploring matters involving proprietary information. I have determined, in accordance with Subsection 10(d) of the Federal Advisory Committee Act (Public Law 92–463), that, should such sessions be required, it is necessary to close these sessions to protect proprietary information. See 5 U.S.C. 552b(c)(4).

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant Designated Federal Employee, Mr. Gary Quittschreiber (telephone 202/634–3267) between 8:15 a.m. and 5:00 p.m., EST.

Dated: April 9, 1980.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 80-11310 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

Regulatory Guide; Issuance and Availability

The Nuclear Regulatory Commission has issued a new guide in its Regulatory Guide Series. This series has been developed to describe and make available to the public methods acceptable to the NRC staff of implementing specific parts of the Commission's regulations and, in some cases, to delineate techniques used by the staff in evaluating specific problems or postulated accidents and to provide guidance to applicants concerning certain of the information needed by the staff in its review of applications for permits and licenses.

Regulatory Guide 10.9, "Guide for the Preparation of Applications for Licenses for the Use of Gamma Irradiators," describes the type of information that the NRC staff needs to evaluate an application for a license to use sealed radioactive sources for the gamma irradiation of materials. The information reported on Form NRC–313(I) should be sufficient to enable the NRC staff to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property. A draft regulatory guide on this subject (Task OH 706–4) was issued for public comment in February 1979.

Comments and suggestions in connection with (1) items for inclusion in guides currently being developed or (2) improvements in all published guides are encouraged at any time. Comments should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

Regulatory guides are available for inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, D.C. Copies of active guides may be purchased at the current Government Printing Office price. A subscription service for future guides in specific divisions is available through the Government Printing Office. Information on the subscription service and current prices may be obtained by writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Publications Sales Manager.

(5 U.S.C. 552(a))

Dated at Rockville, Maryland this 8th day of April 1980.

For the Nuclear Regulatory Commission.

Robert B. Minogue,

Director, Office of Standards Development.

[FR Doc. 80-11311 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

Application for Licenses To Export Nuclear Facilities or Materials

Pursuant to 10 CFR 110.41 "Public Notice of Receipt of an Application", please take notice that the Nuclear Regulatory Commission has received the following applications for export licenses for the period March 31 through April 5, 1979. A copy of each application is on file in the Nuclear Regulatory Commission's Public Document Room located at 1717 H St., N.W., Washington, D.C.

Dated this day April 7, 1980 At Bethesda, Maryland.

For the Nuclear Regulatory Commission.

James R. Shea,

Director, Office of International Programs.

Name of applicant, date of application, date received, application number	Material type	Material in kilograms		End-use	County of destination
		Total element	Total isotope		
U.S. Dept. of Energy, 03/26/80, 04/04/80, XSNM01672	19.79 pct. enriched uranium	27.1	5.37	For fabrication of fuel elements for Univ. of Michigan Reactor.	West Germany.
U.S. Dept. of Energy, 03/26/80, 04/04/80, XSNM01673	19.79 pct. enriched uranium	32.6	6.45	For fabrication of fuel elements for Univ. of Michigan Reactor.	France.

[FR Doc. 80-11312 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

Application for Licenses To Export Nuclear Facilities or Materials

Pursuant to 10 CFR 110.41 "Public Notice of Receipt of an Application," please take notice that the Nuclear Regulatory Commission has received the following application for export licenses for the period March 10, through March 29, 1980. A copy of each application is on file in the Nuclear Regulatory Commission's Public Document Room located at 1717 H Street NW., Washington, D.C.

Dated this day, April 7, 1980, at Bethesda, Maryland.

, For the Nuclear Regulatory Commission.

James R. Shea,

Director, Office of International Programs.

Name of applicant, date of application, date received, application number	Material type	Material in kilograms		End-use	Country of destination
		Total element	Total isotope		
General Elect., 02/07/80, 03/10/80, XSNM01662	4.0 pct. enriched uranium	239,000	4,500	Initial cores for Taiwan Power Units 7 and 8.	Taiwan.
Transnuclear, Inc., 03/12/80, 03/13/80, XSNM01663	3.4 pct. enriched uranium	10,794	367	Reload for Doel 1	Belgium.
Transnuclear, Inc., 03/19/80, 03/19/80, XSNM01664	4.013 pct. enriched uranium	30,746			
	.711 pct. natural uranium	129,224	1,234	Will be used as stockpile in accordance with provisions of offset agreement.	West Germany.
Transnuclear, Inc., 03/21/80, 03/21/80, XSNM01665	3.3 pct. enriched uranium	49,656	1,638.65	Reloads for Bugey 3 and Fessenheim 2 reactors.	France.
Transnuclear, Inc., 03/25/80, 03/26/80, XSNM01667	93.3 pct. enriched uranium	40.480	37.768	Fuel for JMTR and JRR-2 research reactors.	Japan.
Transnuclear, Inc., 03/25/80, 03/26/80, XSNM01668	45.4 pct. enriched uranium	22.142	10.053	For use in JMTRC	Japan.
General Elect., 03/07/80, 03/10/80, XR135	2894 MWT (984 MWE), Taiwan Power Nuclear Units 7 and 8, $200,000,000.				Taiwan.
Rockwell Int'l., 03/14/80, 03/17/80, XC0M0382	Globe stop valves for Bhabha Atomic Res. Center, $1,600.				India.
General Atomic Co., 03/24/80, 03/28/80, XSNM01669	7.4 gms	6.6 gms			
	55.4	11.0	93		
			19.9	For use in TRIGA Mark II Research Reactor.	Bangladesh.
NL Industries, 03/17/80, 03/21/80, ISNM79008(01)	34.64 pct. thru 93.23 pct.	Add'l 24.989	Add'l 15.541	Increase quantity of material authorized for import.	From Canada.
Edlow Intl., 03/03/80, 03/06/80, XU08488	.711 pct. natural uranium	192,326		Fuel for W. Germany reactors	West Germany.
Edlow Intl., 03/05/80, 03/07/80, XU08489	.711 pct. natural uranium	119,242		Fuel for Grohnde reactor	West Germany.
Byron Jackson, 03/06/80, 03/11/80, XC0M0376		Specially designed parts and components for Tarapur $20,000.			India.
Byron Jackson, 03/06/80, 03/11/80, XC0M0377		Specially designed parts and components for Tarapur $3,000,000.			India.
Carpenter Tech, 03/14/80, 03/17/80, XC0M0381		160 pieces Zircaloy—4 alloy fuel channels for Tarapur 1 and 2, $738,720.			India.
Coordination Council for N. American Affairs, 03/10/80, 03/18/80, XMAT0103.		4,000 Deuterium		For Taiwan Research reactor	Taiwan.
Helix Process Systems, 11/19/79, 03/20/80, XC0M0386		Two hydrogen recombiners for Koeberg Nuclear Power Plant.			South Africa.

[FR Doc. 80-11313 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-293A]

Boston Edison Co.; Receipt of Attorney General's Supplemental Advice

The Commission has received, pursuant to section 105c of the Atomic Energy Act of 1954, as amended, the following supplemental advice from the Attorney General of the United States, dated March 17, 1980, with respect to Pilgrim Nuclear Power Station, Unit No. 1:

"By letter dated October 24, 1979, you requested that the Department of Justice ("Department") renderd additional advice pursuant to Section 105(c) of the Atomic Energy Act of 1954 as amended, 42 U.S.C. § 2135c, concerning the application by the Boston Edison Company ("BECO") for a license to operate its Pilgrim Nuclear Power Station.

"On August 2, 1971, the Department advised the then Atomic Energy Commission that allegations advanced by certain Massachusetts Municipals, in petitions to intervene; with respect to antitrust matters, raised substantial questions which warranted an antitrust hearing pursuant to Section 105c. We noted at that time, however, that the competitive situation in New England was improving in that the municipal systems had gained access to some nuclear power plants and were participating in the efforts to form a New England power pool. We concluded by suggesting:

'It is possible that BECO and the intervenors may decide that their interests would be best served by mutual efforts to negotiate arrangements to ensure the intervenors reasonable access to low-cost power, and that a hearing might thereby be rendered unnecessary. We would of course be pleased to provide further advice to the Commission on the need for hearing if in light of subsequent developements the Commission should so request.'

"The petitions to intervene and our request for an antitrust hearing are still pending before the Nuclear Regulatory Commission.

"On June 26, 1974, the Department rendered advice on Pilgrim Nuclear Generating Station, Units 2 and 3, Boston Edison Company, *et al.*, AEC Docket Nos. 50-471A, 50-472A, and pointed out that BECO had demonstrated a commitment to allow municipal utilities in New England to gain access to bulk power from Pilgrim Units 2 and 3 on the same basis as is available to investor-owned utilities and

that this represented a significant step toward improving the competitive situation in New England. The Department concluded that, therefore, an antitrust hearing would not be necessary. The Department also noted that because negotiations between BECO and various municipal utilities for access to Pilgrim Nuclear Power Station were ongoing, we would not change our advice with respect to that nuclear unit.

"On April 20, 1978, in advising the NRC regarding additional applications for participation in Pilgrim Unit No. 2, the Department again concluded that no antitrust hearing would be necessary.

"You have now informed us that the settlement negotiations between BECO and the Massachusetts Municipals have been concluded to the satisfaction of the parties and that the Massachusetts Municipals have filed a 'Withdrawal of Intervention as Moot' with the Nuclear Regulatory Commission. You have asked us whether, in light of that information, the Department still believes that an antitrust hearing should be held.

"Since the Department rendered its advice in 1978, we have received no new information which would indicate that issuance of an operating license to Boston Edison Company would 'create or maintain a situation inconsistent with the antitrust laws.' 42 U.S.C. § 105(c). In light of this, because of the withdrawal of the Massachusetts Municipals' Petition to Intervene and based upon other information we have received, the Department is of the opinion that an antitrust hearing is no longer necessary with respect to the instant application."

For the Nuclear Regulatory Commission.

Jerome Saltzman,

Chief, Antitrust and Indemnity Group, Office of Nuclear Reactor Regulation.

[FR Doc. 80-11314 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-302]

Florida Power Corp., et al., Issuance of Amendment to Facility Operating License

In the matter of Florida Power Corporation, City of Alachua, City of Bushnell, City of Gainesville, City of Kissimmee, City of Leesburg, City of New Smyrna Beach and Utilities Commission, City of New Smyrna Beach, City of Ocala, Orlando Utilities Commission and City of Orlando, Sebring Utilities Commission, Seminole Electric Cooperative, Inc., City of Tallahassee.

The U.S. Nuclear Regulator Commission (the Commission) has issued Amendment No. 29 to Facility Operating License No. DPR-72, issued to the Florida Power Corporation, City of Alachua, City of Bushnell, City of Gainesville, City of Kissimmee, City of Leesburg, City of New Smyrna Beach and Utilities Commission, City of New Smyrna Beach, City of Ocala, Orlando Utilities Commission and City of Orlando, Sebring Utilities Commission, Seminole Electric Cooperative, Inc., and the City of Tallahassee (the licensees) which revised the Technical Specifications for operation for the Crystal River Unit No. 3 Nuclear Generating Plant (the facility) located in Citrus County, Florida. The amendment is effective as of the date of issuance.

The amendment changes the Technical Specifications concerning containment structural integrity to incorporate guidance on selecting the number of tendons for inspection and detensioning requirements.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment. Prior public notice of this amendment was not required since the amendment does not involve a significant hazards consideration.

The Commission has determined that the issuance of this amendment will not result in any significant environmental impact and that pursuant to 10 CFR § 51.5(d)(4) an environmental impact statement or negative declaration and environmental impact appraisal need not be prepared in connection with issuance of this amendment.

For further details with respect to this action, see (1) application for amendment dated November 21, 1977, as revised by letter dated February 15, 1980, (2) Amendment No. 29 to License No. DPR-72, and (3) the Commission's related Safety Evaluation. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. and at the Crystal River Public Library, Crystal River, Florida. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Maryland, this 3rd day of April, 1980.

For the Nuclear Regulatory Commission.

Robert W. Reid,

Chief, Operating Reactors Branch No. 4, Division of Operating Reactors.

[FR Doc. 80-11315 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-538]

Memphis State University; Issuance of Amendment to Facility Operating License and Negative Declaration

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 1 to Facility Operating License No. R-127, issued to Memphis State University, which revised the license and Technical Specifications for operation of the AGN-201 nuclear reactor (the facility) located on the licensee's campus in Memphis, Tennessee. The amendment is effective as of its date of issuance.

The amendment authorizes: (1) an increase in the facility's licensed maximum power level from 100 milliwatts (thermal) to 20 watts (thermal) for continuous operation and authorizes intermittent operation at power levels not in excess of 1000 watts (thermal); and (2) an increase in the amount, from 700 grams to 1400 grams, of contained U-235 enriched equal to or less than 20% for use in connection with the facility.

The application for the amendment complies with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR Chapter I, which are set forth in the license amendment.

Notice of Proposed Issuance of Amendment to Facility Operating License in connection with this action was published in the **Federal Register** on September 7, 1979 (44 FR 52389). No request for a hearing or petition for leave to intervene was filed following notice of the proposed action.

The commission has prepared an environmental impact appraisal for this action and has concluded that an environmental impact statement is not warranted because there will be no environmental impact attributable to the action.

For further details with respect to this action, see (1) the application for amendment dated March 23, 1979, as supplemented August 3, 1979, and August 28, 1979, (2) Amendment No. 1 to License No. R-127, (3) the Commission related Safety Evaluation/ Environmental Impact Appraisal. All of these items are available for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. A copy of items (2) and (3) may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission in Washington,

D.C. 20555, Attention: Director, Division of Operating Reactors.

Dated at Bethesda, Maryland this 28th day of March 1980.

For the Nuclear Regulatory Commission.

Robert W. Reid,

Chief, Operating Reactors Branch No. 4, Division of Operating Reactors.

[FR Doc. 80-11316 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-423]

Northeast Nuclear Energy Co., et al.* (Millstone Nuclear Power Station, Unit No. 3); Order Extending Construction Completion Date

Northeast Nuclear Energy Company, et al.* are the holders of Construction Permit No. CPPR-113 issued by the Atomic Energy Commission** on August 9, 1974, for construction of the Millstone Nuclear Power Station, Unit No. 3, presently under construction at a site located in New London County, Connecticut.

On August 3, 1979, the Northeast Nuclear Energy Company acting for itself and the other owners of the Millstone Nuclear Energy Power Station, Unit No. 3 filed a request for an extension of the completion date. Construction has been delayed due to two deferrals of the in-service date for Unit No. 3. Contributing to the two deferrals were: (1) unexpected rises in the price of uranium and other fuel cost increases, and (2) strikes by the carpenters' union and the boilermakers' union.

This action involves no significant hazards consideration; good cause has been shown for the delay; and the requested extension is for a reasonable period, the bases for which are set forth in the staff evaluation, dated March 26, 1980. The preparation of an environmental impact statement for this particular action is not warranted because there will be no environmental impact attributable to the Order other than that which has already been predicted and described in the Commission's Final Environmental Statement for the Millstone Nuclear Power Station, Unit No. 3, published in February, 1974. A Negative Declaration and an Environmental Impact Appraisal have been prepared and are available, as are the above stated documents, for public inspection at the Commission's Public Document Room, 1717 H Street, N.W., Washington, D.C. 20555 and at the local public document room established for the Millstone Nuclear Power Station, Unit No. 3 facility in Waterford Public Library, Rope Ferry Road, Route 156, Waterford, Connecticut 06385.

In accordance with Section 185 of the Atomic Energy Act of 1954, as amended, and the Commission's rules and regulations, including 10 CFR § 50.55(b), it is hereby ordered that the latest completion date for CPPR-113 be extended from October 1, 1979 to December 30, 1985.

Date of issuance: April 7, 1980.

For the Nuclear Regulatory Commission.

D. F. Ross, Jr.,

Acting Director, Division of Project Management.

[FR Doc. 80-11317 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

[Docket No. 50-423]

Supporting Extension of Construction Permit No. CPPR-113; Expiration Date for the Millstone Nuclear Power Station, Unit 3

The U.S. Regulatory Commission (the Commission) has reviewed Northeast Nuclear Energy Company's (permittee) request to extend the expiration date of the construction permit for the Millstone Nuclear Station, Unit 3 (CPPR-113), which is located in New London County, Connecticut. The permittee requested a six year, three month extension for the permit to December 1985, to allow for completion of construction of the plant.

The Commission's Division of Site Safety and Environmental Analysis has prepared an environmental impact appraisal relative to this change to CPPR-113. Based on this appraisal, the Commission has concluded that an environmental impact statement for this particular action is not warranted because there will be no environmental impact attributable to the proposed action other than that which has already been described in the Final Environmental Statement related to construction of Millstone Nuclear Power Station, Unit 3, dated February 1974.

The environmental impact appraisal is available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC, and at the Waterford Public Library, Rope Ferry Road, Route 156, Waterford, Connecticut.

Dated at Bethesda, Maryland, this 26th day of March 1980.

For the Nuclear Regulatory Commission.

Donald E. Sells,

Acting Chief, Environmental Projects Branch 2, Division of Site Safety and Environmental Analysis.

[FR Doc. 80-11318 Filed 4-14-80; 8:45 am]

BILLING CODE 7590-01-M

POSTAL RATE COMMISSION

California; Visit

April 10, 1980.

Notice is hereby given that the Chairman of the Commission will be visiting the *Sonoma Index Tribune* in Sonoma, California, and the *Point Reyes Light* in Point Reyes, California, on April 14 and 15, 1980, for the purpose of acquiring a general knowledge of preparation of newspapers by mailers. A report of the visit will be on file in the Commission docket room.

Cyril J. Pittack,

Acting Secretary.

[FR Doc. 80-11319 Filed 4-14-80; 8:45 am]

BILLING CODE 7715-01-M

THE PRESIDENT'S ADVISORY COMMITTEE FOR WOMEN

Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463 as amended), notice is hereby given of a meeting of the President's Advisory Committee for Women.

Date, time and place: April 30, 1980.
Open business session: 2:00 p.m. to 4:00 p.m., Room 541, Denver Hilton, 1550 Court Place, Denver, Colorado 80202, (303) 898-3333.

Sarita G. Schotta,

Executive Director.

April 9, 1980.

[FR Doc. 80-11347 Filed 4-14-80; 8:45 am]

BILLING CODE 4510-23-M

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*The following are the holders of Construction Permit No. CPPR-133: Ashburnham Municipal Light Plant, Boylston Municipal Lighting Plant, Central Maine Power Company, Central Vermont Public Service Corporation, Chicopee Municipal Lighting Plant, City of Burlington, Vermont, City of Holyoke, Massachusetts Gas and Electric Department, the Connecticut Light and Power Company, Fitchburg Gas and Electric Light Company, Green Mountain Power Corporation, The Hartford Electric Light Company, Marblehead Municipal Light Department, Massachusetts Municipal Wholesale Electric Company, Middleton Municipal Light Department, Montaup Electric Company, New England Power Company, North Attleborough Electric Department, Northeast Nuclear Energy Company, Paxton Municipal Light Department, Peabody Municipal Light Plant, Public Service Company of New Hampshire, Shrewsbury Light Plant, Templeton Municipal Lighting Plant, Town of South Hadley Electric Light Department, The United Illuminating Company, Vermont Electric Cooperative, Inc., Vermont Electric Power Company, Inc., The Village of Lyndonville Electric Department, Wakefield Municipal Light Department, West Boylston Municipal Lighting Plant, Western Massachusetts Electric Company, Westfield Gas and Electric Light Department.

**Effective January 20, 1975, the Atomic Energy Commission became the Nuclear Regulatory Commission and permits in effect on that day continued under the authority of the Nuclear Regulatory Commission.

Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463 as amended), notice is hereby given of a meeting of the President's Advisory Committee for Women.

Date, time and place: May 1, 1980.
Open public hearings: 8:30 a.m.–2:30 p.m., Old Supreme Court Chambers, The State Capitol, Colfax and Sherman Streets, Denver, Colorado.
Date, time and place: May 1, 1980.
Open public hearings: 7:30 p.m.–9:30 p.m., Auraria Center, 1212 Mariposa Street, Denver, Colorado (303) 534–7614.
Date, time and place: May 2, 1980.
Open public hearings: 10:00 a.m.–12:00 p.m., Denver Indian Center, 1580 Gaylord Street, Denver, Colorado.
Date, time and place: May 2, 1980.
Open public hearings: 2:00 p.m.–5:00 p.m., Lowry Air Force Base, Denver, Colorado.

Sarita G. Schotta,

Executive Director.

April 9, 1980.

[FR Doc. 80–11346 Filed 4–14–80; 8:45 am]

BILLING CODE 4510–23–M

SMALL BUSINESS ADMINISTRATION

Hasidic Jewish Americans; Decision on Request for Group Determination of Social Disadvantage

SBA has received a request on behalf of Hasidic Jewish Americans for designation as a minority group which has members who are socially disadvantaged because of their identification as members of the group, for the purpose of eligibility for SBA's section 8(a) procurement set-aside program. (Section 8(a) of the Small Business Act, 15 U.S.C. § 637(a), as amended by Pub. L. 95–507.) Approving a group designation of social disadvantage for purposes of the 8(a) program also would mean that prime contractors of the Federal Government could presume that any firm owned and operated by members of the group is owned and operated by socially and economically disadvantaged individuals, for purposes of meeting the requirements of the Federal subcontracting program established in Section 8(d) of the Small Business Act, 15 U.S.C. § 637(d), as amended by Pub. L. 95–507.

Pursuant to SBA regulations (13 CFR 124.1–1(c)(3)(iii)), a notice was published in the **the Federal Register** soliciting comments and information from the public in response to the request. (45 FR 7666, February 4, 1980.) SBA received a total of 151 comments pertaining to the request. These comments, as well as supporting data submitted with the request, have been duly evaluated by SBA.

Pursuant to the provisions of 13 CFR 124.1–1(c)(3)(iii)(D), this shall constitute notice that Hasidic firms owned and controlled by socially and economically disadvantaged persons are eligible to participate in the 8(a) and 8(d) programs, but not on the basis of a group designation of social disadvantage. Thus, the Hasidic entrepreneur seeking entry into the 8(a) program must first make an individualized showing of social disadvantage. In order to be certified into the 8(a) program, the firm would then have to meet the other eligibility requirements imposed by law, just as members of groups designated as socially disadvantaged must meet those requirements. With respect to the 8(d) program, a contractor of the Federal Government shall presume that socially and economically disadvantaged individuals shall include those Hasidic Jewish Americans who have been found by SBA to be socially and economically disadvantaged pursuant to Section 8(a) of the Small Business Act.

The full text of the above decision, and the data evaluated by SBA in reaching the decision, are available for public inspection at the Office of the Assistant Administrator for Public Communications, 1441 L Street NW., Washington, D.C. 20416.

Dated: April 9, 1980.

William A. Clement, Jr.,

Associate Administrator for Minority Small Business and Capital Ownership Development, Small Business Administration.

A. Vernon Weaver,

Administrator, Small Business Administration.

[FR Doc. 80–11375 Filed 4–14–80; 8:45 am]

BILLING CODE 8025–01–M

Region III Advisory Council; Public Meeting; Correction

In the matter of a meeting notice published at 45 FR 17709, March 19, 1980 (FR Doc. No. 80–8358): Correction of City.

The Small Business Administration Region III Advisory Council, located in the geographical area of Richmond, Virginia, will hold a public meeting at 10:00 a.m., Thursday, April 17, 1980 through noon on Friday, April 18, 1980, at the Sheraton Beach Inn, Virginia Beach, Virginia, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration and others attending.

For further information, write or call Raymond P. Kuttenkuler, District Director, U.S. Small Business Administration, P.O. Box 10126, Richmond, Virginia 23240—(804) 771–2741.

Dated: April 8, 1980.

Michael B. Kraft,

Deputy Advocate for Advisory Councils.

[FR Doc. 80–11370 Filed 4–14–80; 8:45 am]

BILLING CODE 8025–01–M

Region V Advisory Council; Public Meeting

The Small Business Administration Region V Advisory Council, located in the geographical area of Indianapolis, Indiana, will hold a public meeting at 10:00 a.m. (EST), Wednesday, May 14, 1980, in the Essex House Hotel, 421 North Pennsylvania Street, Indianapolis, Indiana, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call Robert D. General, District Director, U.S. Business Administration, Federal Building, Room 578, 575 North Pennsylvania Street, Indianapolis, Indiana 46204—(317) 269–7272.

Dated: April 8, 1980.

Michael B. Kraft,

Deputy Advocate for Advisory Councils.

[FR Doc. 80–11371 Filed 4–14–80; 8:45 am]

BILLING CODE 8025–01–M

Region VI Advisory Council; Public Meeting

The Small Business Administration Region VI Advisory Council, located in the georgraphical area of Albuquerque, New Mexico, will hold a public meeting from 10:00 a.m. to 3:00 p.m., Friday, May 9, 1980, at the Small Business Administration, 5000 Marble, N.E., Second Floor Conference Room, Albuquerque, New Mexico, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call E. Maine Shafer, District Director, U.S. Small Business Administration, 5000 Marble, N.E. Room 320, Albuquerque, New Mexico 87110—(505) 766–3574.

Dated: April 8, 1980.

Michael B. Kraft,

Deputy Advocate for Advisory Councils.

[FR Doc. 80–11368 Filed 4–14–80; 8:45 am]

BILLING CODE 8025–01–M

Region VI Advisory Council; Public Meeting

The Small Business Administration Region VI Advisory Council, located in the geographical area of Houston, Texas, will hold a public meeting at 10:00 a.m., Thursday, May 8, 1980, in the offices of the Small Business Administration located at One Allen Center, Suite 705, 500 Dallas Avenue, Houston, Texas, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call Joseph J. Luna, Acting District Director, U.S. Small Business Administration, One Allen Center, Suite 705, 500 Dallas Avenue, Houston, Texas 77002—(713) 226–4897.

Dated: April 8, 1980.

Michael B. Kraft,

Deputy Advocate for Advisory Councils.

[FR Doc. 80–11373 Filed 4–14–80; 8:45 am]

BILLING CODE 8025–01–M

Region VIII Advisory Council; Public Meeting

The Small Business Administration Region VIII Advisory Council, located in the geographical area of Helena, Montana, will hold a public meeting at 9:30 a.m., Thursday, May 8, 1980, at the offices of the Small Business Administration located in the Federal Office Building, 301 S. Park, Room 528, Helena, Montana, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call Frank D. Ray, District Director, U.S. Small Business Administration, Federal Building, 301 S. Park, Drawer 10054, Helena, Montana 59601—(406) 449–5381.

Dated: April 8, 1980.

Michael B. Kraft,

Deputy Advocate for Advisory Councils.

[FR Doc. 80–11374 Filed 4–14–80; 8:45 am]

BILLING CODE 8025–01–M

Productivity and Small Business Innovation

Pursuant to statutory authority set forth in Secton 634(d) of Title 15, United States Code, the Chief Counsel for Advocacy of the Small Business Administration, Milton D. Stewart, Esq., with the approval of the Administrator, A. Vernon Weaver, will conduct a public hearing in Boston, Massachusetts on May 8 and 9, 1980, on Productivity and Small Business Innovation. The hearing will convene at 10:00 a.m. (EDT) in Room 1507 on May 8th and Room 505 on May 9th—John F. Kennedy Federal Building; Government Center; Boston, Massachusetts 02110.

The Office of the Chief Counsel for Advocacy will consider how small business innovation affects national productivity including such factors as changes in flows of invested capital, R. & D. expenditures, costs of regulations, increases in inflation, changes in labor force or human resources (skills, experience, and education), as well as environmental or institutional changes which stimulate technological creativity.

The traditional productivity measure which has been used, reflects "output per worker-hour." What has not been made sufficiently clear in this measurement or in overall productivity policy, is the importance of small business activities in improving our overall national productivity efforts and the influence of small business on some of the contributing factors leading to a greater increase in the rate of productivity growth.

Participants will include diverse, innovative, and technology oriented small firms which may be considered currently in or having recently passed through a pre-venture capital raising stage. Such firms will be marketing or close to marketing a product or process which could have some measurable impact in a "national need" area, i.e. energy, medicine, food, etc.

The hearing is open to the public. Any member of the public may make a verbal statement, but must file a written statement prior to the hearing. Any member of the public may file a written statement with the Office of Chief Counsel for Advocacy before, during or after the hearings. All communications or inquiries regarding these hearings should be attentioned to: Jerry Feigen, Associate Advocate, Capital Formation/Venture Capital, Small Business Administration, 1441 L Street, N.W., Room 1010–C, Washington, D.C. 20416, 202–653–6808.

Milton D. Stewart,

Chief Counsel for Advocacy.

[FR Doc. 80–11433 Filed 4–14–80; 8:45 am]

BILLING CODE 8025–01–M

DEPARTMENT OF STATE

[Public Notice CM–8/287]

Shipping Coordinating Committee, Subcommittee on Safety of Life at Sea; Meeting

The Safety of Life at Sea Subcommittee will conduct an open meeting at 9:30 a.m. on Wednesday, May 7, 1980 in room 3201 of the U.S. Coast Guard Headquarters Building, 2100 Second Street, S.W., Washington, D.C.

The purpose of the meeting is to finalize preparations for the 42nd session of the Maritime Safety Committee (MSC) of the Intergovernmental Maritime Consultative Organization (IMCO) which is scheduled to meet May 19–23, 1980 in London. In particular, the SOLAS Subcommittee will discuss development of U.S. positions dealing with, interalia, the following topics:

—Amendments to the 1974 SOLAS Convention;

—Casualty statistics;

—Surveys and inspections;

—Reports of various MSC subcommittees.

For further information contact Mr. Gerard P. Yoest, International Affairs Division, U.S. Coast Guard (G–AIA/21), 2100 Second Street, S.W., Washington, D.C. 20593, telephone (202) 426–2280.

Dated: March 7, 1980.

John Todd Stewart,

Chairman, Shipping Coordinating Commitee.

[FR Doc. 80–11339 Filed 4–14–80; 8:45 am]

BILLING CODE 4710–07–M

DEPARTMENT OF LABOR

Mine Safety and Health Administration

DEPARTMENT OF TREASURY

Bureau of Alcohol, Tobacco and Firearms

[Notice No. 80–6]

Memorandum of Understanding

Following is the text of the revised Memorandum of Understanding between the Bureau of Alcohol, Tobacco and Firearms (ATF) and Mine Safety and Health Administration (MSHA) in which MSHA agrees to perform on behalf of ATF inspections of explosives storage facilities and records required at the storage site of all mines subject to MSHA jurisdiction.

For further information contact the following offices:

Bureau of Alcohol, Tobacco and Firearms, Special Operations Branch, Dan Crowley, 566–7591;

Division of Mine Safety and Health, Office of the Solicitor, Bernard McGuire, 235–1148.

Memorandum of understanding between the Mine Safety and Health Administration, Department of Labor,

and the Bureau of Alcohol, Tobacco and Firearms, Department of Treasury

1. *Purpose.* A. On June 1, 1971, the Mining Enforcement and Safety Administration (MESA), Department of the Interior, formerly the Bureau of Mines (Bureau), and the Bureau of Alcohol, Tobacco anf Firearms (ATF), Department of the Treasury, formerly the Alcohol, Tobacco and Firearms Division of the Internal Revenue Service, entered into a Memorandum of Understanding. This Memorandum provided for MESA inspections of facilities in mines under MESA jurisdiction involving applications for licenses and permits under 18 U.S.C. 841 et seq., and implementing regulations issued in 27 CFR Part 181, Subpart J (soon to be renumbered 27 CFR Part 55), and for MESA to conduct compliance inspections in regard to storage and certain recordkeeping requirements issued by ATF.

B. The Federal Mine Safety and Health Act of 1977 (Mine Act), Pub. L. 91–173, as amended by the Pub. L. 95–164, 30 U.S.C. 801 et seq., which became effective on March 9, 1978, consolidates all mine health and safety under the Mine Act, transfers MESA to the Department of Labor, and changes the name of MESA to the Mine Safety and Health Administration (MSHA), Department of Labor. The purpose of this revision of the original Memorandum of Understanding is to substitute MSHA for MESA, make certain other changes and to execute a memorandum between MSHA and ATF.

C. MSHA agrees to perform on behalf of ATF inspections of storage facilities and records required at the storage site (Under 18 U.S.C. 841 et seq. and applicable regulations in 27 CFR Part 181) of all mines subject to MSHA jurisdiction.

2. *General Authorities.* A. Under Title XI (Regulation of Explosives) of the Organized Crime Control Act of 1970, Pub. L. 91–452, 18 U.S.C. 841 et seq. ATF is responsible for:

(1) Issuing licenses to persons engaged in the business of importing, manufacturing, and dealing in explosive materials;

(2) Issuing permits to persons who rely on interstate commerce to acquire explosive materials or who transport explosive materials in interstate commerce;

(3) Establishing standards for the storage of explosive materials; and

(4) Inspecting storage facilities of licensees and permittees.

B. Under the Mine Act, MSHA is responsible for administering the Federal mine safety and health program, including establishing safety standards for the transportation, storage, and use of explosive materials in mining operations and the periodic inspection and investigation of storage facilities located on mine property.

3. *Standards.* A. MSHA will enforce safety and security standards found in 27 CFR Part 181, Subpart J, and the recordkeeping requirements in Section 181.127 of Subpart G. In the event that these standards conflict with a MSHA requirement, MSHA shall enforce the regulations or standards which provide for the greater safety or security of persons in and around a mine.

B. MSHA safety specifications and security requirements will govern the movement and use of explosive materials taken underground for mining and other activities.

4. *MSHA Inspections.* A. MSHA will conduct on behalf of ATF a compliance inspection of persons holding licenses and permits under 18 U.S.C. 841 et seq., who also are subject to the jurisdiction of MSHA, during each regular MSHA inspection and investigation of mine operators. The mine operator will be cited for violations of ATF regulations observed during both a regular and other inspection. These compliance inspections will consist of inspecting all storage facilities and required records at storage facilities under the applicable regulations of 27 CFR Part 181. The results of inspections conducted on behalf of ATF shall be promptly submitted to ATF. In the event that further administrative or judicial action is necessary, such action will be taken by ATF with the assistance of the MSHA inspector, where needed.

B. ATF accepts the inspection of these storage facilities and records by MSHA as satisfying the purposes of 18 U.S.C. 841 et seq., including the conditions imposed on license and permit applicants with respect to storage facilities for explosive materials.

5. *ATF Inspection. ATF will make inspections of applicants (and their explosive storage facilities) for licenses and permits under 18 U.S.C. 841 et seq., and the implementing regulations and rulings. The results of these inspections will be promptly given to MSHA.*

6. *Listings and Reports.* A. MSHA will furnish ATF Hedquarters a list, updated as necessary, of all mines subject to the jurisdiction of MSHA District and Subdistrict offices. These lists will be distributed by ATF to its regional offices for use in processing applications received from applicants coming under the jurisdiction of MSHA.

B. Each ATF Regional Regulatory Administrator will furnish to MSHA a list of ATF personnel who will provide advice or assistance to MSHA. ATF Headquarters will promptly furnish to MSHA District Managers copies of rulings and variances issued to mines under MSHA jurisdiction.

C. MSHA will furnish the appropriate ATF Regional Regulatory Administrator a copy of accident investigation reports, (including reports furnished by mine operators) relating to accidental detonations which MSHA investigates, and ATF will furnish MSHA District Managers a copy of accident investigation reports relating to accidental detonations of interest to MSHA which ATF investigates.

7. *Working Agreements.* Working or implementing agreements to provide guidelines and procedures relating to inspections of explosives licensees and permittees, who are also subject to MSHA's jurisdiction, shall be prepared in writing and executed as ATF Orders, as necessary, and coordinated with MSHA by ATF Headquarters personnel.

8. *Cooperation.* MSHA and ATF will cooperate in the development of uniform standards for the safe and secure storage of explosive materials and procedures relating to inspections of explosive licensees and permittees, to the greatest extent possible. They will also maintain liaison and cooperation with each other in regard to their respective responsibilities under the Federal mine safety programs and under 18 U.S.C. 841 et seq., and each agency will furnish to the other all information of interest to the other relating to explosive materials.

9. *Training.* ATF will provide, at MSHA's request, training for MSHA inspectors in ATF storage and recordkeeping requirements.

10. *Interagency Coordination.* The Special Operations Branch of Regulatory Enforcement (ATF), and the Chief, Division of Safety, Coal Mine Safety and Health, and Chief, Division of Safety, Metal and Nonmetal Mine Safety and Health (MSHA) shall serve as liaison points to facilitate communication and cooperation between the two agencies.

11. *Termination.* The Memorandum of Understanding of June 1, 1971, shall terminate as of April 9, 1980, at which time it is replaced by this Memorandum. This Memorandum of Understanding shall continue from April 9, 1980: Provided, however, that it may be terminated at any time by either party giving written notice of termination to the other party at least (90) days prior to the date fixed on such notice.

Dated: April 9, 1980.

Robert B. Lagather,

Assistant Secretary of Labor for Mine Safety and Health, Department of Labor.

Dated: April 9, 1980.

Richard J. Davis,

Assistant Secretary for Enforcement and Operations, Department of Treasury.

[FR Doc. 80-11257 Filed 4-14-80; 8:45 am]

BILLING CODE 4810-31-M

Sunshine Act Meetings

Federal Register
Vol. 45, No. 74
Tuesday, April 15, 1980

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).

CONTENTS

1

[M-276 Amdt. 4; April 10, 1980]

CIVIL AERONAUTICS BOARD.

TIME AND DATE: 9:30 a.m., April 10, 1980.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT:

2a. Warsaw Convention Liability Limits. (For Information, dated March 18, 1980, BCP

11. Travel Committee, Inc.—Petition for review of staff action denying waiver of the major change provisions of Part 380. (memo No. 9568, BDA)

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary (202) 673-5068.

SUPPLEMENTARY INFORMATION: Item 2a is being deleted from today's agenda because the staff requires additional time to consider this matter. Item 11 is being deleted from today's agenda because the General Counsel's staff needs more time for coordination. Accordingly, the following Members have voted that Items 2a and 11 be deleted from today's agenda and that no earlier announcement of these deletions was possible:

Chairman Marvin S. Cohen.
Member Elizabeth E. Bailey.
Member Gloria Schaffer.
Member George A. Dalley.

[S-760-80 Filed 4-11-80; 3:52 pm]

BILLING CODE 6320-01-M

2

[M-276 Amdt. 5; April 10, 1980]

CIVIL AERONAUTICS BOARD.

TIME AND DATE: 9:30 a.m., April 10, 1980.

PLACE: Room 1027, 1825 Connecticut Avenue NW., Washington, D.C. 20428.

SUBJECT:

10. Docket 33836, Final rule extending the Board's fare flexibility policy to the Puerto Rico/Virgin Islands markets. (Memo No. 7847-T, BDA, OEA)

32. Docket 36294, Revised NPRM on whether denied boarding compensation must be paid to passengers transfered to an extra section of a flight. (Memo No. 9510-B, OGC).

STATUS: Open.

PERSON TO CONTACT: Phyllis T. Kaylor, the Secretary, (202) 673-5068.

SUPPLEMENTARY INFORMATION: Item 10 is being reinstated on the Agenda for April 10, 1980, as it was inadvertently deleted. Item 32 is being deleted because it was found that additional staff work is required. Accordingly, the following Members have voted that Item 10 be reinstated and that Item 32 be deleted from the April 10, 1980 Agenda and that no earlier announcement of this deletion and reinstatement was possible.

Chairman Marvin S. Cohen.
Member Elizabeth E. Bailey.
Member Gloria Schaffer.
Member George A. Dalley.

[S-761-80 Filed 4-11-80; 3:52 pm]

BILLING CODE 6320-01-M

3

COMMODITY FUTURES TRADING COMMISSION.

TIME AND DATE: 11:30 a.m., April 11, 1980.

PLACE: 2033 K Street NW., Washington, D.C., eighth floor conference room.

STATUS: Closed.

MATTERS TO BE CONSIDERED:

11:30 a.m. Enforcement Matter.
11:45 a.m. Legislative Matter.

CONTACT PERSON FOR MORE INFORMATION: Jane Stuckey, 254-6314.

[S-754-80 Filed 4-11-80; 11:32 am]

BILLING CODE 6351-01-M

4

[FR No. 708]

FEDERAL ELECTION COMMISSION.

PREVIOUSLY ANNOUNCED DATE AND TIME: Thursday, April 10, 1980, at 10:00 a.m.

CHANGE IN MEETING: Due to an emergency situation, the Commission set a meeting to discuss the following matters in executive session.

Title 26 Matching Funds for Honorable Edward M. Kennedy/Kennedy for President Committee.

Title 26 Matching Funds for Lyndon H. La Rouche/Citizens for La Rouche.

PERSON TO CONTACT FOR INFORMATION: Mr. Fred Eiland, Public Information Officer, telephone: 202-523-4065.

Marjorie W. Emmons,
Secretary to the Commission.

[S-753-80 Filed 4-10-80; 4:08 pm]

BILLING CODE 6715-01-M

5

FEDERAL ENERGY REGULATORY COMMISSION.

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 45 FR 24963; April 11, 1980.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10 a.m., April 16, 1980.

CHANGE IN THE MEETING: The following items have been added:

Item Number, Docket Number, and Company

ER-6—E-9563, U.S. Department of the Interior, Bonneville Power Administration.
ER-7—EL79-26 and ER79-600, Central Power & Light Company.
M-5(A)—RM79-35, Exemptions of Small Conduit Hydroelectric Facilities from Part I of the Federal Power Act.
M-5(B)—RM79-52, Continuance of Service.
M-10—RM79-78, Final Rule Under the NGPA Defining the Term New Well.
CP-2—CP79-473, Alabama-Tennessee Natural Gas Company.
CP-3—CP80-11, Southern Natural Gas Company.

Kenneth F. Plumb,
Secretary.

[S-759-80 Filed 4-11-80; 2:27 pm]

BILLING CODE 6450-85-M

6

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION.

April 9, 1980.

TIME AND DATE: 10 a.m., Wednesday, April 16, 1980.

PLACE: Room 600, 1730 K Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. Princess Susan Coal Company, WEVA 79-423-R (Petition for Discretionary Review; issues include miners' right to walkaround pay during MSHA spot inspections).
2. North American Coal Corporation, LAKE 79-118, etc. (Petition for Discretionary Review; issues include interpretation of 30 CFR § 70.100(b)).
3. Windsor Power House Coal Company, WEVA 79-193-R (Petition for Discretionary Review; issues include interpretation of 30 CFR § 75.316).
4. Old Ben Coal Company, VINC 75-267, IBMA 76-21—continued from April 2, 1980 (issues include whether withdrawal order issued under section 104(c) of the 1969 Coal Act was properly affirmed by the Administrative Law Judge).
5. Pacer Corporation, DENV 79-257-PM (Issues include whether the Secretary proved a violation of 30 CFR § 55.5-1(a)).

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen, 202-653-5632.

[S-758-80 Filed 4-11-80; 2:27 pm]

BILLING CODE 6820-12-M

7

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION.

April 9, 1980.

TIME AND DATE: 10 a.m., Monday, April 14, 1980.

PLACE: Room 600, 1730 K Street NW., Washington, D.C.

STATUS: Open.

MATTERS TO BE CONSIDERED: The Commission will consider and act upon the following:

1. Union Rock and Materials Corporation, DENV 78-579-PM (Petition for Discretionary Review; issues include interpretation of 30 CFR § 56.14-6).
2. Duval Corporation, WEST 79-194-M (Petition for Discretionary Review; issues include owner-operator liability for violations committed by independent contractors).
3. Peabody Coal Company, LAKE 80-36, etc. (Petition for Discretionary Review; issues include right to a evidentiary hearing when proposed settlement rejected).

It was determined by a unanimous vote of Commissioners that Commission business required that a meeting be held on these items and that no earlier announcement of the meeting was possible.

CONTACT PERSON FOR MORE INFORMATION: Jean Ellen, 202-653-5632.

[S-257-80 Filed 4-11-80; 2:26 pm]

BILLING CODE 6820-12-M

8

FEDERAL TRADE COMMISSION.

TIME AND DATE: 11:30 a.m., Thursday, April 17, 1980.

PLACE: Room 432, Federal Trade Commission Building, Sixth Street and Pennsylvania Avenue NW., Washington, D.C. 20580.

STATUS: Open.

MATTERS TO BE CONSIDERED: Policy Review Session: Post-Purchase Consumer Remedies—Open Portion (Presentations by Professor Laura Nader, and a representative from an automobile manufacturer, concerning consumer remedies).

CONTACT PERSON FOR MORE INFORMATION: Ira J. Furman, Office of Public Information (202) 523-3830; recorded message: (202) 523-3806.

[S-755-80 Filed 4-11-80; 1:51 pm]

BILLING CODE 6750-01-M

9

POSTAL SERVICE (Board of Governors).

Notice of Meeting

The Board of Governors of the United States Postal Service, pursuant to its Bylaws (39 CFR § 7.5) and the Government in the Sunshine Act (5 U.S.C. § 552b), hereby gives notice that it intends to hold a meeting on Sunday, April 20, 1980, at 10:30 a.m., at Postal Service Headquarters, 475 L'Enfant Plaza SW., Washington, D.C. 20260. The meeting is not open to the public. The Board expects to discuss the matters stated in the agenda which is set forth below. Requests for information about the meeting should be addressed to the Secretary of the Board, Louis A. Cox, at (202) 245-4632.

On April 1, 1980, the Board of Governors voted to close to public observation its next meeting, scheduled for 10:30 a.m. on April 20, 1980. Each of the members of the Board voted in favor of closing this meeting, which is expected to be attended by the following persons: Governors Wright, Hardesty, Allen, Camp, Ching and Sullivan; Postmaster General Bolger; Deputy Postmaster General Conway; Senior Assistant Postmaster General Finch; and Secretary of the Board Cox.

Agenda

1. Discussion of Postal Service ratemaking strategy. (The Board will discuss Postal Service ratemaking plans. As stated above in the Notice of Meeting, the session on this matter will be closed to the public.)
2. Opinion and Recommended Decision upon Reconsideration of Postal Rate Commission, dated March 24, 1980, re Third-Class Carrier Route Presort Proposal, 1978 (Commission Docket No. MC78-2).

(The Governors of the Postal Service will consider the Commission's Recommended Decision. As stated above in the Notice of Meeting, the discussion of this item will be closed to the public.)

3. Discussion of the Opinion and Recommended Decision upon Reconsideration of the Postal Rate Commission re Electronic Mail Classification Proposal, 1978 (Commission Docket No. MC78-3).

(The Governors of the Postal Service will consider the Commission's Recommended Decision. As stated above in the Notice of Meeting, the discussion of this item will be closed to the public.)

Louis A. Cox,

Secretary.

[S-756-80 Filed 4-11-80; 2:25 pm]

BILLING CODE 7710-12-M

federal register

Tuesday
April 15, 1980

Part II

Department of Health, Education, and Welfare

Food and Drug Administration

Viral and Rickettsial Vaccines; Proposed Implementation of Efficacy Review

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 601 and 630

[Docket No. 78N-0100]

Viral and Rickettsial Vaccines; Proposed Implementation of Efficacy Review

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the biologics regulations in response to the report and recommendations of the Panel of Review of Viral Vaccines and Rickettsial Vaccines. The Panel reviewed the safety, efficacy, and labeling of viral and rickettsial vaccines and human and equine immune serum globulins. On the basis of the Panel's findings and recommendations, the Commissioner of Food and Drugs is proposing to classify those products in Category I (safe, effective, and not misbranded) and Category IIIA (on the market during futher studies in support of effectiveness) and is inviting comments and the submission of additional data on the status of these products.

The Commissioner is also announcing his conclusions as to those products which are in Category II (unsafe, ineffective, or misbranded) and Category IIIB (off the market pending completion of studies permitting a determination of effectiveness). In the near future, the Commissioner will publish a notice of opportunity for a hearing (NOH) to revoke the licenses for products in Categories II and IIIB. Comments and additional data will be requested in the NOH.

DATES: Comments on the classification of products into Category I and IIIA and on proposed amendments to the biologics regulations should be submitted on or before July 14, 1980. Comments on the confidentiality of data submitted ror review by the Panel should be submitted on or before May 15, 1980.

ADDRESSES: Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Steven F. Falter, Bureau of Biologics (HFB-620), Food and Drug Administration, Department of Health, Education, and Welfare, 8800 Rockville Pike, Bethesda, MD 20205, 301-443-1306.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 13, 1973 (38 FR 4319), the Commissioner issued § 601.25 (21 CFR 601.25) concerning procedures for the review of the safety, effectiveness, and labeling of biological products licensed prior to July 1, 1972. Under a redesignation of panel assignments published in the **Federal Register** of June 19, 1974 (39 FR 21176), the biological products reviewed were assigned to one of the following categories: (a) bacterial vaccines and bacterial antigens with "no U.S. standard of potency," (b) bacterial vaccines and toxoids with standards of potency, (c) viral vaccines and rickettsial vaccines, (d) allergenic extracts, (e) skin test antigens, or (f) blood and blood derivatives.

Under § 601.25, the Commissioner assigned responsibility for the initial review of each of the biological product categories to a separate independent advisory review panel consisting of qualified experts to ensure objectivity of the review and public confidence in the use of these products. Each panel was charged with preparing an advisory report to the Commissioner which was to: (1) evaluate the safety and effectiveness of the biological product, (2) review the labeling of the biological product, and (3) advise him on which biologcal products under review are safe, effective, and not misbranded. The advisory report includes a statement classifying products into one of three categories.

Category I designates those biological products determined by the panel to be safe, effective, and not misbranded. The panel's statement may include any condition relating to active components, labeling, tests required prior to release of batches, product standards, or other conditions necessary or appropriate for their safety and effectiveness.

Category II designates those biological products determined by the panel to be unsafe or ineffective or to be misbranded.

Category III designates those biological products determined by the Panel not to fall within either Category I or II on the basis of its conclusion that the available data are insufficient for classification and for which further testing is therefore required. Those biological products in Category III for which continued licensing, manufacturing, and marketing are recommended are designated as Category IIIA. Those biological products in Category III for which the suspension of their license is recommended are designated as Category IIIB. The recommendations for either Category IIIA or IIIB are based on assessment of the present evidence of safety and effectiveness of the product and the potential benefits and risks likely to result from the continued use of the product for a limited period of time, while questions raised concerning the products are being resolved by further study.

Because of a recent Federal court decision involving the review and classification of over-the-counter drugs, the agency has reevaluated the legal status of on-going product review procedures. It is FDA's conclusion that the biologics' review Category IIIA designation is proper and is unaffected by the ruling applicable to OTC drugs.

The case, *Cutler* v. *Kennedy*, challenged the propriety of the OTC classification Category III, which authorized the continued marketing of OTC drugs that had been found to be not generally recognized as safe and effective and thus which were new drugs as defined by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321(p), but for which there were no effective new drug applications as required by 21 U.S.C. 355. If a drug is not a new drug because it is generally recognized as safe and effective, no such approval is required.

On July 16, 1979, the United States District Court for the District of Columbia concluded that to the extent that the OTC Category III authorized the marketing of drugs that are new drugs but yet unapproved, that interim status was illegal. The Court ruled that the new drug provisions of the Federal Food, Drug, and Cosmetic Act created a statutory benchmark and that no drug failing to meet the statutory criteria could be classified otherwise while further data were being developed.

The regulations governing the biologics review (21 CFR 601.25) also provide for a classification, Category IIIA, to designate those products for which safety and effectiveness data are incomplete but which remain on the market while further data are developed. However, the biologics under review have been licensed under the Public Health Service Act, 42 U.S.C. 262. The purpose of the review is not to establish, for the first time, the marketing status of a product, as is the purpose of the OTC review, but rather to reaffirm or question, based upon current scientific standards, the data upon which the license is based. Classification of a biologic in biologics Category IIIA does not reflect a finding that a product cannot, as a matter of law, be licensed or that it is not exempt from the licensure requirement, but rather that the data are insufficient to recommend revoking the existing license

or that the data supporting the license should be supplmented. In this respect a Category IIIA biologic is in a regulatory status analogous to that of an interim food additive. See 21 CFR 180.1. Licensed biologicals are not subject to the new drug provisions of the Federal Food, Drug, and Cosmetic Act. See 21 CFR 310.4. The question of their being "new" and thus requiring prior FDA approval or "old" (generally recognized as safe and effective) and thus not subject to prior review is not at issue. All biologics must be licensed whether they are generally recognized as safe and effective or not.

In the **Federal Register** of February 28, 1973 (38 FR 5359), the Commissioner requested data and information regarding viral vaccines and rickettsial vaccines. Additional data and information regarding the safety and effectiveness of related immune globulins and sera were requested in the **Federal Register** of June 19, 1974 (38 FR 21176).

Some concern has been expressed that information submitted to FDA under § 601.25 will become public information. Data and information submitted in response to the February 28, 1973 and June 19, 1974 notices and falling within the provisions of 5 U.S.C. 552(b), 18 U.S.C. 1905, or 21 U.S.C. 331(j) have been handled as confidential. However, with the publication of this proposed implementation and the Panel's findings, such data and information will, under § 601.25(b)(2), be made publicly available after May 15, 1980, and may be viewed at the office of the Hearing Clerk, except to the extent that the person submitting the data and information demonstrates that it still falls within the confidentiality provisions of one or more of the above statutes. Accordingly, comments concerning confidentiality should be submitted on or before May 15, 1980.

The Commissioner appointed the following Panel to review the data and information submitted and to prepare a report on the safety, effectivenes, and labeling of viral vaccines, rickettsial vaccines, and related immune globulins and antiserum:

Panel chairman, Saul Krugman, M.D., Professor, Department of Pediatrics, New York University School of Medicine, New York, NY 10016;

John P. Fox, M.D., Professor, Department of Epidemiology, University of Washington, Seattle, WA 98105;

William S. Jordan, Jr., M.D., Professor, Department of Community Medicine, University of Kentucky School of Medicine, Lexington, KY 40506 (since September 1, 1976, Director, Microbiology and Infectious Diseases Program, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD 20205);

Edwin H. Lennette, M.D., Ph.D., Chief Viral and Rickettsial Diseases Laboratory, California Department of Health, Berkeley, CA 94704;

June E. Osborn, M.D., Professor of Pediatrics and Medical Microbiology, Associate Dean of the Graduate School, University of Wisconsin, Madison, WI 53706;

Kenneth McIntosh, M.D., Professor of Pediatrics, University of Colorado Medical Center, Denver, CO 80262;

Wade P. Parks, M.D., Ph.D., Head, Viral Carcinogenesis Branch, National Cancer Institute, National Institutes of Health, Bethesda, MD 20205 (resigned from Panel June 30, 1976).

The Panel was convened on July 2, 1973 in an organizational meeting. Working meetings were held: July 2, August 30–31, October 29–30, December 17–18, 1973; February 6–7, April 2–3, June 17, September 6–7, November 4–5, 1974; January 6, February 10–11, March 12–13, April 10–11, July 7–9, December 18–19, 1975; February 10–11, June 22–24, 1976; January 24, October 3–4, 1977; and January 23–25, 1978.

Two nonvoting liaison representatives served on the Panel. W. Palmer Dearing, M.D., nominated by the Consumer Federation of America, served as the consumer representative. John Adams, Ph.D., of the Pharmaceutical Manufacturers Association, nominated by a number of producers with products under review by the Panel, served as the industry representative. Karl Bambach, Ph.D, substituted for Dr. Adams during his absences. Morris Schaeffer, M.D., Ph.D., participated in the Panel meetings in his capacity as Director of the Office of Efficacy Review, Bureau of Biologics, FDA. Jack Gertzog, Deputy Director, Office of Efficacy Review, Bureau of Biologics, FDA, served as Executive Secretary of the Panel.

In addition, the Panel considered the advice of the following consultants:

Samuel L. Katz, M.D.
David T. Karzon, M.D.
Edwin D. Kilbourne, M.D.

Over 250 persons requested an opportunity or were otherwise invited to appear before the Panel and present their views on one or more of the vaccines and related matters. Every person who requested an opportunity was heard by the Panel. The names of these persons are on file with the Hearing Clerk.

The Panel on Review of Viral Vaccines and Rickettsial Vaccines evaluated all data submitted for the following vaccines and other related products:

Table 1—*Licensed Vaccines Considered by the Panel*[1]

Manufacturer	Product
Parke, Davis & Co	Adenovirus Vaccine.
	Adenovirus and Influenza Virus Vaccines, Combined, Aluminum Phosphate Adsorbed.
Eli Lilly & Co	Influenza Virus Vaccine.
Lederle Laboratories Division, American Cyanamid Co.	Influenza Virus Vaccine.
Merrell-National Laboratories, Division of Richardson-Merrell, Inc.	Influenza Virus Vaccine.
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Influenza Virus Vaccine.
Parke, Davis & Co	Influenza Virus Vaccine.
Wyeth Laboratories, Inc	Influenza Virus Vaccine.
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Measles, Mumps and Rubella Virus Vaccine, Live.
	Measles and Rubella Virus Vaccine, Live.
	Measles-Smallpox Vaccine, Live.
Dow Chemical Co	Measles Virus Vaccine, Live, Attenuated.
Lederle Laboratories Division, American Cyanamid Co.	Measles Virus Vaccine, Live, Attenuated.
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Measles Virus, Vaccine, Live, Attenuated.
Eli Lilly & Co	Mumps Vaccine.
Lederle Laboratories Division, American Cyanamid Co.	Mumps Vaccine.
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Mumps Virus Vaccine, Live.
Connaught Laboratories, Ltd	Poliomyelitis Vaccine.
Cutter Laboratories, Inc.	Poliomyelitis Vaccine.
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Poliomyelitis Vaccine.
Parke, Davis & Co	Poliomyelitis Vaccine.
	Poliomyelitis Vaccine, Adsorbed.
Lederle Laboratories Division, American Cyanamid Co.	Poliovirus Vaccine, Live, Oral Trivalent, Type 1, Type 2, and Type 3.
Pfizer, Ltd	Poliovirus Vaccine, Live, Oral, Trivalent.
	Poliovirus Vaccine, Live, Oral, Type 1.
	Poliovirus Vaccine, Live, Oral, Type 2.
	Poliovirus Vaccine, Live, Oral, Type 3.
Wyeth Laboratories, Inc.	Poliovirus Vaccine, Live, Oral, Trivalent.
	Poliovirus Vaccine, Live, Oral, Type 1.
	Poliovirus Vaccine, Live, Oral, Type 2.
	Poliovirus Vaccine, Live, Oral, Type 3.
Eli Lilly & Co	Rabies Vaccine.
Lederle Laboratories Division, American Cyanamid Co.	Rocky Mountain Spotted Fever Vaccine.
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Rubella and Mumps Virus Vaccine, Live.
	Rubella Virus Vaccine, Live.
Recherche et Industrie Therapeutiqes, S.A. (Smith Kline and French).	Rubella Virus Vaccine, Live.
Division of Biological Products, Bureau of Laboratories, Michigan Department of Public Health.	Smallpox Vaccine.
Connaught Laboratories, Ltd	Smallpox Vaccine.
Lederle Laboratories Division, American Cyanamid Co.	Smallpox Vaccine.
Massachusetts Public Health Biologic Laboratories.	Smallpox Vaccine.
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Smallpox Vaccine.
Merrell-National Laboratories, Division of Richardson-Merrell, Inc.	Smallpox Vaccine.
Wyeth Laboratories, Inc	Smallpox Vaccine.
Eli Lilly & Co	Typhus Vaccine.
Lederle Laboratories Division, American Cyanamid Co.	Typhus Vaccine.
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Typhus Vaccine.

Table 1—*Licensed Vaccines Considered by the Panel*[1]—Continued

Manufacturer	Product
Merrell-National Laboratories, Division of Richardson-Merrell, Inc.	Yellow Fever Vaccine.

[1] Only biological products that have been licensed prior to July 1, 1972, are reviewed in this report.

Table 2—*Licensed Antiserum and Human Immune Globulin Preparations*[1]

Manufacturer	Product
Istituto Sieroterapico Vaccinogeno Toscano, "Sclavo".	Antirabies Serum.
Lederle Laboratories Division, American Cyanamid Co.	Antirabies Serum.
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Immune Globulin (Human), Pepsin-Modified.
Abbott Laboratories	Immune Serum Globulin (Human).
Armour Pharmaceutical Co.	Immune Serum Globulin (Human).
Division of Biologic Products, Bureau of Laboratories, Michigan Department of Public Health.	Immune Serum Globulin (Human).
Cutter Laboratories, Inc	Immune Serum Globulin (Human).
Dow Chemical Co	Immune Serum Globulin (Human).
E. R. Squibb & Sons, Inc	Immune Serum Globulin (Human).
Lederle Laboratories Division, American Cyanamid Co.	Immune Serum Globulin (Human).
Massachusetts Public Health Biologic Laboratories.	Immune Serum Globulin (Human).
Merck Sharp & Dohme, Division of Merck & Co., Inc.	Immune Serum Globulin (Human).
North American Biologicals, Inc.	Immune Serum Globulin (Human).
Osterreichisches Institut fur Haemoderivate G.m.b.H.	Immune Serum Globulin (Human).
Parke, Davis & Co	Immune Serum Globulin (Human).
Travenol Laboratories, Inc., Hyland Division.	Immune Serum Globulin (Human).
Wyeth Laboratories, Inc	Immune Serum Globulin (Human).
Lederle Laboratories Division, American Cyanamid Co.	Measles Immune Globulin.
Parke, Davis & Co	Measles Immune Globulin.
Cutter Laboratories, Inc	Mumps Immune Globulin (Human)
Travenol Laboratories, Inc., Hyland Division.	Mumps Immune Globulin (Human).
Travenol Laboratories, Inc., Hyland Division.	Vaccinia Immune Globulin (Human).

[1] Only biological products that have been licensed prior to July 1, 1972, are reviewed in this report.

The advisory Panel appointed to review data and information concerning safety, effectiveness, and labeling of viral and rickettsial vaccines has completed their review as follows:

Basis of Evaluation

The development of various viral vaccines has had a profound influence on the course and history of preventive medicine during the past two centuries. The necessary technology is now available to prepare safe, potent, and highly effective vaccines for the prevention of smallpox, poliomyelitis, measles, mumps, rubella, and other viral diseases. The extensive use of these vaccines is responsible in great part for the substantial decline in the morbidity and mortality of infectious diseases.

The terms "safety," "potency," and "effectiveness" are relative, not absolute. The evaluation of these terms and their application to the assessment of a licensed vaccine is based, in great part, on the risk-benefit assessment of the product in question. The importance of this position was highlighted by Sir Graham Wilson when he stated:

> It is fair to conclude that most of the well-known protective immunological agents that we use do a great deal more good than harm. The complications and accidents for which they are from time to time responsible must be looked upon as the price we pay for the protection these agents confer upon us. There is no insurance without a premium. Our business is to provide a greater and more comprehensive insurance and to diminish the size of the premium.

The role of viral vaccines in promoting the health and welfare of mankind may be illustrated by a brief historical review of three vaccines which have had a notable impact in reducing the high morbidity prevalent during the prevaccination era.

1. *Smallpox.* The efficacy of vaccination for the prevention of smallpox was well established at the beginning of the 19th century. In 1796, Edward Jenner performed the first human-to-human vaccination with pustular material obtained from the cowpox lesion of a milkmaid's hand. A typical pox lesion developed on the arm of the boy who was inoculated. Some 2 month later, the boy was shown to be immune to reinoculation with pustular material from an active case of smallpox. Jenner extended these studies and showed that cowpox, a mild disease, was protective against smallpox. His historic observations were published in 1798 and 2 years later his findings were confirmed by Benjamin Waterhouse in the United States.

However, the availability of an effective vaccine did not eradicate smallpox and it remained a serious problem more than a century later. During the 10-year period from 1920 to 1930, there were more than 530,000 reported cases and 4,790 smallpox deaths in the United States. The acceptance of vaccination as a routine public health practice resulted in a decline in the number of smallpox cases in the United States from 110,672 in 1920 to 40,280 in 1925; 15,000 in 1938; 56 in 1948; and 0 in 1954. During the past 20 years, there has been not one confirmed case of smallpox reported in the United States.

The eradication of smallpox from most countries of the world in the 1970's has been an extraordinary achievement. The impact of Jenner's great contribution in incalculable. When he performed his first vaccination in 1796, about 45,000 deaths were caused by smallpox in Britain each year. Moreover, of all reported deaths, one in every five was due to this disease, and during the 18th century smallpox was responsible for the death of more than 60 million people in the world.

2. *Poliomyelitis.* The dramatic decline in the incidence of poliomyelitis in the United States is a direct result of the polio-vaccine program initiated in 1955. In 1954, there were 38,000 reported cases of poliomyelitis, of which 18,500 were paralytic. In 1975, there were only 5 paralytic cases, an alltime low since official reporting of the disease was initiated in 1912. Since 1954, more than 400 million doses of inactivated poliovirus vaccine (Salk) have been distributed in the United States. In addition, since 1961 more than 400 million doses of live, attenuated, poliovirus (Savin) have been used in extensive community-wide and routine immunization programs.

Inactivated poliovirus vaccine was the first safe and effective vaccine to be used for the prevention of poliomyelitis. Despite its excellent record, it did have limitations, namely, the vaccine's antigenic potency was variable and repeated inoculations were necessary to maintain antibody levels which declined rather rapidly (Refs. 1 through 10).

Live attenuated poliovirus has been used extensively throughout the world as a vaccine. Its effectiveness and safety have been well established. It is given orally; it is antigenically potent; and a single dose is followed by a rapid antibody response. Its capacity to produce intestinal resistance to reinfection has been responsible for its capacity to abort epidemics of poliomyelitis. The oral vaccine has been as effective, more acceptable, and more convenient to administer than an injectable vaccine.

3. *Measles.* Measles has been recognized as a disease for more than 11 centuries. It was first described in 850 A.D. by Rhazes, an Arabian physician. This universal disease, occurring on all continents and in all people, has had a major impact on the history and destiny of many nations. For example, Louis XV, King of France, became heir to the French crown after measles killed his brother, mother, and father. During an epidemic in the Fiji Islands in 1875, approximately 20,000 people died of measles, a loss of about one-fifth of the native population. The disease had a tremendous impact on the American Civil War, affecting 75,000 troops and causing approximately 5,000 deaths. Even as late as World War I it was an important cause of military casualties. During 1918 and 1919, 90,000 soldiers

caught the disease and more than 2,000 died. The advent of antibiotics and gamma globulin after World War II was followed by a significant decline in the bacterial complications of measles. However, despite a remarkable decrease in the mortality rate, measles continued to be an uncontrollable disease which attacked most children before adolescence.

The most significant advance toward the control of measles occurred in 1954, more than 1,100 years after the disease was recognized. In that year John F. Enders and his colleagues first isolated a strain of measles virus, later known as the Edmonston Strain. They later succeeded in attenuating the virus. In March 1963, after 9 years of carefully controlled trials by many investigators, a live attenuated measles virus vaccine, Edmonston Strain, was licensed for use in the United States. A further attenuated strain of live measles virus, the Schwarz Strain, was subsequently licensed as a vaccine in February 1965. The use of more than 60 million doses of vaccine during the past 10 years has been followed by a dramatic decline in the incidence of measles and measles encephalitis in the United States (See Figs. A–1 and A–2).

The number of reported cases of measles has declined from approximately 500,000 per year before licensing the vaccine in 1963 to less than 50,000 cases since 1972. The number of reported cases of measles encephalitis has declined progressively from approximately 300 prior to 1963 to an alltime low of 14 in 1974.

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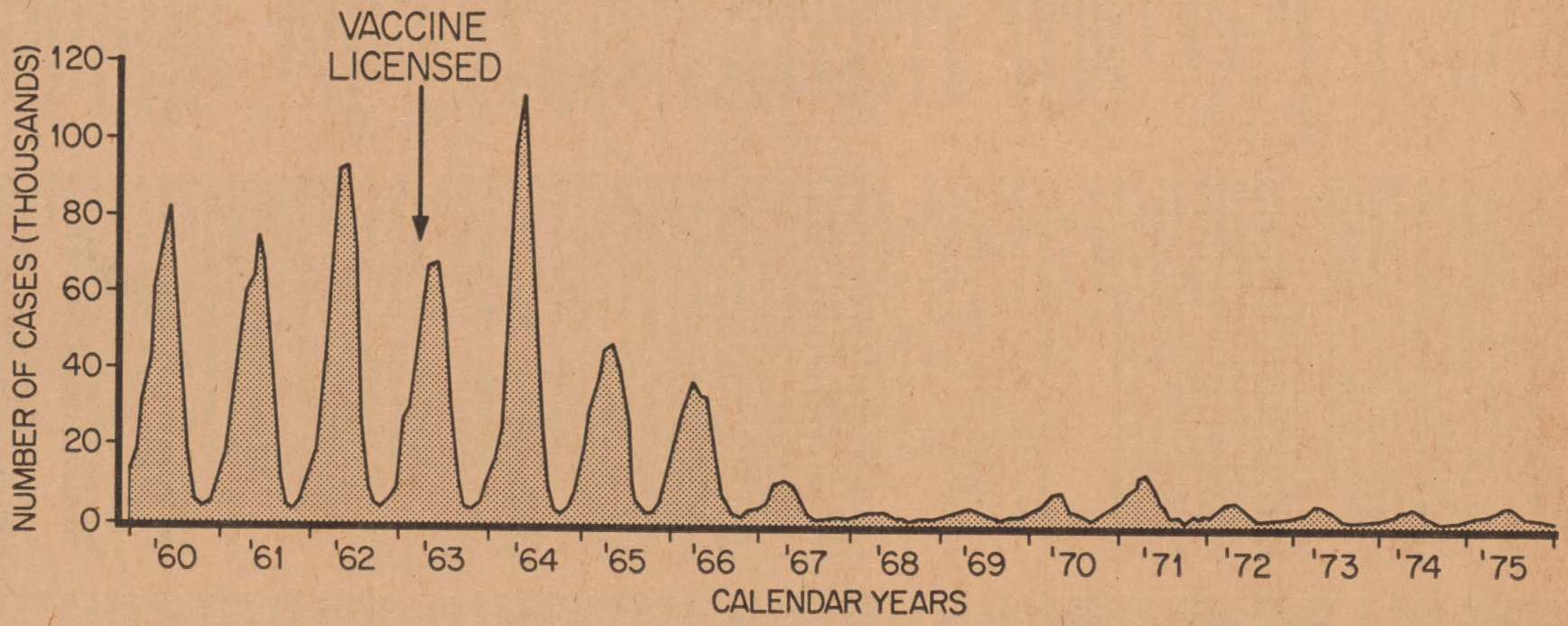
Figure A-1

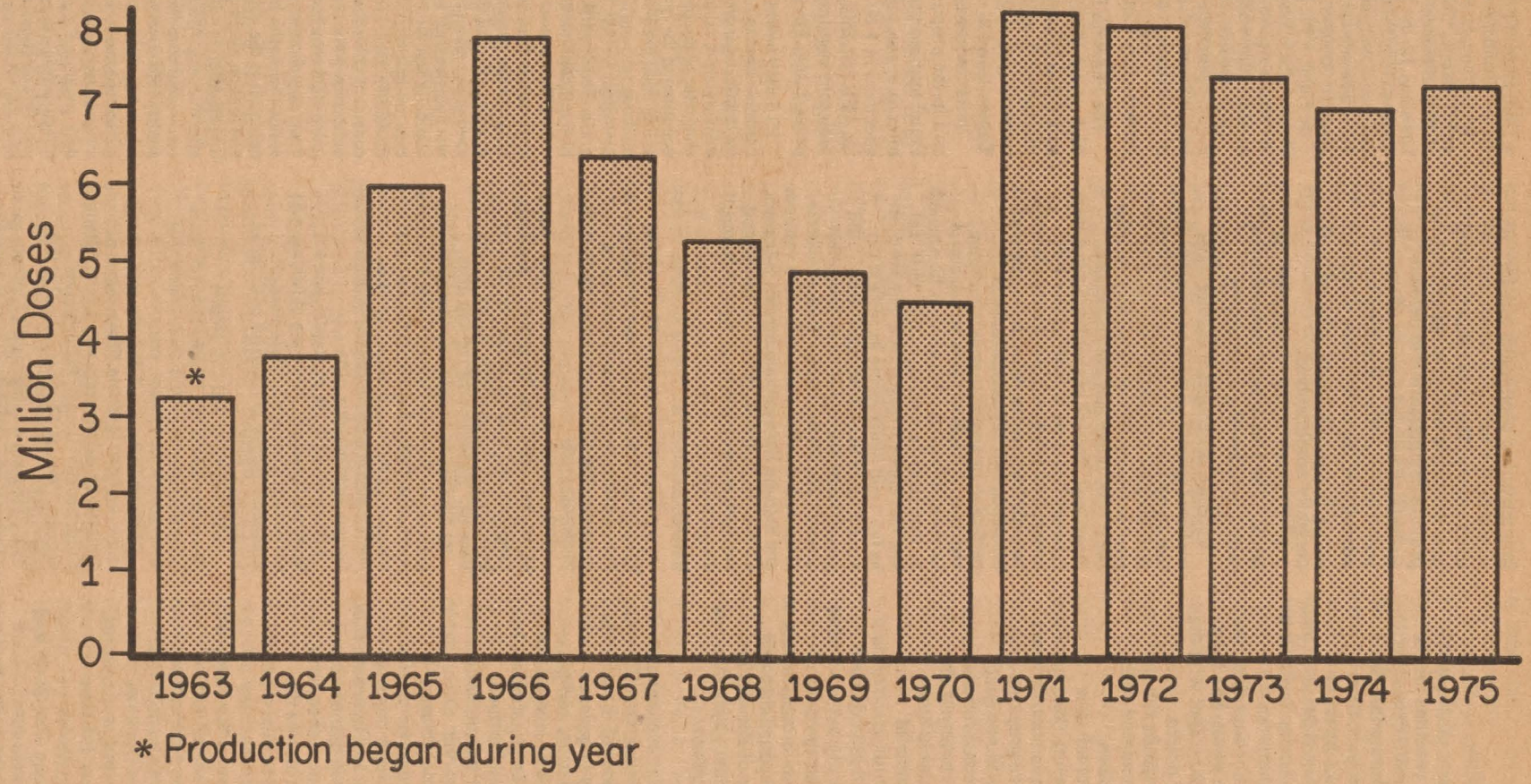
REPORTED CASES OF MEASLES BY FOUR-WEEK PERIODS UNITED STATES, 1960-1975



Source: Center for Disease Control

Figure A-2

Net Doses of Live Measles Vaccine Distributed United States 1963-1975



Source: Center for Disease Control

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Risk and Responsibilities

The development and subsequent licensing of effective vaccines for the prevention of poliomyelitis, measles, mumps, and rubella during the past 2 decades stem, in great part, from important contributions by many investigators in the United States. Thus, this country has been in the forefront in its support of research for the prevention of these infectious diseases. The United States, however, has been backward in its failure to deal with the important problem of public responsibility for the minimal but unavoidable risks associated with immunization procedures.

It is well-known that adverse reactions and even severe complications may occur in rare circumstances, even when vaccine has been prepared and used in accordance with accepted regulations and recommendations. Most reactions of this type represent an unusual and unpredictable host response. The occurrence of postvaccinal encephalitis is a classic example. Also, coincidental disease totally unrelated causally to the vaccine is bound to occur under the laws of probability. Given such circumstances, it is difficult to place responsibility and determine the validity of liability and malpractice suits against physicians and claims for damages against manufacturers.

Since immunizations recommended by national health authorities are of benefit not only for the recipient of the vaccine but for the community in general, several European countries and Japan have established a public compensation system under which the government has accepted responsibility for the recognized hazards of immunization.

In assessing liability, the responsibilities of manufacturer, physician, and State must be clearly defined. The manufacturer has two major responsibilities, i.e., to ensure that each batch of vaccine is manufactured and tested in strict accordance with regulations, and to include in the package insert for physicians a careful description of the risks that may be associated with the use of the vaccine in question. Medical personnel are obligated to inform the prospective vaccinee of any known possible risk.

In contrast with other types of prescription drugs, the major quantities of vaccines used are provided in connection with public health immunization campaigns. The State and Federal governments assume responsibilities for planning, funding, and implementing public health immunization campaigns and for licensing the vaccines which may be used legally. The government should also assume a further responsibility to provide compensation to persons suffering damage because of rare untoward reactions resulting from administration of vaccines which are properly manufactured, labeled, and correctly administered.

Sir Graham Wilson concluded his book, "The Hazards of Immunization," with the following commentary:

> Vaccines, of one sort of another, have conferred immense benefit on mankind but, like aeroplanes and motor-cars, they have their dangers. My intention has been to provide information on these dangers in the belief that, unless they are known and recognized, the task of guarding against them is bound from time to time to meet with unexpected and possibly disastrous failures. Manufacturers entrusted with the preparation of immunological products must, in particular, be careful to maintain eternal vigilance. A single slip may be disastrous. Over-confidence must at all costs be avoided. St. Paul issued a warning against this: "Let him that thinketh he standeth take heed lest he fall"; and Shakespeare expressed the same thought in even stronger terms: "And you all know security Is mortals' chiefest enemy". It is for us, and for those who come after us, to see that the sword which vaccines and antisera have put into our hands is never allowed to tarnish through over-confidence, negligence, carelessness, or want of foresight on our part.

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Introductory Comments

The Panel on Review of Viral and Rickettsial Vaccines evaluated all data submitted in support of the licensure of the vaccines, antisera, and human immune globulin preparations listed in Tables 1 and 2.

In its review of the submitted data and in the preparation of its report, the Panel applied the definitions of safety, effectiveness, and labeling which are specified in § 601.25(d) (1) through (5) (21 CFR 601.25(d) (1) through (5)) of the biologics regulations governing the new procedures. These regulations state:

> (1) Safety means the relative freedom from harmful effect to persons affected, directly or indirectly, by a product when prudently administered, taking into consideration the character of the product in relation to the condition of the recipient at the time. Proof of safety shall consist of adequate tests by methods reasonably applicable to show the biological product is safe under the prescribed conditions of use, including results of significant human experience during use.
>
> (2) Effectiveness means a reasonable expectation that, in a significant proportion of the target population, the pharmacological or other effect of the biological product, when used under adequate directions for use and warnings against unsafe use, will serve a clinically significant function in the diagnosis, cure, mitigation, treatment, or prevention of disease in man. Proof of effectiveness shall consist of controlled clinical investigations as defined in § 314.111(a) (5)(ii) of this chapter, unless this requirement is waived on the basis of a showing that it is not reasonably applicable to the biological product or essential to the validity of the investigation, and that an alternative method of investigation is adequate to substantiate effectiveness. Alternate methods, such as serological response evaluation in clinical studies and appropriate animal and other laboratory assay evaluations may be adequate to substantiate effectiveness where a previously accepted correlation between data generated in this way and clinical effectiveness already exists. Investigations may be corroborated by partially controlled or uncontrolled studies, documented clinical studies by qualified experts, and reports of significant human experience during

marketing. Isolated case reports, random experience, and reports lacking the details which permit scientific evaluation will not be considered.

(3) The benefit-to-risk ratio of a biological product shall be considered in determining safety and effectiveness.

(4) A biological product may combine two or more safe and effective active components: (i) When each active component makes a contribution to the claimed effect or effects; (ii) when combining of the active ingredients does not decrease the purity, potency, safety, or effectiveness of any of the individual active components; and (iii) if the combination, when used under adequate directions for use and warnings against unsafe use, provides rational concurrent preventive therapy or treatment for a significant proportion of the target population.

(5) Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall comply with Section 351 of the Public Health Service Act and sections 502 and 503 of the Federal Food, Drug, and Cosmetic Act, and in particular with the applicable requirements of §§ 610.60 through 610.65 and Subpart D of Part 201 of this chapter.

These definitions are elaborated upon as appropriate within the generic review for each vaccine.

After completing a product-by-product review, the Panel assigned each product to one of the following three categories:

Category I. Biological products determined to be safe and effective and specifying conditions under which they would not be misbranded.

Category II. Biological products determined to be unsafe or ineffective or misbranded.

Category III. Biological products determined not to fall within either Category I or II on the basis of the Panel's conclusion that the available data are insufficient to classify such products, and for which further testing is therefore required. For those products judged to be in Category III, the Panel was asked to recommend whether the license for the product should be retained (IIIA) or revoked (IIIB), while adequate data concerning safety, effectiveness and potency were being generated under controlled conditions.

The report which follows includes the basis for the Panel's recommendations and the details of both generic review of each type of vaccine and an individual review of each licensed product. If there is only a single manufacturer for a product, the generic considerations are included within the review of such single products. In some instances, the generic reviews recommend that additional studies be conducted on vaccines found by the Panel to be safe and effective (Category I). While the charge to the Panel by the Commissioner of Food and Drugs did not specifically ask for such recommendations in relations to safe and effective (Category I) products, the Panel considers such studies as appropriate for assessment of the benefit-to-risk factors which the Panel was asked to consider. With respect to its recommendations for additional studies for Category I products, the Panel believes that the state of the art and the benefit/risk assessments will both benefit by these recommendations.

As a preamble to the generic and individual product reviews, the Panel has prepared the following statement which discusses the overall basic principles and considerations relating to viral and rickettsial vaccines.

Basic Concepts of Immunity to Viral and Rickettsial Infections

Natural infection with virus and rickettsiae, with the important exception of respiratory viruses, is followed by solid and long lasting immunity which protects against clinical disease and reinfection, the latter to a variable extent. For most contact-transmitted agents, reduced susceptibility to reinfection is particularly important since it operates to inhibit spread of such agents in the population. As the number of susceptibles in the population is reduced, there is a corresponding reduction in the likelihood that an infected individual will make effective contact with a susceptible. While other factors such as social behavior, frequency of contact, and physical environment (e.g., temperature, humidity) affect infectivity, the net inhibition of spread reduces the risk of infection for the remaining nonimmune members of the population. This phenomenon of "herd immunity" and its application to immunization strategies will be considered in a later section.

In general, protective immunity to infection depends on humoral antibodies. However, the relatively normal clinical response of persons with agammaglobulinemia to most viral infections suggests that other forms of immunity such as cell-mediated immunity may play important protective roles in the natural course of viral infections. Conversely, delayed hypersensitivity mediated by cellular immunity may also be a major determinant in the clincial symptoms of viral infections, e.g., the rash of measles.

Protective antibodies are specific for surface antigens of viruses. These antibodies can be induced by the whole virus (during infection or as incorporated in an inactivated vaccine) or by purified viral surface antigens. The protective effect of an antibody depends on its reaction with extracellular virus to form complexes which lead to noninfectivity.

Intracelluar virus is not affected by antibody. Thus, once infection has been initiated, the role of an antibody is limited to restricting the spread of virus. Since effective levels of serum antibody rarely develop in response to infection until most, if not all, susceptible cells have been infected, antibody is not thought to play an important role in recovery from viral infections. Thus postexposure use of immune serum globulin containing specific antiviral antibodies is protective only within a limited period after exposure. In addition, use of vaccines to stimulate active immunity is usually protective only when vaccination is begun substantially before exposure occurs (rabies constitutes a possible exception).

The protective effect of humoral immunity, including that induced by vaccines, depends on several factors. One is the relation between antibody titer and the exposure dose of virus. Under naturally occurring conditions, variation in infecting virus dose is probably fairly narrow, thus antibody titer is the usual determinant of whether infection will take place. Even when infection does occur, the antibody tends to restrict spreading of the virus, thereby minimizing the resulting disease. This is a beneficial effect of vaccine-induced immunity that sometimes is overlooked.

While the general rule is that antibody is most protective against the homologous agent, the immunity related to it will be protective against heterologous but related agents to a degree corresponding to the strength of the antigenic cross-relation between the agents. Such heterologous immunity is a potentially important determinant of the natural occurrence of infection and disease and may be an important consequence of vaccine-induced immunity, most notably in the case of vaccinia and smallpox.

Perhaps the most important area relating to the protective effect of humoral antibody is the pathogenesis of infection and disease. Since our concern here is entirely with the acute events following infection from exogenous sources, the development of persisting infection (latent, recrudescent, or continuing patent) will not be discussed except as it relates to new exposures. Portal of entry, site of primary virus localization, target tissues or organs (disease sites), paths by which virus reaches such targets, and total viral replication are more easily illustrated by specific disease examples.

Yellow fever illustrates the situation in which the agent is introduced through

the skin and gains entrance rather rapidly into the blood stream resulting in wide dissemination throughout the host. The systemic nature of the infection permits extensive viral replication. A correspondingly large mass of viral antigen which stimulates a major antibody response may account for the usual lifelong persistence of antibody. The usual portal of entry through the skin exposes the infecting dose of virus directly to humoral antibody present in tissue fluids and blood so that full protection is usually afforded by any detectable level of serum antibody. This situation also exists for other viral and rickettsial agents transmitted by blood-sucking arthropods.

Measles represents a similarly systemic infection which differs chiefly in usual portal of entry, i.e., through respiratory and/or conjunctival mucous membranes. Presumably, the virus replicates initially in mucosal cells and then quickly gains entrance into the lymphatics and/or blood stream by which systemic dissemination occurs. The resulting immunity is effective and usually lifeling. While antibody of the IgA class, when present in mucous secretions, may protect the mucosal cells from infection, clinical disease depends on systemic spread. Because systemic spread generally would be prevented by even low levels of serum antibody, resistance to disease will be lifelong although reinfection may occur. Rubella, chickenpox, and, perhaps, mumps are other important examples of this class of diseases although exhibiting some differences.

The pathogenesis of poliovirus infections is somewhat more complex. The virus usually gains entry via the oropharynx and/or the lower alimentary tract and is shed more copiously from the latter for periods which may exceed 100 days. The virus penetrates the mucosa and localizes initially in the underlying lymphoid tissues (e.g., tonsils and Peyer's patches). Further spread may be by one or both of two paths. Systemic dissemination via the blood probably occurs in all cases and helps insure the abundant antigenic stimulus which results in long-lasting seroimmunity. The motor neurons of the spinal cord and brain stem are the crucial sites of the only significant disease process (that causing paralysis). Fortunately, such central nervous system (CNS) involvement is very rare (1 in 200 to 800 infections). The ususal protective effect of passively transferred serum antibody (demonstrated experimentally in monkeys) suggests that CNS invasion usually is via the blood stream. However, autonomic and olfactory nerve fibers constitute a proven (again in monkeys) alternate path, which would explain the ready induction of paralytic disease following enteric infection in monkeys possessing high titer, homotypic serum neutralizing antibody induced by nonreplicating (Salk-type) vaccine, and also explain the surprisingly large number of cases of paralytic disease in persons with a history of three or more inoculations of Salk vaccine. Natural alimentary tract infection results in substantial but relative resistance to reinfection which depends on antibody of the IgA type present in mucous secretions. Such antibody is induced by inactive poliovaccines only when the vaccines are highly potent. In summary, serum antibody appears to be highly effective in preventing CNS invasion by the blood stream route but affords negligible protection against lower alimentary tract infection. If this occurs, CNS invasion by the nerve fiber pathway remains possible, even though serum antibody is present and the infected host may be a significant source of infection to others.

Influenza viruses, Types A and B, represent agents which may invade the lower respiratory tract where ciliated mucosal cells are the primary sites of localization. Disease results from the destruction of cells lining the tracheobronchial tree and the spread of virus to bronchiolar cells and cells of the alveolar septa. Although viremia is not a prominent feature of infection, viral relication in the nonimmune host is extensive enough to induce major antibody response. However, the effectiveness and durability of postinfection immunity are highly dependent on the degree of antigenic shift by subsequently infecting viruses. Protection of the mucosal cells from infection depends largely on secretory (IgA) antibody. Antibody in serum and tissue fluids (IgA) is believed important in limiting spread of virus from these superficial, primarily infected cells and, as a result, may afford significant protection against disease.

Noninfective Vaccines and Live Viruses

A reasonable goal of vaccine-induced immunoprophylaxis is to achieve a durable, protective immunity against both infection and disease comparable to that which follows natural infection, but with a greatly reduced or negligible risk of disease. Viral vaccines fall into one of two basic types, viz. those which contain nonreplicating antigens and those which contain a viable agent and so immunize by infection. This section will consider the known and potential advantages and disadvantages of each type.

1. *Noninfective vaccines.*—a. *Potency and effectiveness.* To be effective, an immunization schedule using noninfective vaccines must provide an antigenic mass sufficient to elicit an immune response of adequately protective and durable degree. Thus, vaccine potency is the most important criterion for effectiveness. Therefore, the dosage should be established in appropriate clinical trials with selected nonimmune volunteers.

The ultimate measure of vaccine effectiveness is protection against infection and/or disease. This ordinarily is demonstrated directly in small-scale, well-controlled experimental challenge studies and/or in carefully designed field studies during outbreaks which provide a natural challenge. From such studies, or from observations of the effectiveness of naturally-acquired immunity, it is usually possible to determine the type and the relative titer of serum antibody that correlates with protection. If this has been established for a specific agent, the antibody response of vaccinees may afford an acceptable basis for evaluating vaccine effectiveness.

The immunogenicity in man of particular lots of vaccine should be predictable from in vitro assays of specific antigen content and/or from tests for immunogenicity in experimental animals. Immunogenicity for man will, of course, also depend on the size, number, and spacing of vaccine doses (a single dose is the ideal). The need for multiple doses is an obvious public health disadvantage, which possibly might be overcome with the use of adjuvants.

The noninfective vaccines currently licensed are administered parenterally, either subcutaneously or intramuscularly. Possibly because this results in little or no stimulation of secretory antibody, such vaccines afford only relative protection, or no protection, against infection via mucosal portals of entry. Hence, the vaccinee may be protected against disease, but once infected he constitutes a potential source of infection for susceptible contacts. This possibility is lessened if the immunity engendered reduces the amount and/or duration of virus excretion.

The durability of immunity induced by noninfective vaccines can be established by monitoring serum antibody levels in individuals who are not exposed to infection. Generally, in the absence of natural restimulation, such immunity will wane. However, after primary immunization, the host is

specifically conditioned to respond quickly and in high degree to new stimulation. Depending on the length of the incubation period of the disease, this enhanced responsiveness may be sufficiently rapid, when triggered by natural infection, to protect the host against disease.

b. *Possible adverse effects.* These relate to the viral antigen and to the menstrum in which it is contained.

(1) *Viral antigen.* first, there may have been failure to fully inactivate the virus, so that infection and disease may occur, e.g., the so called Cutter episode with Salk poliomyelitis vaccine. (For a discussion of the Cutter episode see Ref. 1) Second, the inactivated antigen may be toxic and cause local and/or systemic reactions, e.g., influenza vaccines. Third, the vaccine may induce hypersensitivity to the viral antigen without inducing protection against infection. As a result, the vaccinee may become susceptible to disease of unusual severity from natural infection with wild-type virus, such as has occurred following immunization with inactivated measles virus vaccine.

(2) *Vaccine menstruum.* Virus for noninfective vaccines is usually propagated in nonhuman cells. The final preparation of viral antigen (vaccine), therefore, may contain host tissue components, trace amounts of antibiotics, small amounts of formalin (or other chemicals) used to inactivate the viral antigen(s), viral components, and killed bacterial contaminants such as endotoxins, etc. although infrequent, sensitization to the host tissue can result in significant disease if the sensitization is organ specific (e.g., sensitization to CNS constituents induced by rabies vaccine). While, in theory, repeated use of a vaccine might induce sensitivity to other nonviral components, the greater hazard relates to reactions elicited in vaccine recipients already sensitive to one or another such component (e.g., antibiotics, traces of substrate, or even formalin). Residual formalin usually causes only slight, transient pain at the site of inoculation. ordinarily, formalin, or other chemical agents will also inactivate microbial contaminants, but this inactivation may not be complete (e.g., SV–40 virus in earlylots of inactivated poliomyelitis vaccine). Bacterial endotoxins pose a particular problem for vaccines produced from egg-grown viruses (e.g., influenza virus) because of the apparent difficulty in avoiding contamination with gram-negative bacteria. If present in sufficient quantity, such endotoxins may cause significant, acute systemic reactions. Menstruum problems concern both noninfective and live virus vaccines, but generally are under better control in the latter.

Although generally considered safer than live virus vaccines, noninfective vaccines are characterized by multiple-dose inoculation schedules, protection against disease but not necessarily infection, relatively short-lived immunity, and an increased likelihood of adverse reactions associated with their administration.

2. *Live virus vaccines.* The basic idea of live virus vaccines is simple but the relevant considerations are numerous and complex. A strain of the virus (or of an antigenically similar agent) must be found or produced, which will induce in man an immunizing infection with an acceptable or negligible risk of disease. Relevant considerations include finding or producing a suitable genetically stable strain of the virus, recognizing its avirulent character, determining the minimal consistently infective dose, demonstrating the effectiveness and durability of the resulting immunity, and establishing both primary safety (for the vaccinee) and secondary safety (for the vaccinee's contacts). These points are considered very briefly in the following presentation along with an abbreviated discussion of issues concerning substrates used for vaccine production.

a. *Origin of candidate attenuated virus strains.* The ability to test candidate strains for possible avirulence requires a suitable animal model (e.g., the monkey for yellow fever virus or poliovirus) or the possibility of using human volunteers (for agents causing disease with minimal risk of serious sequelae). Viruses undergo spontaneous mutation at rates dependent on many factors. The mutations result in virus populations that are heterogeneous with respect to various characteristics including the ability to infect and to cause disease in man. Historically, a variety of approaches have been employed to segregate avirulent strains from viral populations containing wild-type characters. These approaches include the use of isolates from naturally occurring subclinical infections, passage in unnatural animal hosts or in tissue culture systems held at low temperature to provide an environment favoring replication of the avirulent particles or cloning parental populations. Ultimately, it is desirable when possible to produce clones (strains deriving from single virions) which are genetically homogenous (at least originally) and genetically stable, and can be tested for their ability to infect and cause disease.

Testing for avirulence is a major problem in the assessment of live virus vaccines. It is made easier if an appropriate animal model for the disease exists (e.g., the rhesus monkey for yellow fever, poliomyelitis, and measles). Nevertheless, in all instances final testing for avirulence must be conducted with human volunteers. If no animal model exists, the initial testing must be conducted with humans.

Once an acceptable avirulent strain of virus (candidate vaccine strain) is found, the inherent mutability of viruses makes testing the genetic stability of the strain with respect to virulence properties as it is propagated for production of vaccine lots and as it replicates in vaccinees imperative. While further direct testing of ability to cause disease may be necessary, on occasion, this may prove cumbersome and, if human volunteers are necessary, almost prohibitive. This makes comparative studies of avirulent and of wild-type virus strains highly desirable to determine those in vitro characteristics which correlate with virulence or avirulence. When genetic markers which differentiate avirulent from wild-type strains have been identified, examination of new vaccine lots and of viral isolates from vaccinees for these markers may serve as a monitor on the overall genetic stability of the vaccine virus strain. Such monitoring is based on the assumption (not fully justified) that if these markers maintain their character, the avirulence character probably is also unchanged. Changes occurring during replication in the vaccinee are of concern chiefly if spread of the virus to susceptible contacts is possible. Changes which occur as new vaccine lots are produced pose a potential hazard to the vaccinees themselves. The likelihood that genetic reversion will occur can be minimized by use of the "seed lot" system in producing vaccines so that no production lot represents more than three to five passages from an original, thoroughly tested "master seed" (see Recommendations).

b. *Potency and effectiveness.* Since live virus vaccines immunize by inducing infection in the recipient, establishing the minimum dose of vaccine virus required to infect the nonimmune recipient is essential. When this is known, the potency of the vaccine is evaluated simply on the basis of an in vitro assay of its infective titer.

Considerations relating to vaccine effectiveness are essentially similar to those outlined with respect to noninfective vaccine. Maternally derived antibody persisting during the early months of life, may establish an age limit below which vaccination,

particularly by parenteral routes (e.g., measles and rubella) may be less effective at reasonable virus dosage levels. Another important factor is "interference" by which a concurrent infection with a wild virus, or with another vaccine virus, blocks infection with the vaccine virus administered. This has been observed with orally administered poliovirus vaccine and may prove important for possible live respiratory virus vaccines (e.g., influenza).

Experience with current live virus vaccines indicates that excellent and durable immunity against both disease and reinfection can be induced by a candidate vaccine which meets the conditions discussed above. Thus, recipients of a live virus vaccine are effectively removed from the pool of susceptible individuals and ordinarily will play no future role in the spread of the virus within the population.

c. *Consideration of safety.* As discussed in the context of the noninfective vaccines, live virus vaccines contain host cell components, a dose of viable attenuated infective virus, and often a stabilizer. With the exception of smallpox vaccine (vaccinia virus), current live virus vaccines contain very low amounts of host cell proteins. They are presumed, on the basis of current technology, not to contain any known viruses other than the vaccine strain itself (yellow fever vaccine is an exception, and this situation is now being corrected).

(1) *Substrate.* One present concern is with viral contaminants. These may be introduced during the production process or, more likely, may have been present in the cell substrate. This latter possibility is closely related to the origin of such cells and can be reduced (or virtually eliminated) by use of established cell strains (e.g., WI–38 diploid cells of human fetal origin). The established cell strains must be studied for the presence of extraneous agents or must be obtained from cells from animal or egg that are specific pathogen-free. Reliable detection of known viruses is technically possible, although the procedures presently prescribed need to be improved. Since, with the exception of B virus (*Herpesvirus simiae*) from monkeys, the pathogenic potential for man of the recognized indigenous viruses is either not known or believed to be negligible, failure to detect their presence is of unknown importance.

The presence of host cell genetic material and the possible presence of unknown, potentially oncogenic viruses in live virus vaccines poses theoretical risks to vaccine recipients. These risks are best managed by careful monitoring of both the vaccine and its recipients. (However, the problem posed may be more difficult than a quick appraisal suggests. Recognition that a vaccine contains a heretofore unknown viral contaminant of undetermined pathogenicity for man is an epidemiologic problem which will be discussed in a later section.)

Since viruses grow inside cells, the final licensed product actually represents the net product of a particular virus-cell interaction. One poorly understood aspect of this interaction is the influence of the cell on the virulence of the vaccine strains of certain viruses (e.g., poliovirus and rubella). The inability to predict the effect of a particular cell on a given virus property such as reversion rate to neurovirulence (poliovirus) or a side effect such as arthritis (rubella) emphasizes the need for careful clinical trials prior to licensing. Perhaps equally important is the need to support more research into the mechanisms which lead to a loss of undesirable viral properties and to the acquisition of beneficial properties.

(2) *Vaccine virus.* Infection with an attenuated virus may give rise to an attendant immediate effect or to a long-delayed adverse effect. The first concern is with the immediate adverse effects. The frequency and severity of adverse effects in vaccinees are important criteria in determining vaccine acceptability. Also, in view of the immediacy of these reactions their evaluation should be quick and straightforward by means of simply designed clinical trials. The difficulty with such trials lies in size rather than design. To provide assurance that a truly serious outcome will occur in no more than 1 in 10,000 vaccinees would require observation of 100,000 or more individuals. It should also be remembered that the outcome of infection is partly determined by host factors, age in particular. In the nonimmune host, the consequences of infection usually are potentially most important in infancy, least in early childhood, and increasingly important with advancing age thereafter. Thus, if contemplated use of the vaccine includes adults, this age group should be included in the clinical trials. The possible important of pregnancy usually must be deduced from observations on naturally infected pregnant women (and their fetuses). Primary immunologic deficiencies and diseases or therapeutic measures known to impair the normal immune response also are of concern. Once again, evaluation of the part played by immunologic defects hinges on the experience of such deficient patients undergoing a natural infection, or responding to vaccine administered inadvertently.

Shedding by a vaccine recipient of sufficient virus to infect susceptible contacts raises concerns about their risk. As noted previously, an attenuated vaccine virus replicating in the human host may undergo reversion towards the wild type acquiring virulence characteristics. Hence, clinical trials should include studies of two types: (i) analysis of situations (classrooms and/or family units) in which spread to susceptible contacts can be observed and outcome of contact infections evaluated, and (ii) characterization of viral isolates collected from the vaccinees and from infected contacts for evidence of reversion. If contact spread appears to pose a hazard, this should be taken into account in recommendations of vaccine use.

The long delayed adverse effect of a live virus vaccine would depend on a persistent but possibly latent infection. Thus far, no current vaccine virus strain and, with the exception of measles and perhaps rubella, no corresponding wild-type virus has demonstrated such effects. Subacute sclerosing panencephalitis (SSPE), a presumed late and rare consequence of natural measles, is a theoretically possible effect of measles vaccine. (See Generic Reivew of Measles Virus Vaccine and discussion of safety under the summary of this section.)

In summary, live virus vaccines overcome most of the objections raised concerning noninfective vaccines in terms of ease of administration, protection, and durability of protection. However, live virus vaccines are very complex materials genetically and their safe use in man requires careful controls and extensive experience. Under proper conditions, live virus vaccines are safe and effective.

Summary—Live Virus Versus Noninfective Vaccines

1. *Administrative considerations.*—a. *Live virus vaccines.* A single dose ostensibly suffices for parenterally administered vaccine. Except for vaccinia and influenza virus vaccines (when such become available), the need for reimmunization is questionable and probably is required only after a long interval. For orally administered poliovirus vaccine, multiple feedings are recommended to ensure that gastrointestinal infection is established.

b. *Noninfective vaccines.* Primary immunization generally requires a course of two or more doses and maintenance of immunity usually

requires periodic enhancing (booster) innoculations.

2. *Effectiveness and duration of immunity.*—a. *Live virus vaccines.* (1) Measles and yellow fever vaccines give long-lasting (10 or more years) solid immunity against disease and relative protection against subclinical infection.

(2) Oral poliovirus vaccine provides a long-lasting highly effective protection against disease and relative high protection against infection.

(3) Smallpox vaccine provide highly effective protection for a limited period (1 to 3 years).

(4) Rubella and mumps vaccines provide effective protection against disease but the duration of protection has not been established.

b. *Noninfective vaccines.* (1) Inactivated poliomyelitis vaccine is about 95 percent effective against paralytic disease based on experience in the United States, but is relatively ineffective against enteric infection. The duration of immunity is not firmly established. (However, the Swedish vaccine, which seems to be more potent than the early United States vaccine, is apparently effective against infection as well as disease.)

(2) Influenza vaccine is relatively (70 to 80 percent) effective against disease caused by the homologous virus and less effective against subclinical infection. The duration of protection is limited inpart by continuous changes or shifts in the antigenic character of the wild virus.

(3) Rabies vaccine represents a special case. Except in the case of high risk populations (for instance veterinarians) the vaccine is seldom given in the absence of prior exposure.

3. *Safety.*—a. *Live virus vaccines.* Some licensed vaccines cause minor systemic reactions in 5 percent or more of recipients. Vaccinia virus causes true although usually mild disease in 100 percent of successful vaccinations. Serious reactions which are not always clearly caused by the vaccine have been observed in recipients of all live virus vaccines and are extremely infrequent. The best verified instances (and of greatest concern) are those which may follow smallpox and live poliovirus vaccines. Spread of the virus to contacts with subsequent induction of disease has been verified only for polio and vaccinia viruses. Only in the case of early lots of yellow fever vaccine (which contained human serum as a stabilizer) has disease (hepatitis B) caused by a viral contaminant been recognized.

b. *Noninfective vaccines.* The presence of residual live virus has posed a problem only with poliomyelitis vaccine (the Cutter episode; also the presence of SV–40 virus in many lots of vaccine produced between 1955 and 1960). Local and, especially in children, systemic reactions have followed influenza vaccines and have been attributed in part to a toxic effect of the viral antigen. Isolated instances of allergic reactions have been reported in individuals sensitive to egg proteins who received vaccines (influenza and typhus) prepared for egg-grown agents. Vaccine failures, marked by naturally contracted disease, are relatively common despite "adequate" immunization and warrant consideration in relation to vaccine safety.

4. *Contribution to herd immunity.*—a. *Live virus vaccines* make a substantial contribution to herd immunity since successfully vaccinated persons play no future role in spread of the agent.

b. *Noninfective vaccines* make a doubtful or unclearly established contribution. In addition, vaccinees commonly acquire natural infection and often shed enough virus to permit spread to contacts.

The Problem of Subtle and/or Long-Delayed Adverse Effects of Vaccines

In the previous section which considered the adverse effects and safety of vaccines, the possible long-delayed effects were only briefly mentioned. The precise nature of such long-delayed effects is not pertinent to this discussion unless they are identifiable and significant. Indeed, one should be prepared for effects of a completely unforeseen nature. The problem is how to recognize that a relation may exist between administration of a vaccine and instances, perhaps rather isolated, of disease occurring in persons who had received the vaccine at variable but lengthy intervals before the onset of the disease. The value of animal models in the solution of this problem is clearly limited. This problem cannot be solved completely in the abstract and may never be solved in specific instances. Nonetheless, awareness of its existence is important, and approaches to its solution should be developed. It is also important to note that this problem is related to theoretical consequences of vaccination. These consequences are sufficiently tenuous in prospect that when the public health benefits of a given vaccine are under assessment, the risks should not be given undue weight in estimating the benefit/risk ratio of that vaccine.

A basic proposition in epidemiology is that associations consistent with a causal relation are not discovered until the possibility that they exist is recognized. Historically, epidemiologists start with a defined disease and search for its causes. Typically they begin with a case-control (retrospective) study in which "possibly significant experiences" of cases are compared with those of appropriate controls. The decision as to what constitutes "possibly significant experiences" is crucial. The recent "epidemic" of clear-cell adenocarcinomas of the vagina and cervix in adolescent and young adult females is instructive. Someone, either fortuitously or possessing unusual insight, decided to explore the antenatal as well as the postnatal experiences of the patients and the controls. As a result, it was found that diethyl stilbesterol (DES) given to the patients' mothers to counteract threatened abortion was clearly incriminated. The important point is that in future case-control studies of diseases of uncertain etiology, a history of prior immunization (both antenatal and postnatal) must be included in the list of "possibly significant experience."

An opposite but highly relevant approach begins by regarding vaccines as possible causes of diseases yet to be specified. This dictates that vaccine recipients (and some appropriate control group) must be followed indefinitely for the occurrence of significant illnesses. The practical problems of this approach are obvious and, at first glance, so overwhelming that one is tempted to abandon it forthwith. Which recipients? Who would be appropriate controls? How large should the comparison groups be? By what mehcanism and by whom would the follow-up be implemented? Before taking up these questions, we should consider possible patterns of occurrence of vaccine-induced disease and existing or potentially retrievable information on vaccine usage and possibly related disease.

Except for smallpox vaccine, viral and rickettsial vaccines are relatively recent developments, appearing since the late 1930's when yellow fever vaccine was introduced. Since then, new vaccines have been introduced and substantial information exists concerning how much and in what target populations they have been used. Also, much information exists in more or less readily available records concerning both significant morbidity and mortality in the United States population. Finally, large numbers of persons who were vaccinated, and those who were eligible but were not vaccinated, still survived. Conceivably, such survivors can be identified and investigated for disease experience that may have escaped

recording and can be followed for future disease experience. In summary, a large mass of information exists which, although difficult to explore, could greatly hasten recognition of significant, long-delayed adverse effects of specific vaccines.

Assuming that a given vaccine does cause delayed effects, what are possible distinctive features of the vaccine-disease relation? First, a temporal clustering of cases reflecting the incubation period should be evident when disease onsets are plotted on a time axis which begins with date of vaccination. The demonstration of such clustering constitutes a forceful argument for etiologic relationship in the absence of case-control comparison. Related to this, a time plot of numbers of persons vaccinated should rise in parallel with later increasing incidence of the related disease. Next, occurrence of disease may be strongly influenced by one or more host characteristics of which age and perhaps sex are most likely to be important. By analogy with observations in laboratory animals, infants and very young children should be most vulnerable to any oncogenic effects of a vaccine-transmitted virus. Realization that such host factors may operate is clearly important in exploration of the relation between vaccination and vaccine-induced disease.

The Panel's concern and that of FDA, is with determination and establishment of the standards for acceptable safety of vaccines. Hence, beyond trying to educate epidemiologists to include evaluation of immunization histories in case-control studies of disease etiology, a basic approach assumes that vaccines may cause diseases of unforeseen nature after long, but temporarily unknown, incubation periods. The only possible design is a cohort (or prospective) study in which vaccine recipients and comparable controls are monitored over an extended (perhaps indefinite) period. Ideally, provision for such a study should be made in planning and conducting the clinical trials that are required to establish vaccine safety. Volunteers would first be screened to identify susceptibles. Under current practice, the susceptibles are formed into two groups, one to receive vaccine and the other a placebo. For obvious ethical reasons, if the vaccine proves both effective and of acceptable safety, the placebo group must subsequently also be offered the vaccine and, hence can no longer serve or be useful as a long-term control. The revised design would then utilize the volunteers found to have been naturally immune as a third comparison group for prolonged observation. Vaccinated members of the original placebo group would be combined with the original vaccine group for extended observation. If the comparison groups are large enough, such a design would permit detection of the effects of a possible viral contaminant, and also of possible undesirable properties of the vaccine virus acquired through genetic reversion or mutation during propagation in cell cultures.

The necessary size of the comparison groups depends on the estimated rate of loss to followup and how one defines acceptable safety. Presently, acceptance of a new live vaccine virus strain requires that it cause no significant acute disease in a specified large number of susceptible vaccines. Observation of 10,000 vaccine recipients would afford reasonable assurance that, in normal use, no more than one individual in 1,000 would experience a significant serious consequence. The study design suggested above would provide an initial vaccine group of about twice that number but the size of the long-term comparison group would depend on the extent of prevalence of natural immunity. Current regulations for some of the viral vaccines such as rubella require that the manufacturer obtain (and transit to the Bureau of Biologics) identifying information sufficient to permit a followup of 5,000 vaccinees. This design would require such information for all members of the two long-term comparison groups. Since the adequacy of the control group suggested here is open to question with respect to size, and to a possible confounding effect of natural acquisition of immunity in this group (natural infection in some members may give rise to delayed consequences similar to those referable to the vaccine virus strain), it should be recalled that analysis of the experience of the vaccine recipients alone should be revealing, i.e., vaccine-related disease should show clustering in time and the frequency might vary with age and sex. The followup operation is clearly feasible, although admittedly costly. Who should be responsible for it is a political question, but simple logic would suggest FDA or the Center for Disease Control (CDC), both part of the Public Health Service (PHS).

How the foregoing design can be applied to vaccines already licensed is more difficult to determine. One highly unacceptable possibility is to conduct new trials for long-term followup only. More realistically, attempts should be made to identify those persons who received a specific vaccine soon after it was introduced.

For vaccines licensed in recent years, such approaches would include thousands of participants in the original clinical trial who were identified by the manufacturer. Others might be identified from the records of health agency immunization clinics, prepaid medical care plans, etc. Construction of truly appropriate control groups poses such a seemingly insoluble problem that evaluation of the vaccines might have to rest entirely on the experience of the vaccinated individuals. However, at least some control groups are possible. For the reportable diseases, persons who experienced the disease (and presumably had not been vaccinated) might be identified. Aslo, for vaccines used largely during childhood, individuals whose childhood shortly preceded the advent of the vaccine could be identified. Finally, the experience of persons identified as recipients of one vaccine could be compared with that of recipients of other vaccines. Undoubtedly, other possibilities exist, but the main point is that it should be possible, with respect to current vacines, to take advantage of the experience that has accumulated since the vaccines were licensed and thereby hasten the recognition of their possible adverse effects.

Problems Involving Political and Ethical Considerations

The approval and licensure of vaccines, the development of standards for effectiveness and safety, and policies concerning recommended usage of vaccines involve judgments and decisions which are based only in part on scientific knowledge. The following is an examination of some of these problems together with a few notes intended to identify the nature of the pertinent considerations. In none of these problems is vaccine effectiveness the issue, although the degree of effectiveness may be a factor.

1. *The clinical trial to explore safety.* Scientifically, using the established design of double-blind studies with placebo controls, a clinical trial can yield reliable estimates of the risk of serious consequences, of whatever degree, associated with a vaccine. For estimation of very small risks, larger numbers of volunteers are required. The questions at issue are: "What degree of risk is acceptable?" and "How does one define serious consequences?" The answers are obviously influenced by any sequelae associated with the naturally occurring disease and with the risk associated with other available preventive measures. These are value

judgments and cannot (or should not) be made only by scientists. The more difficult question concerns the acceptable degree of risk. The answer to this question determines the required size of the clinical trial.

It was emphasized earlier that host factors, age in particular, may play an important part in response to viral infection. This is particularly relevant to live virus vaccines. Hence, the clinical trial should include individuals of all age groups likely to receive the vaccine. For most vaccines, infants and young children comprise the primary target population. The ethical problem of gaining fully informed consent for such young individuals is well recognized but is emphasized here as a clearly restrictive factor which affects the conduct of adequate trials. An obviously helpful aspect is that, in most cases, the young volunteers would benefit from the immunization.

2. *Benefit/risk ratio.* The ultimate approval of a vaccine hinges heavily on the benefit/risk ratio. This term implies a quantitative formula which, unfortunately, is not attainable with exactitude. However, as a statement, it does carry the important implication that measurable risk is not of itself an adequate reason for disapproval, a decision to be made only after assessment of possible offsetting benefits.

Both benefit and risk can be expressed as quantitative estimates which, however, often are not fully reliable. These can be expressed in terms of individual risk, e.g., vaccination is associated with a possibility of one per million that serious related disease will occur as compared with a lifetime risk of one per thousand that serious natural disease will occur if no vaccine is given. According to these estimates, the odds that an individual will not experience specific serious disease are improved 1,000-fold by vaccination. The problem also can be viewed in terms of an entire population. Using the probabilities suggested above, vaccination of a million young children would eventuate in one case of serious disease whereas without vaccination some 1,000 individuals in this age group would eventually acquire such disease during their lifetime. With the comparative risks as stated, approval would be clearly indicated.

Unfortunately, the problem is seldom so clearly delineated. Often, alternative effective methods of prophylaxis may already be available, e.g., noninfective versus live virus poliomyelitis vaccine. This particular example serves to illustrate a number of other factors that must enter into any assessment. One factor is vaccine cost. The viral antigen content of inactivated poliomyelitis vaccine must be much greater than that of a live virus vaccine, and hence its cost presumably is greater. Another is acceptability; live virus vaccine, because it is taken by mouth rather than via a needle, is much more acceptable, a factor important to extending immunization to the lower socioeconomic segments of the population. Still another factor is the possible benefit to susceptible members of the population who may escape vaccination. Because the killed-virus poliomyelitis vaccine affords little protection against intestinal infection, recipients may continue to participate in the spread of wild poliovirus whereas recipients of live virus vaccine become highly resistant to infection and usually play no further role in viral spread. Thus, extensive use of live virus vaccine reduces the probabilities that unvaccinated susceptibles will be infected with wild virus.

In the above discussion, "serious consequences" were not defined. If these include possible lethal outcome, they take on additional weight and especially so in the case of a vaccine used against a rarely lethal disease. This latter situation has not yet been encountered. However, in this connection, concerns have been expressed about potential oncogenic effects due to presence in the vaccine of unknown viral contaminants, or to genetic fragments of oncogenic viruses somehow incorporated into the genome of the vaccine virus. As suggested previously, such a theoretical risk should carry little or no weight in estimating the benefit-risk ratio when, on practical grounds, the ratio is highly favorable. Nevertheless, even the theoretical possibility of such risk makes it mandatory to maintain a continuing surveillance to detect the postulated effects and to reevaluate the benefits against the risk if such effects are recognized.

Another major consideration is economic, which for lack of adequate data often is ignored. These data would contrast the cost of a vaccine and its administration plus the costs (medical care, rehabilitation, impairment of ability to earn income) of vaccine-related disease with costs of a similar nature that would have accrued from cases of the natural disease. For an "acceptably safe" and effective vaccine against a serious disease, again the ratio should be highly favorable. However, if the preventable disease occurs chiefly in young children and is infrequently associated with permanent sequelae, a different answer might result. The question then might become "how much cost can be justified to prevent one crippling or lethal case of disease?" This clearly requires a societal rather than a scientific judgment.

3. *Recommendations for vaccine usage.* Vaccines necessarily are administered to individuals under the direction of a physician as part of a program for protection of the recipient as an individual, or as part of a publicly sponsored or encouraged program directed toward control of the specific disease. In their use of vaccines, physicians are guided by "official" recommendations which typically indicate who should be immunized, the circumstances requiring or justifying immunization, any specific precautions that should be observed, and absolute or relative contraindications to vaccination. Inattention to precautions and contraindications may constitute medical malpractice although the decision to vaccinate is otherwise basically left to the physicians' judgment.

While vaccination must afford benefit to the recipient, it is also usually a matter of public concern. At the least, the illness prevented obviates loss of time from school or work and lessens by one case the need for medical services and facilities. For vaccines which protect effectively against infection as well as disease, extensive vaccination makes contact spread more difficult. Thus, the risk of disease is reduced for any remaining unvaccinated susceptibles. If the vaccination program is sufficiently extensive and sustained, eradication of the wild-type virus from increasingly large geographic areas may be an attainable goal.

The Federal government has accepted responsibility, implemented by the PHS Advisory Committee on Immunization Practices (ACIP), for the development and promulgation of recommendations on vaccine use. An additional advisory group, theoretically independent but in practice closely coordinated with ACIP, is the Committee on Infectious Diseases of the American Academy of Pediatrics whose parallel recommendations, largely focused on pediatric use of vaccines, appear in its periodic report (known as the "Red Book"). The published recommendations reflect public policy and serve as a guide to the use of vaccines in populations as well as in individual cases. Exampls are the efforts to increase the use of measles and poliomyelitis vaccines to achieve virtual eradication of the wild agents, and to concentrate on prepubertal children as recipients of rubella vaccine

to reduce the chance that susceptible women will be infected during pregnancy.

The FDA through the Bureau of Biologics is charged with approval and licensure of vaccines and regulation of their production, packaging, advertising, and release. The packaging aspect covers the inserts which contain recommendations on use, statements of risk, etc. Inevitably, decisions concerning approval also involve consideration of how a vaccine will be used. On this point, there is some overlap in attitude and philosophy with ACIP, but there is no question that the matters of safety and effectiveness are, by law, the responsibility of the Bureau of Biologics. Since both factors are potentially influenced by how the vaccines are used, the Bureau of Biologics also should be basically responsible for promulgating vaccine usage recommendations. In view of the present commendable collaboration between CDC (and its ACIP appendage) and the Bureau of Biologics, the question might appear to be academic, but it is nonetheless an important political question which should be further considered.

4. *Public liability for adverse effects of vaccines.* The intent of this section is to state briefly a very real problem which needs urgent resolution. Through FDA, the Federal government assumes responsibility for the effectiveness and safety of licensed vaccines. Through CDC, the government also has accepted responsibility for recommending how vaccines should be used. These responsibilities as noted above, reflect the major public interest served by vaccines; hence, the continued availability of vaccines is also a major public concern, and one which is now being threatened.

It is not possible to produce an effective vaccine that is absolutely and infallibly safe. Hence, an occasional recipient will suffer significant injury and, in at least some instances, unrelated disease when it coincides with vaccination will be (and has been) attributed to the vaccine. There is little argument but that persons truly injured by a vaccine should receive fair monetary compensation. However, under present circumstances they seek redress from the manufacturer and from the administering physician or nurse who have been held liable in the courts when adverse effects are judged due to a vaccine, even when it has been produced and administered in strict compliance with existing standards and regulations. The resulting judgments are causing such financial loss to the manufacturers that some at least are abandoning vaccine production, and others are said to be considering it. Indeed, for these reasons the continued availability of poliovirus vaccine is in serious jeopardy.

The obvious solution to this problem requires legislation. Victims of established adverse effects of vaccines which have been produced and released in full compliance with Federal regulations should be compensated adequately by the Federal government. Concomitantly, the manufacturer of the vaccine, assuming no culpability on its part, should be held free of liability. The laws enacted in Denmark and the Federal Republic of Germany provide for compensation from public funds to persons suffering damage consequent upon vaccinations that are recommended to the public by the competent authorities. In both countries, a reasonable probability of the causal relationship between the immunization and the injury is regarded as sufficient basis for payment of damages. In Germany, damages are paid as a pension, and this is the case also in Denmark provided that the disablement is 50 percent or more. If the disablement is less than 50 percent, damages are usually paid as a capital sum. Children, however, receive their compensation only after they have reached an age of 15 years. Below this age, financial aid can be obtained from public funds under the general social laws.

Reference

(1) Nathanson, N. and A. D. Langmuir, "The Cutter Incident," *American Journal of Hygiene*, 78:16–81, 1964.

Generic Review of Poliomyelitis Vaccine

Background

Poliomyelitis emerged in the late 1800's as a disease of significance in temperate zones. Its viral etiology was established in 1909 and the existence of three antigenically distinct serotypes was recognized in 1949. The work of Enders and his colleagues, beginning in 1949, demonstrated that polioviruses could be propagated in tissue and cell culture with easily discernible cytopathic effects. This landmark discovery opened the door to major studies which led to nearly complete epidemiologic understanding of the disease, basically because cell cultures replaced monkeys (1 tube culture = 1 monkey) for virus isolation attempts and for assay of neutralizing antibodies. More important, for present purposes, the discovery made possible the development and production of effective vaccines, first the inactivated virus type (inactivated poliomyelitis vaccine (IPV)) licensed in this country in 1955 and then the live attenuated virus vaccine for oral use (oral poliomyelitis vaccine (OPV)) licensed in 1961.

The situation in the United States immediately preceding and following the introduction of these vaccines for general use is summarized in Figures 1 and 2.

As shown in Figure 1, the reported incidence of poliomyelitis rose consistently from 1941 to an apparent peak in 1953 when nationwide attack rates reached nearly 23 per 100,000 for paralytic disease and 37 per 100,000 for all forms. The effectiveness of IPV is reflected in the dramatic decline in incidence of the disease after 1955. With the virtual replacement of IPV by OPV in 1962, incidence further decreased to the point where rates are no longer meaningful. The total number of paralytic cases in 1971, 1972, 1973, 1974, 1975, and 1976 was only 17, 29, 7, 4, 5, and 8, respectively.

The overall pattern of usage of vacines is reflected in Table 3 and Figure 2A.

The chief points of interest are: (1) from 1964 on, the distribution of IPV declined dramatically, reaching the point where it is now obtainable only with difficulty, although still licensed; (2) reflecting its use in large community-wide programs, monovalent OPV (MOPV) was most extensively distributed in 1962 to 1964; and (3) since 1966, trivalent OPV (TOPV) has virtually replaced MOPV. The reasons for these changes are fairly obvious. OPV is easier to administer than IPV is more acceptable, and the resulting immunity is more like that following natural infection, i.e., it is longer lasting and provides greater resistance to alimentary infection. MOPV represents three separate oral vaccines, thus making maintenance of stocks and keeping of records more difficult than with the single product represented by TOPV.

The most important remaining aspect of vaccine use is identification of the population segments which are not vaccinated. Even though OPV is readily more accepted than IPV, the problem remains a significant one.

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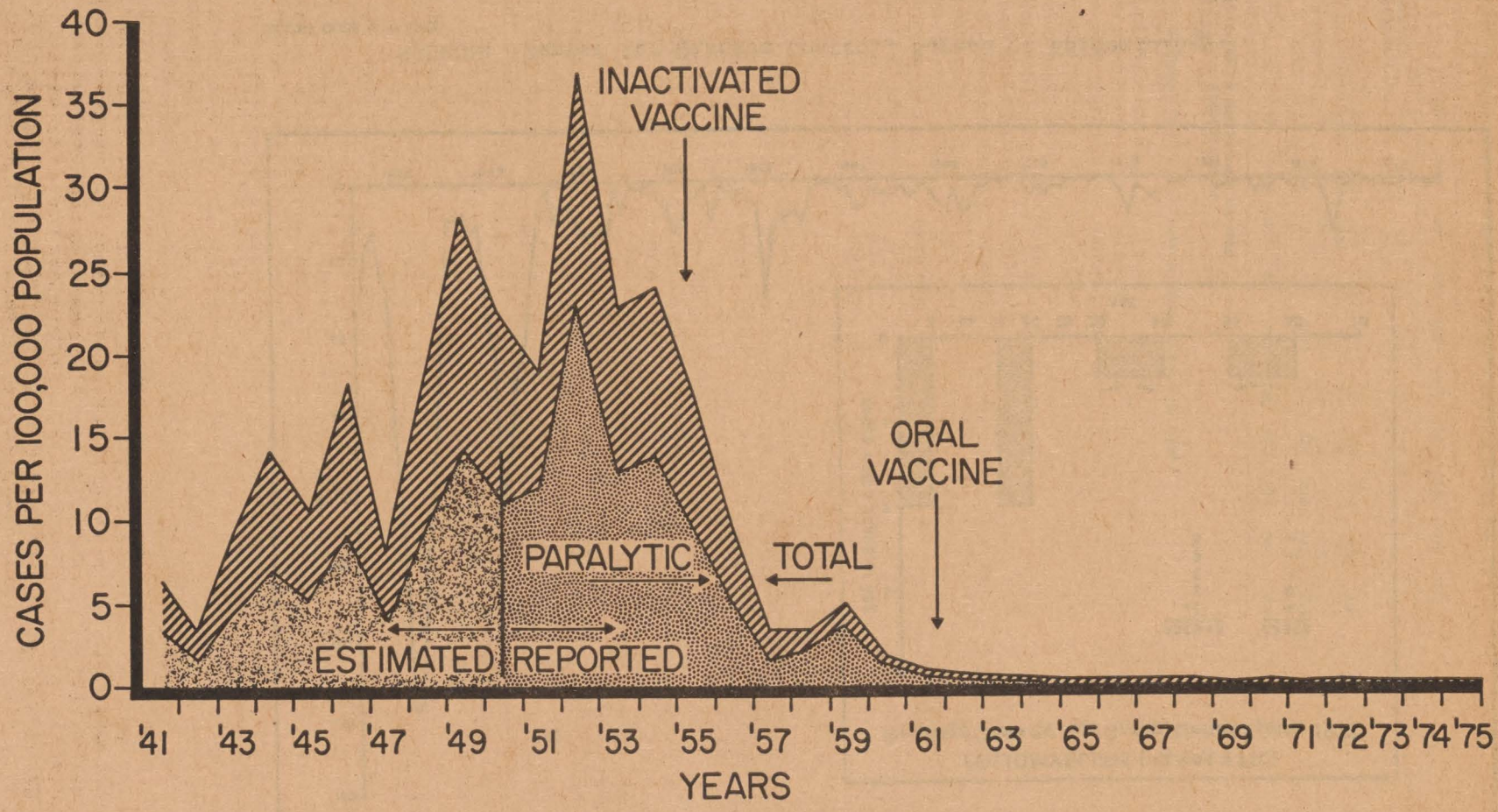
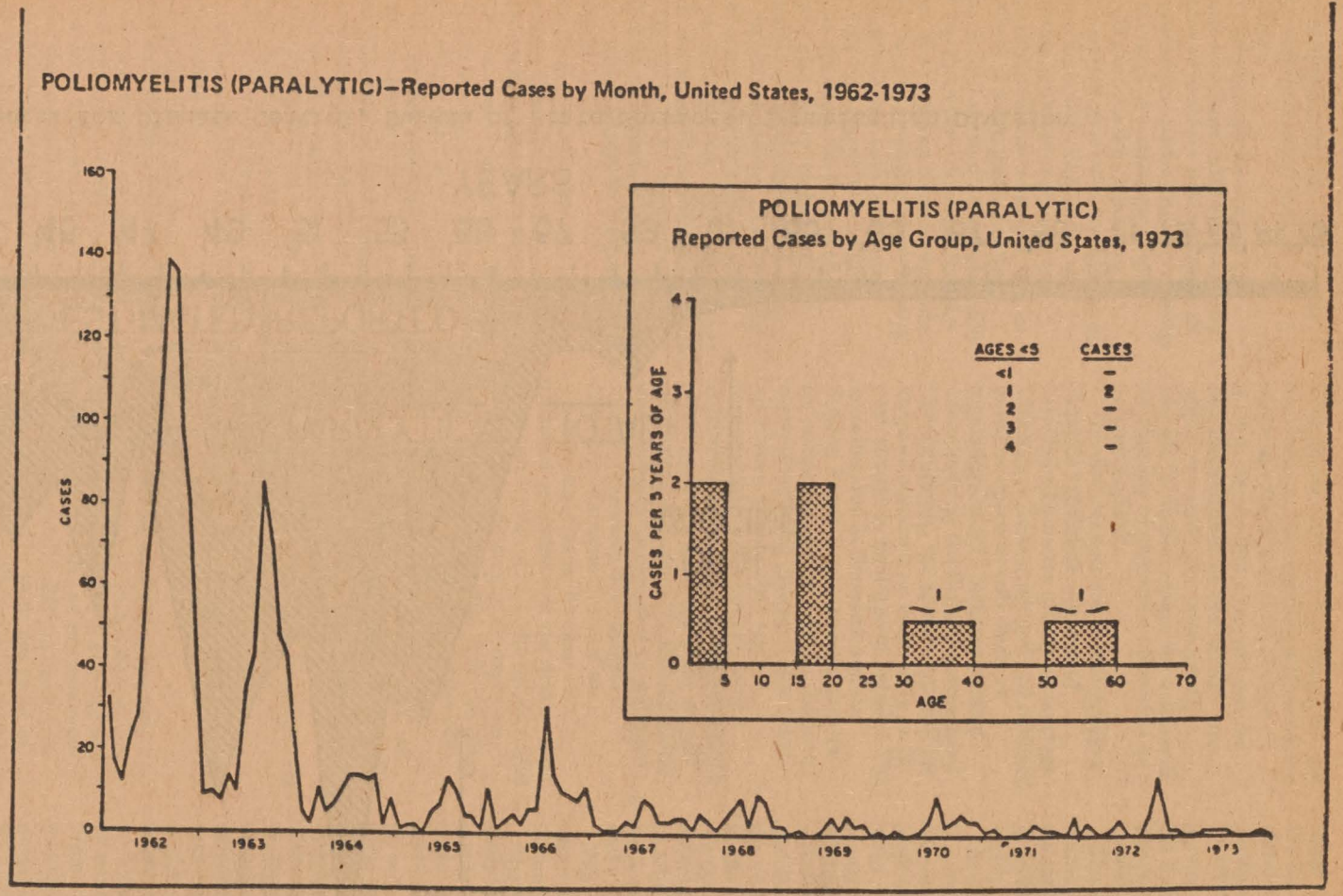
Figure 1

ANNUAL POLIOMYELITIS INCIDENCE RATES UNITED STATES, 1941-1975



Source: Center for Disease Control, Bureau of State Services, Immunization Division

FIGURE 2



SOURCE: Center for Disease Control, Bureau of Epidemiology.

BILLING CODE 4110-03-C

Table 3.—*Poliomyelitis Vaccine Distribution, Net Doses (Millions) by Year, United States, 1962–71*

	1962[1]	1963	1964	1965	1966	1967	1968	1969	1970	1971
Inactivated poliomyelitis vaccine (IPV)	15.3	19.0	8.8	7.5	5.5	4.0	2.7	[2]	.....	.....
Oral poliomyelitis vaccine, live (OPV):										
Monovalent (MOPV):										
Type 1	33.1	38.7	24.9	4.7	1.4	1.3	0.5	0.4	0.3	0.2
Type 2	37.0	34.2	29.8	3.4	1.3	0.9	0.5	0.4	0.2	0.1
Type 3	13.7	54.2	26.4	3.7	1.4	1.0	0.6	0.4	0.3	0.2
Trivalent (TOPV)	.....	[3]4.2	24.0	17.4	24.0	18.0	23.9	22.5	25.8	25.5
Total	99.1	150.3	115.9	36.7	33.6	25.2	28.2	23.7	26.6	25.9

[1] July-December (biologics surveillance program began July 1962).
[2] Not shown since fewer than three distributors reported.
[3] Production began in Mid-1962.

Source: "Immunization Against Disease—1972," page 37, Center for Disease Control, PHS, DHEW.

BILLING CODE 4110-03-M

Figure 2A

Net Doses of Trivalent Polio Vaccine Distributed United States-1964-1975

Source: Biologics Surveillance Program

Source: Center for Disease Control, Bureau of State Services, Immunization Division

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In central city populations during 1974, 13.1 percent of children between the ages of 1 to 4 and 9.9 percent of children between the ages of 5 to 9 had never received any type of polio vaccination (Ref. 16).

The 1977 recommendations of the Public Health Service Advisory Committee on Immunization Practices (ACIP) are as follows (Ref. 1):

Rationale for Choice of Vaccine. Although IPV and TOPV are both effective in preventing poliomyelitis, when the benefits and risks for the population as a whole are balanced, TOPV is the vaccine of choice for primary vaccination of children in the United States. The choice of TOPV as the principal polio vaccine in the United States has also been made by the Committee on Infectious Diseases of the American Academy of Pediatrics (1) and a special expert committee of the Institute of Medicine, National Academy of Sciences (2). This is because TOPV establishes intestinal immunity to reinfection, is simple to administer, is well accepted by patients, does not require periodic booster doses, and has a record of having essentially eliminated disease associated with wild polioviruses in this country.

Some countries successfully use IPV, either wholly or in part, to control poliomyelitis. However, because of many differences between them and the United States, particularly with respect to risks of exposure to wild polioviruses and the ability to achieve and maintain very high vaccination rates in the population, their experiences with IPV are not directly applicable here. It is seriously doubted, in fact, based on current achievements in the United States with other injectable antigens, that a sufficient number of persons would regularly be given primary and booster vaccination with IPV to sustain the general level of poliomyelitis protection in the community needed to prevent recurrence of outbreaks.

When considering the immunization of specific individuals, there are occassions when TOPV and IPV are viewed as being alternatives, or when either TOPV or IPV is the specific vaccine of choice, or when both TOPV and IPV may be useful. Prospective vaccinees or their parents should be made aware of the polio vaccines available and the reasons why recommendations are made for giving specific vaccines at particular ages and under certain circumstances. Furthermore, the benefits and risks of the vaccines for individuals and the community should be stated so that vaccination is carried out among persons who are fully informed.

TOPV. Primary immunization. Infants, children, and adolescents through age 18 years: The primary series is 3 doses. The first 2 doses should be given not less than 6 and preferably 8 weeks apart. The third dose should follow in 8–12 months. For infants, the first dose is commonly given at the same time as the first dose of DTP, at 6–12 weeks of age. For older children and adolescents, the third dose may be given as early as 6 weeks after the second if circumstances do not permit the optimal 8–12 month interval.

Adults: Routine polio vaccination of adults residing in the continental United States is not necessary. This is because most adults are already immune, because the risk of exposure to poliomyelitis is generally very small, and because there may be a slightly greater risk of vaccine-associated paralysis among adults than among children receiving TOPV. However, a susceptible adult at increased risk of exposure to infection by virtue of travel to an area where poliomyelitis is common should complete primary immunization with either IPV or TOPV. The schedules are the same as for other age groups.

Supplementary Doses. Entering school: On entering kindergarten or first grade, all children who completed the primary series of TOPV in early childhood should be given a single dose of TOPV. This additional dose will assure immunity to all 3 poliovirus types in the event the original primary series failed to do so. All other children should complete the primary series.

Preadolescent vaccination: A special expert committee of the Institute of Medicine, National Academy of Sciences, reviewing poliomyelitis immunization proposed giving a single dose of TOPV (or completing a full series if required) to children (about 11–12 years old) entering seventh grade. In the committee's view, this supplementary dose could help to assure solid immunity among young adult parents who if susceptible might contract vaccine-associated polio through household contact with infant or childhood vaccinees. The Advisory Committee on Immunization Practices (ACIP) considers the available serologic data to be an insufficient basis on which to recommend routine revaccination of this particular age group. However, the preadolescent years are a good time to evaluate polio immunity and to complete vaccination of those who are inadequately protected. If serologic evidence indicates the value of more generalized revaccination at this time, such an effort could be useful.

Increased risk: Anyone who has completed the primary TOPV series in the past should be given a single additional dose of TOPV when there is a substantial risk of exposure to poliomyelitis, as in traveling. The actual need for this supplementary dose has not been established, but there is value in assuring protection against infection with wild polioviruses when exposure can reasonably be expected.

Pregnancy: Pregnancy is neither an indication for vaccination against poliomyelitis nor a contraindication when protection is needed, as during an epidemic. There is no evidence to suggest that a pregnant woman or her fetus is at greater risk from TOPV than are other persons. (See also, General Recommendations on Immunization, in MMWR 25(44), 1976.)

TOPV-Associated Risk. As indicated above, administration of oral polio vaccines has been associated temporally with paralysis in healthy recipients and their contacts. Other than efforts to identify persons with immune deficiency conditions, no currently available screening procedures can identify those persons likely to experience such an adverse reaction. Although the risk of vaccine-associated paralysis is extremely small for vaccinees and their susceptible family and other close personal contacts, they should be informed of this risk. When the attenuated vaccine strains are to be introduced into a household with adults who have never been vaccinated, some physicians may choose to give these adults at least 2 doses of IPV a month apart, if not the full primary series, before the children receive TOPV. (Vaccination of the children should be assured and not unnecessarily delayed by this process.)

Contraindications. Immune deficiency diseases and altered immune states: Patients with immune deficiency diseases, such as combined immuno-deficiency, hypogammaglobulinemia, and agammaglobulinemia, should not be given TOPV because of their significantly increased risk of vaccine-associated disease.

Furthermore, patients with altered immune states such as those occurring in leukemia, lymphoma, or generalized malignancy or by lowered resistance from therapy with corticosteroids, alkylating drugs, antimetabolites, or radiation should not be given TOPV because replication of the vaccine viruses theoretically might be potentiated. When possible, all patients with altered immunity should avoid close, household-type contact with recipients of TOPV for at least 2–3 weeks after vaccination. IPV may be the preferable vaccine for immunizing all persons in this setting. (See also: IPV-Other Uses.)

IPV. Primary Immunization. All ages: Four doses should be given; volume and route of injection are specified by the manufacturer. Of these, 3 doses should be given at approximately 1-to 2-month intervals, and the fourth, 6–12 months after the third. This schedule should be integrated with DTP vaccination begining at 6–12 weeks of age.

Booster doses. A booster dose every 2–3 years has generally been recommended to sustain optimal levels of antibody. It should be noted that this recommendation was developed when the IPV in use was less potent than that available today. As experience is gained with newer IPV products, the recommended interval between booster doses will probable be increased.

The need for IPV boosters could be obviated by supplementing IPV vaccination with primary vaccination with TOPV. In this regard, individuals at particular risk of exposure to poliomyelitis who have received 3 or more doses of IPV should be given at least 1 dose of TOPV, preferably the full primary series.

Other Uses. Children or adults with immune deficiency diseases or altered immune states who are at risk of exposure to poliomyelitis should be vaccinated with IPV. Their antibody responses cannot be assured, but they may derive some protection from vaccination.

Physicians may elect to give a primary series of IPV or, when constrained by time, at least 2 doses 1 month apart to adults who have never been vaccinated ahd who: (1) by reason of travel are at risk of exposure to poliomyelitis or (2) are likely to come in contact with vaccine virus following routine immunization of their children. Less than full

primary immmunization should be supplemented later with the additionally recommended doses.

Precautions. Since IPV contains trace amounts of streptomycin and neomycin, there is a possibility of hypersensitivity reactions in individuals sensitive to these antibiotics.

IPV-Associated Risk. No serious side effects of IPV have been reported.

Case Investigation and Epidemic Control.

The occurrence of a single case of polio should prompt an immediate epidemiologic investigation, including an active search for other cases. if evidence implicates wildpolio virus, a vaccination plan designed to contain spread should be developed. Within an epidemic area, TOPV should be provided for all persons over 6 weeks of age who have not been completely immunized or whose immunization status is unknown.

References

(1) Committe on Infectious Diseases, American Academy of Pediatrics, "Poliovirus Immunization Reexamined," *News and comment*, 27(12 Supp.), 1976.

(2) Nightingale, E., "Recommendations for a National Policy on Poliomyelitis Vaccination," *New England Journal of Medicine*, 297: 249–253, 1977.

A number of aspects of the Food and Drug regulations for manufacture of poliomyelitis vaccine warrant comment, in part to emphasize their importance and in part to raise questions regarding possible revisions.

1. *Poliomyelitis Vaccine, Inactivated (IPV).*—a. *Virus strains.* A manufacturer may employ any virus strain which will give a vaccine that meets the established criteria for safety and potency, but the use of any specific strain may be prohibited whenever the Commissioner "finds that it is practicable to use another strain of the same type that is potentially less pathogenic to man and that will produce a vaccine of at least equivalent safety and potency" (21 CFR 630.1(b)).

The IPV manufactured in this country contains the same strains of Type 2 (MEF–1) and Type 3 (Saukett) polioviruses that were first employed by Salk, and all manufacturers but one have included antigen derived from the Mahoney strain of Type 1 virus, which is highly neurovirulent for monkeys. This manufacturer has, for reasons not indicated in his submission, used the Parker strain of Type 1 virus. The British turned to the Brunenders Type 1 strain after an episode of vaccine-associated disease which involved persistent lived Type 1 Mahoney strain virus. While important changes in the procedures mandated by the regulations make occurrence of similar episodes very unlikely, it would seem reasonable to consider the use of existing known attenuated strains for any IPV that is produced in the future.

b. *Safety.* The regulations reflect concern with both the occurrence of extraneous agents and the persistence of active (live) polioviruses.

(1) *Extraneous microbial agents.* In addition to requirements for testing the "inactivated" monovalent virus pools and the trivalent vaccine for lymphocytic choriomeningitis virus and SV–40, the regulations specify testing each virus harvest or monovalent virus pool, prior to inactivation, for the presence of *Mycobacterium tuberculosis*, B virus (*Herpesvirus simiae*), and SV–40. Fluids from control vessels (uninoculated cultures representing the tissue from which the virus was prepared) may be tested in place of the virus sample.

The Panel recommends that, as well as the tests prescribed on the vaccine itself, the regulations require more extensive testing of control cell cultures, e.g., appropriate observation of control vessels and examination of the control vessel fluids by the most sensitive available methods, on order to exclude the agents named as well as others that might be present in monkey kidney cells (MKC).

(2) *Residual active polioviruses.* The regulations in their present form reflect lessons learned from the earlier episode of vaccine-associated disease. Because of their implications for other products, some of these lessons warrant restatement here.

One is that man, the intended recipient of the "inactivated" product, is a highly sensitive detector of minute amounts of live virus and may well be more sensitive than the available laboratory test systems. In recognition of this, much more stringent tests for active virus were mandated. These included the testing in cell cultures of two sizable and properly timed (see below) samples of each monovalent pool and of the final product in a large number (20) of monkeys. In the latter test, the animals were inoculated by combined intracerebral, intraspinal, and intramuscular routes; in addition, they were given cortisone to enhance susceptibility, and an irritant (procaine penicillin) was injected into the muscle of one limb to simulate the provoking effect seen in man.

A second lesson (enunciated especially clearly by Gard (Ref. 2) is that the curve of viral inactivation becomes asymptotic as the extinction limit is approached and is not a straight line. This makes it impossible to predict precisely from an inactivation curve the time when all the virus will have become inactive. Thus, in addition to tests conducted during the inactivation process (to determine the rate), it is required that two samples (mentioned above) be taken after the estimated baseline time (when 1 milliliter (ml) should contain no more than 1 $TCID_{50}$), the second of which must be taken at least 3 days after the first.

Finally, it was recognized that, when the amount of virus present is exceedingly small, attempts to detect it in any given instance may be unsuccessful. Therefore, occasional vaccine lots which do contain active virus may appear satisfactory because of false negative tests. To insure that the basic procedures routinely employed by a manufacturer do result in complete inactivation (and thus safe lots of vaccine), the rule of consistency was introduced. No lot shall be released unless (1) it is one of five consecutive lots produced by the same manufacturing process, all of which were virus negative and (2) each of the monovalent pools included in the vaccine is similarly one of a series of five consecurive virus-negative monovalent pools of the same virus type.

c. *Potency.* The concept underlying the current potency standard is valid. Vaccine potency is judged on the basis of the titers of antibody elicited in monkeys using a standard multidose regimen reasonably analogous to that recommended for man. Such titers are expressed as the relation of the geometric mean titer (GMT) values (for 10 monkeys) to the titers determined in the same test of reference antisera for each type. A satisfactory vaccine must induce titers which equal or surpass prescribed multiples (different for each type) of the titers of the reference sera. The tests are performed after the final processing, including addition of any preservative (but excluding any adjuvant), with samples from the bulk lots. Dating of vaccine is based on potency tests by the manufacturer on vaccine stored in final packages. This guards against loss of antigen by adsorption to glass container walls, as occurred in the early period of licensure.

Historically, the IPV available prior to the Cutter incident and presumably that used during the Francis trials of the Salk Vaccine, were generally more potent than that produced after 1955, when a requirement for filtration prior to inactivation was imposed. Furthermore, in the post-1955 period, vaccines were acceptable if they induced antibody levels which were two-thirds or more of

the prescribed levels of the reference sera. The regulations governing poliovirus vaccines which were implemented in 1968 required that the concentration of each viral immunotype in the vaccine be increased. However, it is not known how the potency of the one IPV now available (Connaught) compares with that of the vaccine produced in Sweden.

2. *Poliovirus Vaccine, Live, Oral (OPV)*

a. *Virus strains.* The regulations specify criteria for what constitutes acceptable strains and seed virus rather than requiring that only designated strains be used.

The initial crucial criterion for acceptance of an original strain was the demonstration that it be "free of harmful effect upon administration in the recommended dosage to at least 100,000 people susceptible to poliomyelitis, under circumstances where adequate epidemiologic surveillance of neurological illness has been maintained." The present regulations require testing in 1 million subjects for acceptability of new strains (21 CFR 630.10(b)(2)). An accepted set of these strains currently exists with which extensive experience has been gained in this country (as well as elsewhere).

Provision is made for possible replacement of strains, inasmuch as the Commissioner may "prohibit the use of a specified strain whenever he finds it practicable to use another strain of the same type which is potentially less pathogenic for man, and that it will produce a vaccine of greater safety and of at least equivalent potency" (21 CFR 630.10(b)(6)). From a practical viewpoint, assuming that any new candidate strain would have to satisfy the criterion of "one million susceptibles" (21 CFR 630.10(b)(2)), this provision is not very meaningful since nowhere could such a trial be conducted today.

Two properties of the poliovirus vaccine strains are important with respect to safety for man, viz., the neurovirulence for monkeys of the strain per se and the genetic stability of the virus during its replication in the gut of recipients. Although each of the accepted strains displays a satisfactory and comparable low degree of neurovirulence when tested directly in monkeys, experience in the United States with presumed vaccine-associated disease in recipients and contacts of recipients of vaccines prepared since 1961 from these strains suggests that the genetic stability of the respective types is not the same. It is recommended that the problem of genetic stability be critically evaluated and that some thought be given to a more realistic approach to the replacement of the less stable strains. It is suggested that for a strain with an acceptable degree of monkey neurovirulence and, as seen from limited clinical trials in man, more stable "virulence" markers and an equivalent or superior immunogenicity, allowance might be made for authorized (licensed) use of this strain to provisionally replace the current strain. Such authorization should be coupled with a careful monitoring program designed jointly by the Bureau of Biologics and CDC.

The regulations concerning criteria for a seed virus prescribe rigorous scrutiny of monkey neurovirulence and include rescrutiny when a new production seed lot is introduced or when there is evidence of a change in neurovirulence of the production virus.

Provision is made for FDA to supply reference viruses to be used by the manufacturers to control potency (virus titer) and monkey neurovirulence of vaccines. Trivalent and monovalent vaccine lots of all three types are to be compared for potency with reference virus preparations of the corresponding types but, for monkey neurovirulence, the single yardstick is Reference Attenuated Poliovirus, Type 1.

b. *Vaccine production.* The seed lot system is formalized in the provision that virus in the final product may represent no more than five cell culture passages from the original strain, each such passage material having met the criteria established for seed viruses.

The original regulations specified that cultures of kidney cells from only Macaca or Ceropithecus monkeys may be used as the substrate for virus propagation and included generally appropriate and reasonably adequate precautions concerning the selection of monkeys and freedom of the cultures from adventitious microbial agents.

In October 1971, the regulations (21 CFR 631.10(a)) were amended to permit use of human cell cultures as the substrate. This general question is dealt with separately but the stated requirements are of interest. In particular are the requirements that the cell line be capable of producing a vaccine which, by experience in at least 10,000 persons, has been found safe and antigenic; that at least 5,000 of these vaccinees must reside in areas where health-related statistics are regularly compiled by appropriate procedures; and that data adequate to identify the vaccinees be filed with the Bureau of Biologics. The latter requirement is presumably to facilitate uncovering any possible relationship of long-delayed adverse effects to the fact of vaccination.

Provision for long-term followup is a very commendable requirement. However, to date it has not been possible to develop a feasible and economically realistic mechanism for carrying out such a followup. In addition, the specified number is small and would reasonably assure detection of adverse effects with a true incidence of only 1 or more per 1,000. Ideally, for a product that is to be given to millions of individuals, we should be concerned with frequencies at least as low as 1 in 100,000.

c. *Safety and potency.* The basic test for potency is viral infectivity titer and the $TCID_{50}$ content of one dose of vaccine is specified for both MOPV and TOPV. The latter includes different amounts of each viral immunotype.

The regulations prescribed reasonable and generally appropriate measures to exclude unwanted microbial agents (except perhaps Type C RNA containing retroviruses) that might be in the substrate initially or might be acquired by contamination during manufacture. Obviously, these measures should be updated as new technology develops.

Perhaps a more crucial problem has to do with assurances of the safety of the vaccine virus strains themselves which, by selection and mutation, might change character during replication. This problem is dealt with in two ways. Less difficult to interpret is the required test for in vitro genetic markers associated with virulence. These markers should include the rct/40 marker and at least one other. While such markers are in no sense measures of virulence, they do help to identify the strains. The more difficult requirement is the test for monkey neurovirulence. This involves separate groups of monkeys inoculated intrathalamically and intraspinally with each monovalent vaccine lot. The monkeys are observed clinically for paralysis and histopathologically for the qualitative and quantitative presence of poliomyelitis-like lesions, i.e., the grade of severity and degree of dissemination. Observations are compared with similar observations of monkeys inoculated with the Reference Attenuated Poliovirus. A lot is acceptable "if a comparative analysis of the test results demonstrate that the neurovirulence of the test virus pool does not exceed that of the Reference Attenuated Poliovirus" (21 CFR 630.16(b)(1)(iii)).

The verdict of Judge Newcomer (*Griffin* v. *United States*, U.S. Court of Appeals for the Third Circuit, No. 73-1326) makes it clear that an appropriate statistical definition of the phrase "does

not exceed" must be incorporated in the criterion.

We note, however, that the regulations include the principle of consistency in the requirement that each monovalent pool must be one of a series of at least five successive pools that pass the monkey neurovirulence test. When an adequate statistical definition is developed, for example, one with 95 percent confidence limits, it can be expected that 5 percent of the vaccines will fail the test. Therefore, it will be necessary to reevaluate the consistency requirement and redefine it so that it continues to assure vaccine safety without seriously affecting the continuous availability of the product.

Analysis

1. *Efficacy.* The purpose of both IPV and OPV is to prevent the paralytic consequences of infection with polioviruses. Only IPV has been the subject of a rigorously controlled field trial which not only affirmed its relative effectiveness (see below) but established beyond question the protective significance of specific neutralizing antibody. Thus, for checking on the efficacy of specific products, and even of OPV generically, the ability to raise antibody became a valid criterion of efficacy. Additional criteria include the duration of immunity, apparent alteration of epidemiologic patterns, resistance to infection, and the related ability to contribute to development of herd immunity with a possible goal of eradicating wild-type polioviruses from large areas. The generic evidence for efficacy is summarized below.

a. *IPV.* While poliomyelitis vaccine may be regarded as a generic product, there have been changes in the product with time, largely towards higher potency, so that generic experience may not be completely relevant to current products, i.e., it may understate the case. The 1954 Francis trial established that inactivated polio vaccine (IPV) as produced by several manufacturers was relatively effective (90 percent) in preventing paralytic disease. Continued monitoring by CDC of vaccine usage and the vaccination status of reported cases indicate that reasonable protective effectiveness was being maintained. Data for 1959 indicate effectiveness (percent) by age and number of doses of vaccine (Table 3A).

Table 3A.—*Percent Effectiveness*

Age in years	3 doses	4 or more doses
0–4	91	96
5–14	93	96
15–39	82	86
Total	91	95

Nonetheless, in 1959 there were 3,401 reported cases of paralytic disease, of which 750 (14.2 percent) had received three doses of vaccine and 177 (3.4 percent) had been given four or more doses. Failure of high titer homotypic antibody induced by Salk vaccine to prevent paralytic disease in orally infected cynomolgous monkeys suggests that the reason for many, if not most, of the above vaccine failures was not failure to elicit antibody but rather failure to prevent enteric infection, the virus invading the CNS via the nerve fibre (autonomic) pathway rather than the blood stream (Ref. 3). The Swedish experience with ostensibly much more potent vaccine (resulting in virtual elimination of wild polioviruses) suggests that IPV can be highly effective. Over a 2-year period (1969–1970), weekly sewage samples from three Stockholm sewage plants yielded polioviruses on only 11 occasions, all in 1969; on seven of these occasions the virus recovered was Type 3 which is the least immunogenic component of IPV (Ref. 4). Considered in the light of this information, the purification and concentration of the vaccine viruses represent steps in the right direction.

In summary, properly administered IPV reliably induces antibody formation (90 percent to all three types after three doses), is highly effective in preventing paralytic disease, and has clearly altered the epidemiologic pattern of disease in the United States. However, significant numbers of paralytic cases have occurred in adequately vaccinated persons, and, in the United States at least, dissemination of wild-type virus continued with significant frequency (Refs. 5 and 6).

b. *OPV.* There is abundant epidemiologic evidence that subclinical infection with wild polioviruses confers effective, long-lasting protection against paralytic disease. The most compelling points are: (1) In earlier times in this country, the disease, despite the abundant spread of polioviruses, was virtually restricted to very young children (hence the name infantile paralysis) and nearly the entire older population was immune as the result of silent infection acquired early in life. This situation obtains at the present time in the developing countries. (2) In isolated communities, i.e., Alaskan Eskimos, antibody persisted over long periods in the absence of reintroduction of viruses. When virus was introduced, i.e., in Tahiti, it was virtually restricted to individuals born since the particular virus type (Type 1) was last present. There is less abundant, but convincing, evidence that prior infection (reflected by possession of homotypic neutralizing antibody) also affords relative protection against infection in the face of exposure within a household sufficient to infect most nonimmunes. (In the Louisiana families studied, 90 percent of the susceptibles but only 20 percent of the immunes became infected.)

The high frequency of subclinical infections suggests that some, and perhaps many, strains of the wild virus are of low virulence, thus raising the possibility that strains selected for low virulence (or modified in the laboratory) might safely induce an immunity comparable to that arising from natural infection, i.e., protecting against infection as well as disease. Use of such strains as a vaccine should not only protect the recipients against disease but, by making spread of wild strains more difficult, afford indirect protection to those individuals who remain nonimmune. Exploration of this possibility by several investigators, using the behavior of candidate strains in monkeys as a main criterion for selection, was attended with both failure (poor immunizing ability or production of disease in recipients) and success; the latter presently represented by the Sabin strains, whose exhaustive testing in the laboratory was completed in 1957 and 1958.

In considering evidence for the efficacy of the Sabin strains, it must be recalled that an apparently effective inactivated trivalent vaccine developed by Salk had been available and widely used since 1955. The huge field trial which terminated in 1955 established that the Salk vaccine induced formation of neutralizing antibody in a high proportion of nonimmune vaccinees indicating protection against the disease. The proportion of those who developed neutralizing antibodies varied with different lots of vaccine. Subsequent experience appeared to confirm the efficacy of the Salk vaccine, since its widespread use was followed by a dramatic decline in the incidence of paralytic disease. Indeed, based on reasonably accurate estimates of the proportions in each population age group that had received vaccine and the vaccination status of the cases reported, CDC showed that the operational efficacy continued at about 90 to 95 percent for those who had received three or more doses of vaccine. Despite this, a disturbing absolute number of adequately vaccinated persons (three or more doses) experienced paralytic disease (927 cases in 1959 or nearly 18 percent of all cases in that year). We

now know, partly from the Louisiana studies (Ref. 6), that the Salk vaccine then in use (probably much less potent than that produced by Gard in Sweden) induced little protection against enteric infection. We also know from the work of Craig and Brown in 1959 that enteric challenge infection of vaccinated cynomolgous monkeys frequently resulted in paralytic disease despite rather high levels of vaccine-induced antibody (Ref. 3). This suggests the operation of an alternate pathway to the CNS that is unguarded by serum antibody and which probably exists also in man.

Evidence for the efficacy of the Sabin strains needs to be considered in the light of the foregoing experience as well as independently. There has been no large controlled trial of efficacy analogous in scale to the Francis trial of the Salk vaccine. There have been numerous small trials in which the ability to induce antibody in 90 percent or more of susceptibles has been demonstrated for individual monotypic vaccines and for trivalent formulations (these also have served as safety tests, as discussed later). Also, the development of secretory antibodies (coproantibodies) has been demonstrated. Limited followup of children given the vaccine in early clinical trials suggests good persistence of antibody over periods of 6 to 8 years. The stability of the titers suggests that antibody would persist indefinitely.

However, later serologic surveys have revealed a less than satisfactory antibody response and persistence. Relatively poor responses that remain inadequately explained (possibilities include interference due to other enteroviruses and maternal antibody in breast milk) have been encountered among infants in warm climate, developing areas. Studies in Israel suggest that whatever the factors involved, they can be overcome by beginning vaccination at a very early age by using a three-dose regimen of trivalent vaccine routinely and, for lower socioeconomic groups, giving a fourth reinforcing dose later, preferably in the cooler months (Ref. 7). A possibly analogous situation also may exist in the United States. Rasmussen et al. Studied antibody levels in children of low income families in six United States cities, and found that not only had 60 percent received less than three doses (38 percent had received none) but, of those who had received three or four doses, only 28 percent (three doses) or 41 percent (four doses) had antibody to all three viral types (Ref. 8).

The protective significance of neutralizing antibody induced by the vaccine can be inferred from the Louisiana studies (among others) for infection and from the Francis trial (1954) for occurrence of disease (Ref. 9). While no challenge experiments with wild virus strains have been reported, challenges have been done with the vaccine strains by Sabin and others. Although persons lacking homotypic antibody are almost uniformly susceptible to infection, the strains infect few who possess high-avidity antibody, or who have had previous infection with the homotypic vaccine strain. Such reinfection is apparently a function of infecting dose. However, the vaccine strains, as did the wild polio strains in Louisiana, readily infected persons who lacked antibody but who had received the Salk IPV.

Some degree of protective antigenic cross-relation does exist between the three poliovirus serotypes. This crossing occurs between Type 2 and both Types 1 and 3 but not between Types 1 and 3. In this light, the great uniformity with which the Type 2 strain induces antibody (virtually 100 percent) as compared with that to Types 1 and 3 becomes significant. The Francis trial (1954) provided general evidence for the importance of heterotypic immunity by the finding that 64 percent of the virus-positive paralytic cases among controls were in children originally triple negative serologically (only 13 percent of all controls were triple negative). The protective effect of Type 2 virus against Type 1 virus infection was specifically demonstrated in Singapore in 1958 when administration of Sabin Type 2 vaccine was followed by a clear protection against disease in an epidemic due to Type 1 virus (Ref. 10).

Evidence of general effectiveness for protection against disease is derived partly from the very large mass immunization trials carried out in the U.S.S.R. and Central European countries, and also from the virtual elimination after 1963 of paralytic poliomyelitis in the United States as well as other countries following OPV mass vaccination (including Great Britain where the Sabin strain vaccines have replaced vaccines of the Salk type). This is reflected in the "Annual Poliomyelitis Summaries" from which the following data are taken (Refs. 11, 12, and 13). Wide use of OPV began in 1962, a year in which 691 paralytic cases were reported in the United States. This number fell to 336 in 1963, 103 in 1966, 48 in 1968, 33 in 1970, 19 in 1971 including 9 "vaccine-associated" cases (8 in contacts), about which more will be said later, and an all time low of 4 in 1974. All three virus types were nearly equally represented. Effectiveness obviously depends on potency. Although titration of the vaccine strains in susceptible children suggests that the MID_{50} for man is 1 to 10 $TCID_{50}$, the current regulations specify that the dose for each monovalent vaccine contain $10^{5.3}$ to $10^{6.0}$ $TCID_{50}$ and, because of relative differences in competitive interference, the trivalent formulation contain $10^{5.4}$ to $10^{6.4}$ of Type 1, $10^{4.5}$ to $10^{5.5}$ $TCID_{50}$ of Type 2, and $10^{5.2}$ to $10^{6.2}$ $TCID_{50}$ of Type 3 virus.

To summarize, OPV reliably induces the formation of long-persisting serum antibody, enteric secretory antibody, and relative protection against enteric infection, and it clearly protects against disease. That it contributes to eradication of wild-type strains is not readily demonstrable because the vaccine strains induce abundant shedding of virus that is not always unquestionably distinguishable from wild-type strains and because of reversion and the apparent selective advantage of reverted virus, may develop marker characteristics which resembles the wild-type virus. These factors also make it difficult to establish unequivocally a cause and effect relationship on the basis of marker testing of isolates from cases of presumed vaccine-associated disease.

There are important problems concerning the development of poliovirus antibody response of infant vaccines already infected with other enteroviruses. This situation clearly exists in certain economically disadvantaged parts of the world, but its significance in the United States is not known at present.

2. *Safety.*

a. *IPV.* The vaccine-associated disease episode in 1955 focused concern on the need for complete inactivation of the virulent virus strains comprising the viral antigen.

Because of the inherent difficulty in detecting trace amounts of living poliovirus in the vaccine which was made evident by this experience, consistent freedom from detectable virus (in a consecutive series of production lots) is an important safety criterion.

Following the discovery of SV–40 in 1961, tests revealed that certain lots of vaccine produced in the period 1961 to 1963 did contain SV–40 after formalin inactivation. As an interim measure, these lots were further treated with *beta*-propiolactone to inactivate residual SV–40. It is probable, of course, that many lots produced prior to 1961 also contained live SV–40. In 1964, the

regulations required that vaccines be free from SV–40 before formalin inactivation, and tests of the final product in animals and in vitro were modified accordingly.

The question of oncogenic risks associated with SV–40 or other components of the vaccine substrate remains a theoretical concern; to date, however, followup of children in the United States vaccinated with lots known to have contained live SV–40 has failed to reveal any excess incidence of tumors (Ref. 14).

The 1955 episode also led to institution of continuing surveillance by CDC for detection of possible vaccine-associated cases. As criteria CDC used the time of onset after vaccination (4 to 30 days); possible paralysis of the injected arm; and, of special importance, the clustering of suspected cases among recipients of a particular vaccine lot. On this basis, no further cases associated with the use of IPV were recognized, but numerous cases of paralytic disease not meeting all of the above cited CDC criteria did occur within 30 days after receipt of a dose of Salk vaccine. Thus in 1959 there were 259 such cases of which 11 manifested the first paralysis in the inoculated limb (site-correlated). In the 2 succeeding years, the corresponding figures were 116 and 26 total cases with 11 and 2 cases, respectively, site-correlated. These experiences, to a large extent, presumably reflect coincidental occurrence of infection in recently inoculated persons. They also may well include a number of cases directly attributable to IPV by virtue of either the provoking effect of inoculation in an already infected person or even possible residual live virus in the vaccine. From the various reports of product-specific experience, few other reactions of significance were seen including possible hypersensitivity reactions.

The main adverse effect, thus, became vaccine failure, i.e., the occurrence of paralytic disease despite adequate immunization rather than disease induced by vaccination, although the latter, as already indicated, cannot be completely excluded.

b. *OPV.* Generically, safety concerns relate to the vaccine strains themselves (both the original strains and progeny viruses in the vaccine recipients) and to the exclusion of other microbial agents, bacterial or fungal but especially viral. These agents could be introduced by contamination during manufacture, be present in the serum employed in the culture media, or come from the monkey kidney cells used for virus propagation. Recently, this concern has carried over to the use of the WI–38 (human fetal lung) strain of diploid, fibroblastic cells now employed by one manufacturer for viral propagation.

c. *Vaccine virus.* The same vaccine strains are used by all manufacturers and were selected by triple plaque purification in an attempt to obtain genetically homogeneous progeny with a very low order of neurovirulence for monkeys (and hence presumably for man). Progressively larger field trials in man (most relevant being those which involved several million people under 20 years of age in the U.S.S.R., where the age pattern of immunity resembled that in the United States) confirmed the basic acceptability of all three strains with respect to safety for man. However, as suggested by study of numerous isolates from vaccinees, some reversion towards increased monkey neurovirulence does occur during passage in man and conceivably could occur during passage in cell culture. To minimize this possibility and to detect any changes that might occur, the former Division of Biologics Standards (DBS) prescribed certain procedures to be employed by manufacturers. These procedures included use of a seed-lot system (master seed lot, production seed lots, production lots of vaccine) to limit the number of passages to no more than five from the original strains, a series of tests of seed lots and, most important, tests of production lots for level of monkey neurovirulence and possession of certain vitro markers (rct/40 and d) which may be correlated with neurovirulence. This topic was covered in discussion of the FDA regulations. The extensive experience of all manufacturers and of DBS-Bureau of Biologics with the foregoing neurovirulence tests of production lots is currently being analyzed by virus type by the Bureau of Biologics. Such analysis could be the basis for the essential statistical definition of the requirement that the neurovirulence of a production lot cannot exceed that of the reference attenuated virus.

Fortunately, considerable data are available concerning human experience. Early experience with at least one candidate strain (Type 1) in Miami and Berlin raised the specter of vaccine-induced disease—the clinching evidence was recovery of vaccine-like virus from the spinal cord of a fatal case. However, no such episodes were reported in relation to the very extensive trials which preceded approval of the Sabin strains. These strains were approved separately and monovalent vaccines were released as approved, Type 3 being last, in the spring of 1961. By August of that year, it became apparent that in certain areas cases of poliomyelitis apparently related to immunization were occurring following mass use of the Type 3 vaccine. A special advisory committee was formed by the Surgeon General to study the situation. Basically, cases were more frequent in older (20+ years) persons and followed inoculation with Type 3 vaccine, although some also followed Type 1 virus vaccine. There was no association of cases with individual vaccine lots or manufacturers. Surprisingly, there were few documented cases in contacts. In the summer of 1964, at its final meeting, the committee evaluated all suspected cases using the following criteria:

(1) Onset of illness within 4 to 30 days and of paralysis not sooner than 6 days after feeding; (2) significant residual lower motor neuron paralysis; (3) laboratory data not inconsistent with respect to multiplication of the virus fed; (4) no evidence of other motor neuron disease, definite sensory loss, or progression (or recurrence) of paralytic disease 1 month or more after onset.

Several criticisms concerning these criteria are appreciated by the Panel. Nevertheless, using these criteria, the original review, committee identified 57 cases as "compatible" with vaccine association, and CDC has continued to use the same criteria since 1965. A comparison of vaccines employed during those two periods, 1961–1964 and 1965–1972, and the instances of reported cases are summarized in Table 4 (Ref. 13).

Table 4.—*Occurrence of Vaccine-Associated Cases of Poliomyelitis According to Vaccine Virus Type and Vaccination Intervals*

Class of patient (time)	Vaccine administered				
	Type 1	Type 2	Type 3	Trivalent	All
Recipients:					
1961 to 1964	[1]16 [2](0.15)	2(0.02)	39(0.37)	5(0.18)	62(0.18)
1965 to 1972	1(0.11)	0	6(0.81)	9(0.05)	16(0.08)
Contacts:					
1961 to 1964	0	0	3(0.03)	.....	3(0.01)
1965 to 1972	2(0.23)	2(0.29)	0	38(0.20)	42(0.20)

[1] Number compatible cases.
[2] Incidence (cases per million distributed doses).

More recent CDC data (M. Gregg, presented August 11–12, 1975 at the American Academy of Pediatrics) extend through 1974 and add five recipient and eight contact cases (all TOPV related). During 1965–74, 151 million doses of vaccine were distributed. Hence, the frequency of adverse reactions in this period remained at one event (recipient or contact) per 4.8 million doses distributed although, with the advent of TOPV, the ratio of contact to recipient cases has increased to 3.3:1.

Proper interpretation of the 83 recipient cases and the 53 contact-associated cases is seriously complicated by several factors: (1) Only monovalent types of OPV were used in the 1961 to 1964 period; subsequently, primarily trivalent OPV has been used. (2) A major use of MOPV in the 1961 to 1964 period was as a part of mass vaccination campaign in locations where abundant wild-type virus was still present. (3) Since 1965, the vaccine (chiefly TOPV) has been used in public health immunization campaigns and by private physicians in their practice. (4) According to data presented to the Panel by the Bureau of Biologics, vaccines prepared and administered from 1965 to the present are comprised of virus strains with significantly lower neurovirulence potential than earlier strains. (5) Although there were remarkably few vaccine-associated cases (136 through 1974 or about 1 per 4 million distributed doses of vaccine), many were incompletely analyzed and include an unknown proportion representing disease in immunodeficient children. (6) Adults, who were a major source of recipient cases in 1961 to 1964, have not been routinely immunized since 1964.

With these reservations, the following statements can be tentatively made. Administration of trivalent OPV is associated with less than one "compatible" case among recipients per 15 million doses (or, including contacts, less than 1 per 4.8 million doses), and omission of individuals with altered immune status would probably reduce this rate even further. The special vulnerability of immunodeficient children to vaccine virus infection will be emphasized in a forthcoming CDC report. Finally, an analysis of the contact-associated cases occurring since 1965 reveals that these cases are nearly equally distributed between Type 2 and Type 3 strains, thus suggesting a previously unappreciated instability to Type 2 virus with respect to neurovirulence.

d. *Vaccine substrate.* Procedures for the exclusion of extraneous agent from production lots depend on the cells used for virus propagation, i.e., primary monkey kidney (MKC) or WI–38. For MKC, the monkeys used are observed in quarantine to insure general good health and, by specific test, freedom form tuberculosis. The initial unit of production is the pair of kidneys from one animal. Tests for specific agents are conducted separately in parallel on cell culture fluids removed immediately prior to virus inoculation, on fluids from control cell cultures held an additional 14 days, and on viral harvests from inoculated cultures. These include cultures for various bacteria and mycoplasma; obsevation of the control cultures for possible nonpoliovirus effects (cytopachic effect (CPE), hemadsorption, interference); subinoculation into various monkey, human, and rabbit cell cultures to exclude known simian agents, including SV–40, pox viruses, *Herpesvirus simiae* (Bvirus), and measles virus; and inoculation into adult and suckling mice and into rabbits and guinea pigs to exclude coxsackie-viruses, LCM virus,other neurotropic viruses, *Herpesvirus simiae* (B virus) again, and tubercle bacilli. All these tests involve the use of specified (large) sample of the production material (commonly 500 doses or 50 ml, whichever represents the greater volume).

Despite these specified precautions, the question of the presence of contaminating viruses in nonhuman primate substrates persists. The safety record is clear in terms of at least 15 years of followup. However, it might be suspected that viruses such as papovaviruses (other than SV–40), cytomegaloviruses, foamy virus, C type viruses, and perhaps other unknown viruses of primates could theoretically be present in a vaccine and not be detected by test methods currently prescribed by regulations. The presence of any such viruses would be clearly undesirable even though no increase in oncogenic risk to vaccines has thus far been detected. The principal theoretical advantage of vaccine produced in MKC culture is its freedom from human genetic material. The principal practical advantage is the 15–year record of safety associated with its use.

Recent amendments to the regulations allow production of vaccine in an approved strain of human cell cultures (in this case, WI–38 cells) which are identified by historical records; shown to be free of oncogenic properties and of adventitious microbial agents; and shown capable of producing a vaccine which, by experience in at least 10,000 persons, has been found to be safe and antigenic. Cell cultures used for vaccine production must be monitored karyologically and shown to fall within 95 percent confidence limits of the status of the original cell strain. Cultures are also checked for CPE before inoculation, and growth fluids tested in monkey, rabbit, and primary human cell cultures are checked for possible adventitious agents. Uninoculated control cultures (25 percent of a production batch) are similarly observed and further checked by hemadsorption and inoculation into embryonated eggs. The actual viral harvests are then checked in a manner similar to that prescribed for MKC viral harvests.

Introduction of a human diploid celline as the vaccine substrate raises two questions, one relating to the vaccine viruses and the other to transmissible effects of the substrate. While the Pfizer experience suggests that virus in production lots of vaccine is of acceptable neurovirulence (i.e., meets the requirements specified in the regulations), the information on reversion rates for virus so produced is not adequate. As detailed in the review of the Pfizer submission, vaccine

progeny virus shed by vaccinated children proved reasonably stable with respect to rct/40 and d markers but showed a clear trend towards increasing monkey neurovirulence over time ("early" versus "late" isolates), especially in the case of Type 2 and Type 3 virus isolates. While a similar trend has been observed with the progeny of MKC produced vaccine strains, direct comparison of the magnitudes of change would be desirable. Another question, so far unexplored, is whether poliovirus vaccines cultivated in WI–38 cells contain human DNA or RNA and, if so, what the signficance might be. The question of genetic stability has been raised previously, but the effect of the substrate upon genetic reversion after gut passage is a subject for further study. There is as yet no information that will allow comparison of the stability (rct/40 and d markers as well as monkey neurovirulence) of vaccine virus progeny shed by children fed virus propagated in WI–38 and those fed virus propagated in MKC.

As mentioned earlier, the WI–38 cell line has been widely studied in terms of karyotype, presence of adventitious agents and tumorigenic potential. All of the data available to date indicate that the line is "safe" in terms of its use in vaccine production although, as with any candidate cell substrate, one can pose a number of theoretical risks.

Thought should be given to the future availability of WI–38 cell stocks as well as to any problems which might arise and preclude the use of WI–38 cell stocks for vaccines. Since large volumes of cells are required in producing bulk lots of vaccine, and since the WI–38 strain enters the early phase of senescence at about population doubling level (PDL) 31–33, cultures for production must be initiated with low passage stock. PDL 8 material represents the lowest level available, and hence the current supply of low passage WI–38 cells represents a finite resource.

For these reasons the Panel recommends that the Bureau of Biologics continue its programs on the development of candidate cell lines which can serve as alternative to WI–38. Based on broad experience with WI–38 cells, it is recommended that efforts be directed toward the development of a similar human cell line. However, since characterization of a new cell line is a time-consuming, complex procedure requiring years of work with no guarantee of success, other options should be exercised, such as continued studies to characterize the diploid fetal rhesus lung line developed by the Bureau several years ago. While cultures of this type have not been used for vaccine preparation, they merit consideration. Use of the WI–38 (and potentially other lines) of human diploid cells as an accepted viral substrate for vaccines greatly improves the safety aspects of OPV in that the possibility of adventitious agents endogenous to the substrate are greatly reduced. Furthermore, the uniformity or consistency of the WI–38 cell line in PDL 20–29 provides the most thoroughly evaluated cell substrate employed for human viral vaccines. To date no adventitious human viral agent has been recovered from these cells. Also, live virus vaccines, including OPV, produced in these cells have been administered to hundreds of thousands of persons with no recognized adverse effects. However, it is possible that infrequent acute complications might have been missed or that possibly more frequent complications with long latent periods (over 10 years) would not yet be apparent.

The theoretical long-term oncogenic or latent virus risk of WI–38 cells has been particularly criticized. It should be noted that there is little evidence that viruses homologous to a host species are more virulent for that host than viruses from a heterologous host, whereas the opposite has been observed, e.g., monkey B virus in man and SV–40 in hamsters. Except for the unexpected occurrence of clustered untoward reactions, the risk from vaccines produced in WI–38 (or other human cell strains) will be known only from carefully organized, large-scale prospective studies designed to detect low incidence complications. The problems of conducting such studies have already been commented upon.

3. *Benefit/risk.* The considerations here are all generic rather than product-specific. Prior to the advent of Salk vaccine, the incidence of paralytic poliomyelitis was clearly rising and had reached about 25,000 cases. In 1971 the actual number was 17, including 9 "vaccine-associated" cases (8 of which were in contacts). None of these occurred in persons with a history of adequate vaccination. This compares with 3,400 cases in 1959 (when Salk vaccine had been widely used since 1955) of which 18 percent (over 900 cases) were in persons who had been adequately vaccinated. Based upon the experience with United States licensed vaccines, either type is highly beneficial. However, oral vaccine is clearly superior to Salk vaccine, despite an overall risk (contacts included) of about 0.2 case per million distributed doses of vaccine. Further comparisons would require comparison of age-specific risks of the vaccinees and their contacts with the projected similar risks in the total population, had no vaccine become available. This probably would show a great benefit among children and some among adults for whom the risk of contact-acquired vaccine infection with disease seems to be greatest. It would be important to know just what the risk to contact adults is, since it may be greater than the risk they would experience as vaccine recipients.

4. *Labeling.* Labeling should conform to FDA's regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

Recommendations.

1. *IPV.* In light of the current limited availability and use of IPV, the Panel recommends that, if there is a continued demand for the product, consideration should be given to making changes in Federal regulations governing manufacture of IPV as follows:

a. It would be prudent if virus strains employed to produce IPV were of low neurovirulence.

b. The feasibility of propagating vaccine virus in human diploid cell should be explored.

c. Comparative testing of vaccines licensed in the United States and of those currently in use in Europe should be undertaken to determine the relative potency of these products. The United States potency standards should then be reevaluated in light of these results.

d. The package inserts should state the indications for IPV and relate these indications to those recommended for OPV.

e. Manufacturers who have not produced IPV for 2 or more years should again be required to demonstrate their capability to produce a satisfactory product before new vaccine lots are released.

2. *OPV.* a. The Panel suggests that PHS should consider revising their recommendations for use in terms of the following:

(i) The Panel sees no reason to continue recommendation of MOPV as an alternative method for routine immunization. MOPV is most logically used to combat epidemics of known virus type and inserts of any MOPV should reflect the use.

(ii) Risk of disease, given poliovirus infection of a nonimmune person, is age-dependent and is greater for adults than for children. Risk of disease due to virus of vaccine origin is greater for those infected by contact (because of possible virus reversion) than for vaccinees. With

routine immunization limited to children, most vaccine virus infections in adults will be contact-acquired and, logically, be most frequent among nonimmune adults. While the magnitude of the related risk of disease is not precisely known, the Panel believes that unimmunized parents of children undergoing OPV immunization should be included among the adults for whom TOPV is recommended.

(iii) Vaccinees should be informed of the occurrence of fecal shedding of virus and the related potential for spread of infection should be emphasized together with appropriate precautions to minimize such spread. (See also (ii), above.)

(iv) Since wild enterovirus infections existing at the time of vaccine feeding may, by interference, prevent immunizing infection, the recommendations should indicate that when circumstances do not dictate otherwise, OPV for other than infant immunization should be administered when enterovirus prevalence is usually low (perhaps November through June).

b. Several issues concerning neurovirulence of the vaccine virus strains should be resolved.

(i) PHS regulations should be revised after the analysis being carried out by the Bureau of Biologics has been completed to include an appropriate statistical definition of the requirements for interpretation of the neurovirulence test of vaccine lots.

(ii) The Panel is concerned with the apparent genetic instability of the currently licensed poliovirus strains employed in TOPV. The Bureau of Biologics should give consideration to developing a program that will attempt to resolve current problems and eventually permit the selection of strains for licensing which are adequately immunogenic, of acceptable low neurovirulence, and of maximum genetic stability with respect to neurovirulence.

This problem has both practical and theoretical aspects. On the practical side, the potential future nonavailability of primates for the critical testing of neurovirulence makes it imperative to identify in vitro marker correlates of neurovirulence. On the theoretical side, possibly related to its review of the statistical evaluation of monkey neurovirulence tests, the Bureau of Biologics should support research to better understand the genetic basis of attenuation.

(iii) To make substitution of strains possible, the criteria for strain acceptability in the Federal regulations should be modified. Emphasis should be given to the importance of documentation of the monkey neurovirulence characteristics of the strains and to definitive characterization of the genetic stability of strains recovered after gut passage in intensive, carefully conducted clinical trials, supplemented by intensified postlicensing surveillance during the year or two after the vaccine is first released. These requirements would be more attainable and more meaningful than the current requirement to test in 1 million susceptibles.

c. Review of problems relating to the virus substrate lead the Panel to the following recommendations:

(i) A technical workshop should be convened to evaluate the relative merits of simian and human cell substrats for viral vaccine production. This should be composed of presently active investigators representing expertise in virology, cell culture karyology, immunology, and epidemiology. The apparent merits of the human cell substrates clearly imply an advantage over simian or other primary cell substrates and, if this advantage is valid, only human cell substrates should be employed. The workshop should consider in detail the actual and theoretical risks of the two types of substrate and what, if any, research should be sponsored by the Bureau of Biologics to resolve the issue.

(ii) PHS regulations governing tests for adventitious agents should be revised to insure that full advantage is taken of new methodology as it evolves for detecting such agents as well as foreign nucleic acids or proteins.

(iii) As part of the overall vaccine surveillance effort, large (100,000 or more) comparison groups of recipients of vaccines produced in diploid and in simian cell substrates, should be identified for followup.

d. The Panel strongly urges that legislation be enacted to provide reasonable compensation to the injured person, and protection of the manufacturers against liability, in cases of adverse effects attributed to licensed vaccines produced in accordance with PHS regulations and properly administered (see Preface and Introduction).

Review of Individual Poliomyelitis Vaccine Products

Poliomyelitis Vaccine (Purified) Manufactured by Connaught Laboratories, Ltd.

1. *Description.* The vaccine is prepared according to the method of Salk. It is a suspension of the three types of poliovirus, Type 1 (Mahoney strain), Type 2 (MEF strain), and Type 3 (Saukett strain), which are grown in monkey kidney cell cultures and inactivated with formalin. The vaccine is purified and reconstituted to contain approximately twice the original concentration of virus antigen. It contains no more than 200 micrograms (mcg) of streptomycin and 7 mcg of neomycin per ml. It contains no serum.

a. *Recommended use.* For the prevention of poliomyelitis.

(1) *Precautions.* Vaccination should be deferred in the presence of active infection, acute respiratory disease, and during the course of steroid or other immunodepressant therapy. It should not be given to individuals sensitive to streptomycin and neomycin.

(2) *Caution.* Discard any vaccine which is not perfectly clear and cherry red in color.

(3) *Adverse reactions.* There are remarkably few, but it is always possible that the recipient may be highly sensitive to a vaccine component, hence it is advisable to have epinephrine 1:1000 available.

(4) *Dosage and administration.* The vaccine is given in 1 ml doses, subcutaneously or intramuscularly. The regimen is a series of 3 doses separated by 4 or more weeks and a booster dose given 6 to 12 months after the third dose. Recall doses every 2 to 3 years are recommended.

b. *Contraindications.* No contraindications are stated as such.

2. *Analysis.* a. *Efficacy.* The general evidence for efficacy of IPV is presented in the generic review.

The manufacturer's data provides convincing evidence that given to infants 2½ to 4 months of age, the vaccine alone or in any of several combinations (DPT, DT, T, DP, Measles) will induce an antibody response to all three poliovirus types in about 97 percent of individuals with a titer of 1:16 and in 89 percent of individuals with a titer greater than 1:16. Evidence also is presented to show that a satisfactory proportion of the Canadian population possesses antibody to all three types, presumably attributable largely to widespread use of IPV and that, at least in Ontario, paralytic disease has fallen to a very low level, from 0 to 2 cases per year since 1962. (This observation alone, however, does not firmly establish IPV efficacy since OPV is also used.)

b. *Safety.* The safety of IPV generically is discussed elsewhere. Review of the manufacturer's data indicates that the Connaught Laboratories, Ltd. vaccine has been rigorously tested and that the methods employed consistently give a product free from any detectable (by the tests employed) viable microbial agents including poliovirus as well as SV–40

virus and other adventitious agents. Apropos SV–40, kidney cells from only Cercopithecus or Cynomolgous monkeys are used.

c. *Benefit/risk.* This discussed in the generic statement.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of the ACIP. The summary under the heading indications and usage should include indications for preferring IPV and OPV.

3. *Conclusions.* a. *Critique.* In general, the submission is adequate. The procedures, etc., are clearly described, and the necessary documentation on use of the vaccine in man has been provided. Several specific comments, however, seem cogent:

(1) Vaccine seed pools are defined but the history of the virus strain from the time of its isolation should be given. Of all the manufacturers considered in this review, Connaught Laboratories, Ltd. demonstrates the highest concern for seed pool characterization and identification. However, reliance on a complement fixation test for strain identification rather than virus neutralization should not be encouraged.

(2) Because of the details provided by Connaught in its submission, which could well serve as a model, this vaccine is comparatively easy to evaluate.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness.

Poliomyelitis Vaccine Manufactured by Cutter Laboratories, Inc.

This product has not been manufactured for a number of years and the only way to assure that competence for its production exists, and to guarantee its safety and efficacy, is to require a new submission when and if Cutter laboratories, Inc., desires to resume marketing of this vaccine. It is recommended that 21 CFR 601.5 be invoked, whereby the Commissioner may recommend that a license be suspended or revoked upon finding that "manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made."

Furthermore, if the manufacturer proposes to resume production, the Panel recommends that this product be placed in Category IIIB and that appropriate license(s) be revoked pending completion of additional testing and conformance with the recommendations of this report because there is no evidence presumptive of safety or effectiveness for this product.

Poliomyelitis Vaccine (Purivax) Manufactured by Merck Sharp & Dohme, Division of Merck & Co., Inc.

This product has not been manufactured since 1965, and the only way to assure that competence for its production exists, and to guarantee its safety and efficacy, is to require a new submission when and if Merck Sharp & Dohme, Inc. desires to resume marketing of this vaccine. It is recommended that 21 CFR 601.5 be invoked, whereby the Commissioner may recommend that a license be suspended or revoked upon finding that "manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made."

Furthermore, if the manufacturer proposes to resume production, the Panel recommends that this product be placed in Category IIIB and that appropriate license(s) be revoked pending completion of additional testing and conformance with the recommendations of this report because there is no evidence presumptive of safety or effectiveness for this product.

Poliomyelitis Vaccine; Poliomyelitis Vaccine, Adsorbed Manufactured by Parke, Davis & Co.

These two products have not been manufactured for some years and the only way to assure that competence for their production exists, and to guarantee their safety and efficacy, is to require a new submission when and if Parke, Davis & Co. desires to resume marketing of these vaccines. It is recommended that 21 CFR 601.5 be invoked, whereby the Commissioner may recommend that a license be suspended or revoked upon finding that "manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made."

Furthermore, if the manufacturer proposes to resume production, the Panel recommends that this product be placed in Category IIIB and that appropriate license(s) be revoked pending completion of additional testing and conformance with the recommendations of this report because there is no evidence presumptive of safety or effectiveness for this product.

Poliovirus Vaccine, Live, Oral Trivalent, Orimune; and Poliovirus Vaccine, Live, Oral, Types 1, 2, and 3 Monovalent, Orimune Manufactured by Lederle Laboratories Division, American Cyanamid Co.

1. *Description.* This description is taken from the package insert.

Trivalent is a mixture of three types of attenuated polioviruses which have been propagated in Cercopithecus monkey kidney tissue culture. The cells are grown in the presence of a nutrient medium consisting of Earle's balanced salt solution containing lactalbumin hydrolysate, antibiotics, vitamins and calf serum. After cell growth, the medium is removed and replaced with fresh medium containing the poliovirus inoculum but no calf serum. The final vaccine is diluted: with sorbitol solution for use in a 2 ml dose; with modified tissue culture maintenance medium containing sorbitol for use in a 0.5 ml dose; and with modified tissue culture maintenance medium for the use in the 2 drop (0.1 ml) dose.

Each dose (whether 2 ml, 0.5 ml or 2 drops) contains less than 5 micrograms of streptomycin, neomycin and mycostatin.

Potency is expressed in terms of tissue culture infective doses ($TCID_{50}$) of virus contained in the recommended vaccine dose. The approximate $TCID_{50}$ of each strain of poliovirus in a human dose is as follows: Type 1—800,000; Type 2—100,000; and Type 3—500,000.

The description for the monovalent vaccines differs from the above in that it refers to the specified virus type; states the limit of each antibiotic per dose to be 1 microgram; and, for each type, the virus content to be 200,000—1 million $TCID_{50}$ per dose.

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.* a. *Efficacy.* This is covered in large part in the generic review. Lederle Laboratories has complied with the licensing requirement (21 CFR 630.11) that five consecutive production lots of each monovalent vaccine be tested in susceptible persons and that each lot elicit serum neutralizing antibody in at least 80 percent of recipients after one dose. The results were as follows:

Table 5.—*Neutralizing Antibody Response to Monovalent OPV*

Preimmunization antibody titer	Antibody response to viral type					
	Type 1		Type 2		Type 3	
	Number of vaccinees	Sero-conversion [1]	Number of vaccinees	Sero-conversion [1]	Number of vaccinees	Sero-conversion [1]
<1:4	141	89.3	134	91.0	182	86.8
1:4 or 1:8	81	81.4	71	97.1	49	83.6

[1] Percentage of group seroconversion.

For trivalent vaccine, the Biologic Regulations prescribe that after the required feeding regimen, each of five consecutive production lots must attain in susceptible individuals a seroconversion rate of at least 99 percent for each of the three viral types. Again, Lederle Laboratories has complied with this requirement; of 422 children with no antibody to any of the three virus types, seroconversion after two feedings of vaccine was 90.4 percent for Type 1, 99.7 percent for Type 2, and 98 percent for Type 3. A third feeding raised the proportion of seroconversions to Type 1 to 98.3 percent. They also showed that preexisting enterovirus infection had some inhibitory effect on infection with polivirus vaccine. In populations which included children possessing antibody to one or two serotypes, similar seroconversion rates were observed to the lacking type.

Finally, in a followup of these trials it was found that antibody persisted for over three years in a high proportion of vaccine recipients.

Table 6.—*Persistence of Antibody Induced by Oral Poliomyelitis Vaccine*

Postvaccination interval	Percentage of individuals with antibody to:		
	Type 1	Type 2	Type 3
One years	90.0	100.0	96.7
Two years	90.0	100.0	94.5
Three years	81.3	100.0	94.5

b. *Safety.*

(1) *In vivo and in vitro tests.* The Lederle Laboratories submission consists of detailed descriptions of the various test procedures (in the original licensing submission and amendments) and a sample protocol for a lot of Type 1 virus said to be representative of all protocols (including these for Types 2 and 3) submitted to FDA. Also included were sets of review information, one set each for single monovalent lots and one for a trivalent lot formed from the same three monovalent lots. Thus actual data were provided for two lots of Type 1 virus, one each of Type 2 and Type 3 viruses, and data for one lot of trivalent vaccine. The reported testing was amply documented and appeared in all cases to have yielded satisfactory results, including the crucial monkey neurovirulence test. The most troublesome and least stable strain of poliovirus for all manufacture is Type 3. Examination of the data submitted for the single lot of Lederle Type 3 virus tested showed that its apparent neurovirulence was less than that of the Type 1 reference vaccine. Later data submitted by the Bureau indicated that testing of five successive lots of each type had indicated acceptable low neurovirulence for all.

(2) *Information on vaccine recipients.* Individuals included in the field trials mandatory for licensure were observed for possible immediate adverse effects. None of significance were reported.

(c) *Benefit/risk.* See generic discussion.

d. *Labeling.* Labeling should conform to the FDA's regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions.*

a. *Critique.* The principal defects in the submission are a lack of information on range of variations encountered in the monkey neurovirulence tests of successive vaccine lots, especially Type 3, (the desired data was later furnished by the Bureau) and the failure to report product-specific adverse experiences. The generic monovalent and trivalent vaccines are effective, useful, and safe. These products are acceptable examples of the generic vaccine.

b. *Recommendations.* The Panel recommends that these products be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for these products.

Poliovirus Vaccine, Live, Oral, Trivalent, (Diplovax) Manufactured by Pfizer Ltc.

1. *Description.* Diplovax is a mixture of monovalent (Types 1, 2, and 3 Sabin strains) vaccines propagated in a human diploid cell line (WI–38 Hayflick); each dose contains approximately 800,000 Type 1, 100,000 Type 2, and 500,000 Type 3 $TCID_{50}$.

The WI–38 strain of human diploid cells represents a cell line propagated by repeated serial passage. It has been shown to be free of any known adventitious agents by extensive testing.

Further statements in the labeling indicate that the vaccine strains, manufacturing methods, and testing comply with the PHS requirements. Lactalbumin hydrolysate medium is employed in the tissue culture host system for viral propagation. Potency is expressed in terms of $TCID_{50}$ with ± 0.5 log accuracy and the meaning of this term is explained. Sucrose is added to the vaccine as a stabilizer and inclusion of phenol red gives the vaccine a variable red color. If the color of an entered vial changes from red to yellow on storage, bacterial contamination should be suspected and the vial discarded.

Also included in the description is the following statement of vaccine action:

> Usually, both a systemic and local response are produced. A systemic response involves production of serum or humoral antibodies which help protect the individual against clinical poliomyelitis infections. A local response is one in which resistance to further infection by the same virus type is produced in the intestinal tract. The resistance to further infection may reduce the incidence of temporary carriers, individuals who harbor and disseminate naturally-occurring wild poliovirus although they may show no clinical symptoms of infection.

a. Recommended use. See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.*

a. *Efficacy.* Basic to efficacy is potency. Assay data for 10 filling lots (derived from a single large lot) indicate that all contained the requisite amounts of virus of each type. Also, in the review information submission, data were included to show the stability of potency for each virus type during 6 months of storage at 4° C and for one year at −20° C.

Also included were data on the response in seronegative children given monovalent vaccines (five consecutive production lots of each type) and trivalent vaccine (also five consecutive lots). For comparison, previously acquired data for vaccine produced by this manufacturer in MKC are also presented in the submission. Single feedings of the monovalent WI–38 diploid cell-produced vaccines resulted in satisfactory seroconversion for all viral types (Type 1, 92.3 percent; Type 2, 90.6 percent; Type 3, 88.9 percent) based on studies of from 144 to 191 children. Trivalent feeding (three dose series) of 100 children negative for antibody to all three viral types resulted in higher rates, viz., 96, 99, and 94 percent, respectively.

These results are equivalent or superior to the earlier ones with MKC vaccine prepared by this manufacturer. Otherwise, the case for efficacy is based on the aggregate generic experience with the Sabin strains of poliovirus.

b. *Safety.* This submission includes a summary brochure on the comparative virtues of WI–38 human cells versus primary monkey kidney cells, and a Pfizer-produced pamphlet which describes the WI–38 cell strain and its use in vaccine production. The pamphlet contains pertinent references on the subject. The essence of the presentation is that the WI–38 cell strain constitutes a single cell source for which a 20-year reservoir exists, and that it has undergone considerable scrutiny for adventitious agents and undesirable (e.g., oncogenic) properties, all with negative results. Recent evaluation of the situation regarding supply put in question the 20-year availability of the cell strain.

Also included are data concerning the characteristics of the vaccine progeny virus shed by the children given the monovalent vaccines. Data on the rct/40 marker are given for isolates grouped by time since feeding but they show no consistent trend related to increasing time between feeding and viral recovery (intervals 1–22, 23–42, and 43 or more days). The results, combining all time intervals, are shown in Table 7.

Table 7—*Distribution of rct/40 Markers of Progeny Virus Shed by Children Given Monovalent OPV*

Poliovirus	Percentage of isolates with rct/40 marker		
	t–	t±	t+
Type:			
1 [1]	78	22	0
2 [2]	43	54	3
3 [3]	34	66	0

[1] 125 isolates.
[2] 124 isolates.
[3] 59 isolates.

There was least shift in marker characteristics with Type 1 virus, but the few rct+ isolates were all Type 2. These data are said to closely parallel similar data on progeny virus shed after feeding vacine virus grown in monkey kidney cells. Tests for the d marker were made on 137 isolates (all three types were represented). Since none indicated a shift from d (virus grows poorly under low concentrations of bicarbonate) to d+ (virus grows well under low or high bicarbonate concentrations), this test was discontinued in the evaluation of shed virus.

Some of the isolates, representing viral recoveries made both early (first 2 weeks) and late (3 or more weeks) after feeding the vaccine, were tested by intracerebral inoculation in monkeys using first cell culture passage fluid (undiluted) and two monkeys per isolate. The results are summarized in Table 8.

Table 8—*Results of Tests for Neurovirulence of Progeny Virus Shed by Children Given Monovalent OPV*

Virus type	Viral isolate	No. of monkeys	Percent of monkeys showing		
			Negative for lesion and/or paralysis	Histologic lesions	Paralysis
1	Early	13	77	23	0
	Late	31	45	35	6
2	Early	16	69	31	0
	Late	22	32	64	18
3	Early	14	29	71	36
	Late	41	10	90	34

The submission concludes that:

Although there is some evidence of increased neurovirulence for monkeys in the later specimens of virus of all three types, the pattern follows that which has been seen and extensively reported in the literature for monkey kidney vaccines. It also should be pointed out that 10 of the Type 3 specimens had titers greater than 10^8 $TCID_{50}$ per dose, i.e., 10 times that which is used in the standard neurovirulence test. It is our view, therefore, that preparations of the vaccine in human diploid cells instead of monkey kidney tissue has not resulted in any significant change in the biological characteristics of the vaccine viruses.

It is unfortunate that parallel concurrent studies were not done with vaccines produced in MKC.

Other than data on the potency and animal safety of the final containers of trivalent vaccine from 10 filling lots, the only data on in vitro and animal testing of production lots are those for five consecutive lots of monovalent Type 1 vaccine. These covered tests in eggs; hemadsorption on control cultures; chromosome studies; tumorigenicity (comparing WI–38 cells with HEP–2 cells in adult mice); and tests in suckling and adult mice, guinea pigs, rabbits, mycoplasma medium, other bacteriologic media, human embryonic lung cells, human embryonic kidney cells, vervet monkey kidney cells, and rabbit kidney cells, all for possible adventitious or contaminating agents. The material tested included control cultures, fluids representing medium changes (from production cultures), fluids from control cultures, and the actual virus-harvest fluids. All such tests were judged satisfactory. Similar data for consecutive lots of Types 2 and 3 were later supplied by the Bureau of Biologics. However, it should be noted that in the past occasional lots had to be discarded because of bacterial or fungal contamination, and that in two instances batches of WI–38 cells being built up to passage 29 (that used for vaccine production) had to be discarded because of contamination with attenuated polioviruses of still unknown origin. Since then, the manufacturing procedures were modified (in 1972–1973) and the problem has not recurred.

Tests on the vaccine virus itself were the same as those prescribed for MKC vaccine which incorporated in vitro markers (rct/40 and d), identity of the virus, and its neurovirulence in monkeys. These five lots of Type 1 virus were tested in parallel with reference lots of Type 1 virus. Careful comparison fails to reveal significant variation of results between test lots of vaccine or between test and reference lots and thus for Type 1 vaccines points to a desirable consistency in the product. Later, similar data were submitted for Type 2 and Type 3 virus vaccines by the Bureau.

Other than data on the viral isolates from vaccine recipients mentioned above, there is no product-specific information regarding human safety. The Pfizer brochure mentions use of WI–38 cells to produce vaccines containing poliovirus; adenovirus Type 4; rhinovirus; and measles, rubella, smallpox, varicella, and arboviruses which, in the aggregate, have been given in the United States and Eurpoe to over 2 million persons with no reports of any untoward effects due to adventitious agents. No specific reference is made to poliovirus vaccines or to possible effects of vaccine strain polioviruses. The material on file in the Bureau of Biologics contains a fairly detailed summary of the experience of Ikic' in Yugoslavia with vaccines produced in WI–38 cells, and this was accepted as evidence of compliance with the requirement that the human cell line be "shown to be capable of producing a vaccine which, by experience in at least 10,000 persons, has been found to be safe and antigenic" (21 CFR § 630.12(b)).

c. *Benefit/risk.* The available evidence suggests that Diplovax does not differ in safety or efficacy from trivalent vaccine produced in MKC. The generic discussion should be consulted.

d. *labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions.*

a. *Critique.* A serious effort was made to study reversion rates in progeny virus descended from vaccine virus propagated in human diploid cells, but a concurrent parallel study of progeny derived from virus grown in MKC

unfortunately was not done. Such a study is urgently needed.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product. The need for a stury on the reversion rate of vaccine virus grown in MKC has been noted. The potential superiority of established human strains, such as WI–38, as a long-lasting, single source of cells over primary cells obtained from animals is such that a special effort should be made to identify, and follow over an extended period, a sizeable group of recipients of Diplovax. This would gradually provide a more solid basis for judging the safety for man of vaccines so produced.

Poliovirus Vaccine, Live, Oral, Types 1, 2, and 3 (Sabin) Manufactured by Pfizer, Ltd.

Insufficient information was provided by the manufacturer for these monovalent products, which the company was licensed to manufacture at the time of this review. The manufacturer has never marketed the monovalent components of the currently licensed product in this country. In the absence of sufficient information from the manufacturer concerning labeling and marketing experience with the monovalent products, the Panel can make no determination regarding their relative benefits and risks, and the panel must recommend that these products be placed in Category IIIB and that the appropriate licenses be revoked.

Poliovirus Vaccine, Live, Oral, Trivalent (Sabin); and Poliovirus Vaccine, Live, Oral, Types 1, 2, and 3 (Sabin) Manufactured by Wyeth Laboratories, Inc.

This vaccine has not been manufactured for a number of years and the only way to assure that competence currently exists for its production, and to guarantee its safety and efficacy, is to require a new submission when or if Wyeth Laboratories, Inc., desires to resume marketing of the vaccine. It is recommended that 21 CFR 601.5 be invoked, whereby the Commissioner may recommend that a license be suspended or revoked upon finding that "manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made."

Furthermore, if the manufacturer proposes to resume production, the panel recommends that this product be placed in Category IIIB and that appropriate license(s) be revoked pending completion of additional testing and conformance with the recommendations of this report because there is no evidence presumptive of safety or effectiveness for this product.

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Generic Review of Smallpox Vaccines

Background

To our knowledge, smallpox vaccines have not before been subjected to a thorough systematic review for safety and effectiveness. The basis for the standards used in their licensure in many cases are decades old. Because these vaccines present certain generic problems which can be addressed in a general way, the specific product reviews are introduced with this broad statement. Some of the general recommendations will appear at the end of this review; others will be outlined in the product reviews which follow.

It must be recognized that there are no other licensed vaccines which permit a measurable bacterial count in an injectable product. In addition, there are no other live viral vaccines where the passage history of the seed virus is unregulated and where a seed lot system of some sort is not uniformly in use. Furthermore, there are few other vaccines whose administration is associated with such a degree of morbidity. Nevertheless, smallpox vaccine is, generically speaking, of proven effectiveness. There is a problem, however, in proving the effectiveness of specific products which have never been used under field conditions in the control of an epidemic. This is not a purely academic consideration, since it seems quite possible that vaccine made from a strain of vaccinia virus distantly related to established strains might no longer protect against smallpox. A classic protection study of course, cannot be reasonably demanded from each company producing vaccine. Is protection against challenge with a standard strain of vaccinia virus an adequate substitute for such efficacy trials? Perhaps, but it should be noted that the studies of Wesley and other describe the capacity of the CV–1 strain to protect against challenge while at the same time apparently inducing only low or undetectable amounts of neutralizing antibody (Refs. 1 and 2).

For many years, routine smallpox immunization of all children in the United States was both the recommended and the accepted medical practice. As the World Health Organization (WHO) smallpox

eradication progressed, and as worldwide importation smallpox outbreaks decreased in frequency, it became increasingly evident that the morbidity of vaccinia virus inoculation outweighed the risk of exposure to smallpox itself. For this reason, in 1972 routine smallpox immunization was no longer considered advisable, and the recommendation of ACIP in that year (the latest available) reads as follows:

At the present time, the routine use of smallpox vaccine as part of pediatric immunization schedules is not recommended in the United States. Selective vaccination of persons at potential risk of contracting smallpox should be continued.

International travelers. All travelers going to endemic or infected areas should be vaccinated before departing from the United States. For purposes of validating an International Certificate of Vaccination, primary vaccinations must be inspected, and the traveler revaccinated if the initial vaccination were not successful. Although inspection of revaccination is not required by international regulations, health workers are strongly encouraged to examine the revaccination site and again revaccinate the traveler if a major reaction has not occurred (see General Vaccination Information).

High risk groups. Hospital and health personnel constitute the first line of defense after importation. The large percentage of secondary cases acquired in hospitals following importations in Europe warrants maintaining high level immunity in this group. A regular program of revaccination every 3 years is recommended for all hospital and medical personnel and public health and allied professions.

More recently, in an interim report ("Morbidity and Mortality Weekly Report," January 17, 1976) ACIP has withdrawn its recommendation for systematic programs of routine vaccination of hospital and health personnel.

In spite of these recommendations, smallpox vaccination is still widely practiced in this country. There are many physicians who disagree with the discontinuance of routine smallpox immunization and who vaccinate all children after their first birthday. Many adults are immunized for international travel, even though published requirements for entry into many countries no longer require it. Moreover, largely because of frustration with other therapeutic modalities, vaccination is widely performed for treatment of such common ailments as aphthous stomatitis, recurrent herpes labialis, and recurrent gential herpes, in spite of a conspicuous lack of evidence for its efficacy. It is hoped that, as the eradication of smallpox becomes a reality and with increasing education of physicians, these misguided practices will cease.

The ACIP enumerates the following contraindications to smallpox vaccination (1972):

Skin disorders. Eczema and other forms of chronic dermatitis in the individual to be vaccinated or in a household contact are contraindications to vaccination. An inquiry into the family history for skin disorders should always take place before vaccination. If vaccination is required for an individual with dermatitis because of potential exposure in an endemic or infected area, Vaccinia Immune Globulin (VIG) should be administered to the vaccinee at the time of vaccination. VIG will not prevent successful vaccination. If there is real need to vaccinate an individual who may thus create a hazard for a household contact with dermatitis, consideration should be given to separating the vaccinee from his contact until the vaccination lesion has healed.

Pregnancy. In rare instances, vaccinia virus crosses the placental barrier and infects the fetus. Of the few reported cases of fetal vaccinia, virtually all have followed primary vaccination. If vaccination is indicated because of possible exposure to smallpox, VIG should generally be given simultaneously with the vaccine, particularly in cases of primary vaccination.

Altered immune states. Leukemia, lymphoma, and other reticuloendothelial malignancies; dysgammaglobulinemia; therapy with immunosuppressive drugs, such as steroids and antimetabolites or radiation are strong contraindications to vaccination. Vaccination should be considered only under circumstances of actual smallpox exposure. If such a person is exposed to smallpox making vaccination mandatory, VIG should be given at the time of vaccination.

Analysis

1. *Efficacy.* Recommendations concerning effectiveness are based on the conviction that the protective effect of a smallpox vaccine is dependent on the strain of virus used, the infective titer of the product at the time of its use, and the mode of its administration. If these can be regulated, effectiveness will be assured in so far as possible.

2. *Safety.* Safety is to a large extent dependent on the strain of virus used, the mode of its administration, and the proper selection of recipients. Although immediate safety can be monitored for each product regardless of the strain of virus used in manufacture, possible long-term effects and rare events such as encephalitis may be difficult to control. Thus, for safety as well as efficacy, the virus strain appears to be important.

3. *Benefit/risk.* The benefit/risk ratio of smallpox vaccines varies with the circumstances of their use. In the United States the benefit probably exceeds risk only for travelers to endemic areas and for hospital and other personnel directly exposed to risk. This judgment is based on statistics of morbidity due to smallpox vaccination. The data are summarized in Table 9.

Table 9.—*Complications Associated With Smallpox Vaccination per 1 Million Vaccinations*

Complication	Complications per million primary vaccinations					Complications per million revaccinations—all ages
	Age at vaccination				All ages	
	<1	1 to 4	5 to 19	20+		
Death (from all complications)[1,2,3]	5.0	0.5	0.5	[6]	1.0	0.1
Postvaccinal encephalitis	6.5	2.2	2.6	3.5	2.9	0
Vaccinia necrosum[3]	0.0	0.4	1.0	6.9	.9	.7
Eczema vaccinatum[4]	14	44	35	30	38	3
Generalized vaccinia[4]	394	233	140	212	242	9
Accidental infection[4]	507	577	371	606	529	42
Erythematous urticarial reactions[5]	[6]	[6]	[6]	[6]	[6]	[6]

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[6] Unknown.

Source: "Morbidity and Mortality Weekly Report," 9/25/71, CFC, PHS, DHEW.

In 1968, there were at least 9 deaths due to vaccination (6 in primary vaccinees, 2 in revaccinees, and 1 in a contact), 16 cases of postvaccinia encephalitis (all in primary vaccinees), 11 of vaccinia necrosum (5 in primary vaccinees), 126 of ecxema vaccinatum (58 in primary vaccinees, 8 in revaccinees, and 60 in contacts), 143 of

generalized vaccinia, and 193 accidental infections. All of these figures are derived from reported cases. The true rates of the various complications of smallpox vaccination are unknown but are undoubted higher than this.

When there is danger of exposure to smallpox, the benefit-risk ratio rises. This important concept should be made clear to individuals using and receiving vaccine.

Recommendations

1. *Efficacy.* Because control of the strain of vaccinia virus in the vaccine appears to be the most feasible way of assuring efficacy, it is recommended that all manufacturers use the same strain and assure uniformity by use of a seed lot system. At the present time, only vaccine produced by certain manufacturers has been proven effective. The possibility should be explored that a primary seed lot produced by one of these manufacturers might be provided for use as seed for all licensed manufacturers. The regulation of the seed lot system can be based on the recommendations made in 1965 by WHO and incorporated in World Health Organization Technical Report Series, No. 323, Annex 4, Section 3.1, pp. 60–61, 1966.

2. *Potency.* Potency in vitro should be better defined. In this regard, we look on the rabbit scarification method as being inferior in its quantitative aspects to the pock counting method. It is recognized that a rabbit skin response possesses some physiologic meaning since it measures dermotropism as well as infective units, and in this and other respects it may be closer to a measurement of vaccine potency in man. However, control of vaccine strain and passage history should control these variables. Moreover, the use of the present "either/or" requirement does not seem logical if one system is clearly better than the other or if both are necessary. Therefore, in vitro potency should be defined by the pock counting method and, as at present, the vaccine lot in question should be compared with an FDA standard. The Panel notes with approval that the Commissioner published a proposed change to this effect in the **Federal Register** of March 14, 1975 (40 FR 11884), which was adopted November 19, 1976 (41 FR 51009) (21 CFR 630.70, 630.73, 630.74).

b. Each manufacturer should provide a clear statement of the product's potency in man. Each manufacturer should test initially, and in addition whenever there is a change in its manufacturing protocol, one lot of its vaccine in 50 primary vaccines, with a required take rate of greater than 95 percent.

3. *Sterility.* The Panel questions whether the present standards for sterility are adequate. It is recommended that the standards for percutaneous vaccine be raised to those for jet-gun vaccine (1 organism per 100 doses) and that the jet-gun vaccine be bacteriologically sterile.

4. *Extraneous organisms.* The question is raised as to whether in addition to bacteria, other types of extraneous organisms should be searched for in calf lymph vaccines. Because the potential presence of such organisms has not caused any proven problems, it seems appropriate that at this time the matter should be examined in research labpratories before any decisions are reached requiring such tests of the manufacturers. An effort should be made to examine smallpox vaccines for adventitious viral agents and particles, and to cultivate mycoplasmas from calf lymph before preservatives are added.

5. *Quality of vaccine.* The Bureau of Biologics should continue to examine records of each manufacturer to ascertain the consistency of quality in production of vaccine including any lots not submitted for release.

6. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP. Inclusion of the following specific information is emphasized:

a. Indications for vaccination, according to the latest recommendations of ACIP;

b. Contraindications and precautions for vaccination, according to the latest recommendations of ACIP;

c. Anticipated complications of vaccination, including all those mentioned by ACIP, with some information as to their expected frequency;

d. A dating of ACIP recommendations which are being quoted;

e. A statement that certain contraindications to vaccination may be only relative in the face of exposure to smallpox, and that in such cases vaccinia immune globulin should be used;

f. The strain of vaccinia virus used to make the vaccine;

g. The potency of the vaccine, in pock forming units per ml, as related to the United States Reference Smallpox Vaccine.

Review of Individual Smallpox Vaccine Products

Smallpox Vaccine in Three Formulations: Glycerinated Vaccine; Dried Vaccine; Dried Vaccine for Jet Injection Manufactured by Connaught Laboratories, Ltd.

1. *Description.* Complete details of the production and processing are supplied for each formulation which describe the origin of the virus (Bureau of Laboratories, Department of Health, New York City in 1927), its passage history (renewal approximately every two years, until 1967, by exclusive passage on calves), and seed-lot system in use since 1967, (no more than five passages removed from the primary seed lot). Also given are the details of production of secondary seed lots and final production lots on calves, including selection of calves, skin preparation, inoculation procedure, measures to minimize soiling of vaccination area, treatment of the vaccination area during the incubation period, and, finally, the harvesting of the pulp followed by necropsy to insure the calves were free of any pathological condition. From this point on processing of the pulp differs according to the final vaccine formulation desired. The following descriptions are quoted from the package inserts submitted to the Panel.

Smallpoc vaccine (glycerinated) "is a suspension of live vaccinia virus propagated on calf skin. The vaccine has been shown by appropriate test methods to contain not more than 200 nonpathogenic organisms per ml and it will retain its potency until the date stamped on the package, providing it is constantly kept at not above 0° C. The virus is quickly inactivated at room temperature."

Smallpox vaccine (dried) is prepared "from partly purified suspensions of vaccinia virus propagated on calf skin and shown by appropriate test methods to contain not more than 200 nonpathogenic organisms per cubic centimeter (cc). During the preparation of the vaccine small amounts of streptomycin and neomycin are added. When reconstituted with the diluent provided, the vaccine contains not more than 0.5 mcg streptomycin and 0.25 mcg neomycin per 0.01 cc (approximately 1 dose) as well as 0.3 percent phenol.

The dry powder dissolves without difficulty in the diluent which consists of 40 percent glycerin in McIlvaine buffer containing 0.2 percent phenol.

Smallpox vaccine (dried) for jet injection is prepared "from partly purified suspensions of vaccinia virus propagated on calf skin and shown by appropriate test methods to contain not

more than one organism per 100 doses. During the preparation of the vaccine small amounts of streptomycin and neomycin are added. When reconstituted with the diluent provide, the vaccine contains not more than 0.25 mcg streptomycin and 0.13 mcg neomycin per 0.1 cc (approximately 1 dose) as well as 0.3 percent phenol. The diluent contains 0.2 percent phenol."

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic reviews.

2. *Analysis.* Information concerning safety, bacterial contamination, potency, stability, and final identity is given in complete detail in sections II and IV of the corresponding separate partial submissions.

The glycerinated vaccine must contain at least 10^8 plague forming units (pfu) per ml of vaccinia virus and, after 18 hours incubation at 37° C, must retain at least 10^7 pfu. The vaccine must be innocuous for guinea pigs and mice, must contain no more than 200 viable nonpathogenic organisms per ml and must contain no pathogenic bacteria, as judged by inoculation into guinea pigs of positive cultures from the tests for viable bacteria. Identity of vaccinia virus is established by the agar gel immunodiffusion technique, using antivaccinia virus serum and normal rabbit serum. For the freeze-dried formulation, basically similar criteria must be met except that in the freeze-dried state there must be no more than 1 percent residual moisture and there must be no loss of potency during 30 days storage at 37° C. For the freeze-dried material intended for jet injection, the criteria for acceptance differ from those just described chiefly with respect to bacterial content. This must not exceed more than one non-pathogenic bacterium per 10 ml (100 doses) of reconstituted product.

a. *Efficacy.* Data concerning efficacy are provided in the form of detailed reports of clinical trials with material from each of the three formulations. The criteria for efficacy are the proportion of primary takes in previously unvaccinated individuals and major reactions in those undergoing revaccination. All three formulations performed satisfactorily.

b. *Safety.* Data concerning human safety are supplied in consolidated form for all three formulations. During 1960–1972, many millions of doses of vaccine were distributed. Review of the data submitted on complications attendant upon vaccination revealed no unusual rate for this product.

c. *Benefit-risk.* See generic review.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions.* a. *Critique.* This submission is well documented and fully adequate.

b. *Recommendations.* The Panel recommends that these products be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for these products.

Smallpox Vaccine, Avianized Manufactured by Lederle Laboratories Division, American Cyanamid Co.

1. *Description.* The package insert states the following:

> Smallpox vaccine, avianized, Lederle, is a suspension of vaccinia virus obtained from infected portions of the chorioallantoic membranes of embryonated chicken eggs. It is used for active immunization against smallpox * * * Antibiotics added to the virus inoculum in the preparation of this product are present in the final product at concentrations per vaccination which do not exceed 0.27 mcgm of neomycin sulfate, o.5 units of polymyxin B sulfate, and 0.03 mcgm of tetracycline. The vaccine is stabilized and preserved with approximately 45 percent sorbitol w/v. The product contains no more than 200 viable organisms per ml.

The history of the origin of the Lederle vacinia strain is throughly detailed in the supplement to the submission.

RIF-free flocks which "meet the requirements of U.S. Pullorum-clean standards" are used for the production of eggs.

Potency is measured in eggs, and an equivalence has been shown for the avianized vaccine of pfu to potency determined in rabbits by scarification.

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.*

a. *Efficacy.*

(1) *Animals.* Not pertinent.

(2) *Humans.* In their submitted material, and in information from the Bureau of Biologics there is adequate information to conclude that this vaccine produces takes in an acceptable proportion of both primary recipients and revaccinees. Actual protection against smallpox by egg-grown vaccines has been claimed by at least three groups quoted in a paper by Espmark, (Ref. 3). In addition, unpublished reports claim that egg-grown vaccines were largely responsible for the eradication of smallpox in Brazil. None of these reports refers specifically to the Lederle product.

More recently, the Lederle egg-grown vaccine has been compared to the Wyeth "Dryvax" in a detailed protocol involving primary vaccination, revaccination, and extensive serologic studies, which was coordinated by the Infectious Disease Branch of the National Institute of Allergy and Infectious Diseases. The results of this study support the conclusions that the avianized vaccine performed identically to the calf-lymph product, from the points of view of reactogenicity infectivity in human skin production of hemagglutination-inhibiting and neutralizing antibody and protection against subsequent challenge with a standard vaccination (Ref. 4). In this study, 143 children received the Lederle vaccine subcutaneously and none experienced necrotic local reactions.

b. *Safety.* (1) *Animals.* The required tests for sterility and animal safety are performed. As mentioned above, RIF-free eggs are used. It is of interest that in spite of claims of the manufacturer (which, it must be said, do not appear in the package insert or in advertising), that the egg product is bacteriologically safer than calf-lymph vaccine; 47 percent of the chorioallantoic membrane (CAM) pools were contaminated, in some instances exceeding the allowable standards. Sorbitol has a bactericidal effect.

(2) *Humans.* Reported complications for 1968–1973 are enumerated, but are marketing data are not, so a denominator is not available. The company does not report an excess of adverse reactions with percutaneous vaccine. An unpublished manuscript was brought to the attention of the Panel (Ref. 5). According to this report, about 15 percent of recipients of egg-grown (Lederle-produced) vaccine developed deep necrotizing reactions when jet injector vaccine was used. These findings were discussed by the manufacturer at a meeting, and no satisfactory explanation for the reactions emerged. The company has never marketed jet injector vaccine.

c. *Benefit/risk.* See generic review.

d. *Labeling.* Labeling should conform to the FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions.* a. *Critique.* The avianized vaccine is in many ways a product preferable to the calf-lymph vaccine. Specialized facilities are not needed for its production, bacteriologically sterile vaccine is a

resonable possibility, and production is efficient and inexpensive.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product. Additional analysis of the experience in India and Brazil with avianized vaccines, with special reference to effectiveness, should be done. In addition, the possibility of variable dermal toxicity among lots should be monitored because of the importance of this product and others like it in the future of smallpox vaccines.

Smallpox Vaccines Manufactured by Massachusetts Public Health Biologic Laboratories

No data have been provided by the manufacturer for Smallpox Vaccine for which they were licensed at the time this review was undertaken. In the absence of any information from the manufacturer, the Panel can make no determination regarding the relative benefits and risks of this product.

Recommendations. The Panel recommends that this product be placed in Category IIIB and that the appropriate license be revoked pending submission of evidence regarding the safety and effectiveness of this product.

Smallpox Vaccine Manufactured by Merck Sharp & Dohme, Division of Merck & Co., Inc.

This submission deals with a discontinued product. The submission and other available information fail to provide sufficient evidence to justify continued licensing. The license, therefore, should be revoked. It is recommended that § 601.5 be invoked whereby the Commissioner may recommend that a license may be suspended or revoked upon finding that "manufacturing of products or of a product has been discontinued to an extent that a meaningful inspection or evaluation cannot be made." Furthermore, if the manufacturer proposes to resume production, the Panel recommends that this product be placed in Category IIIB and that appropriate license(s) be revoked pending completion of additional testing and conformance with the recommendations of this report because there is no evidence presumptive of safety or effectiveness for this product.

The Panel believes that the Bureau of Biologics interpretation of the regulations concerning permissible combinations (21 CFR 610.17) of licensed products to mean that a manufacturer must hold a license for smallpox vaccine in order to purchase and market another producer's licensed smallpox vaccine for a combined product should be modified, and if necessary, the regulation should be changed to allow an exception to be approved in this and perhaps other related instances.

Smallpox Vaccine and Smallpox Vaccine Freeze-Dried Manufactured by Merrell-National Laboratories, Division of Richardson-Merrell, Inc.

1. *Description.* Liquid vaccine is stated to be a glycerinated live virus vaccine, prepared from calf lymph * * *. The vaccine has been shown by appopriate test methods to contain not more than 200 organisms per ml. For color contrast, brilliant green (1:6,000) has been added. Preservative: 0.4 percent phenol. [The freeze-dried vaccine] contains a purified suspension of the live virus of vaccinia (cowpox) and is derived directly from calf lymph. The vaccine has been shown by appropriate test methods to contain not more than 200 organisms per ml. The purified virus, prior to freeze-drying, is suspended in an aqueous solution of sodium chloride (0.85 percent), 1:10,000 benzalkonium chloride, 1:6,000 brilliant green for color contrast and stabilized with peptone (5 percent). The diluent for the reconstruction of Smallpox Vaccine, Freeze-Dried consists of glycerin 50 percent in sterile distilled water. The preservative is phenol (0.25 percent).

Potency in vitro is measured in pock-forming units in relation to FDA standards and is acceptable (data supplied on five lots).

The manufacturing process is adequately described; although care of the calves and harvest of lymph are not outlined in the submission, subsequent treatment of the vaccine is detailed.

a. *Recommended use.* See the generic discussion.

b. *Contraindications.* See the generic discussion.

2. *Analysis.* a. *Efficacy.* (1) *Animals.* Not pertinent.

(2) *Humans.* Data are submitted for trials in 1961 when 19 primary vaccinees (out of 19) had takes, and the considerable data on revaccinees indicate a potent vaccine.

b. *Safety.* (1) *Animals.* The product satisfies the FDA regulations in regard to sterility and animal safety.

(2) *Humans.* The information presented is based on the marketing experience from 1968 through 1972 and includes many millions of doses of both liquid and freeze-dried vaccine. Review of the data submitted on complications revealed no unusual rate for this product.

c. *Benefit-risk.* See generic review.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the Federal Register of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions.* a. *Critique.* See the generic product review.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Smallpox Vaccine Manufactured by Division of Biologic Products Bureau of Laboratories, Michigan Department of Public Health

1. *Description.* The vaccine consists of a 50 percent suspension in glycerol with 0.5 percent phenol of liquid vesicular material from healthy calves vaccinated with vaccinia virus. This suspension is put up in capillary tubes, five per package, together with scarifying needles and rubber bulbs.

The virus strain employed is derived from strain #999 obtained in 1937 from the Massaschusetts Antitoxin and Vaccine Laboratory (the origin of strain #999 is not known). Since then, it has been given annual cycles of rabbit-calf passage, with each calf passage providing the seed for one season.

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.* a. *Efficacy.* Prior submissions, together with supplementary ones, report on tests of activity of smallpox vaccine conducted from 1948 through 1972. The results are summarized in Table 10.

Table 10.—*Results of Potency Tests, Smallpox Vaccine, Michigan Department of Public Health*

Year	Results of vaccination (takes/recipients)	
	Primary vaccination	Revaccination
1948	2/2	6/7 (1 [1])
1950	6/6	17/38 (21 [1])
1958	5/5	5/10 (5 [1])
1963	8/8	
1965	9/9	
1970–72	24/26	21/35

[1] Classed "immune."

Such tests are conducted periodically. The results suggest potency for man is basically adequate for primary vaccination. The record for revaccination, 49/90 or 55 percent, is less reassuring but may reflect a combination of poor vaccination technique, the inclusion of many recently vaccinated persons, and failure to use WHO criteria for classification of response.

b. *Safety.* (1) *Animals.* The submission cites the standard tests in animals and the potency test in rabbits.

(2) *Humans.* Data are provided on millions of doses distributed between 1961–72. A review of the data submitted on complications revealed no unusual rate for this product.

c. *Benefit/risk.* See generic review.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions.* a. *Critique.* See generic review.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Smallpox Vaccine ("Dryvax") Manufactured by Wyeth Laboratories, Inc.

1. *Description.* This is a lyophilized preparation of calf lymph containing vaccinia virus. The vaccine is reconstituted with 50 percent glycerine for inoculation by the multiple pressure technique or with .02M phosphate buffered saline for administration by jet gun. The reconstituted vaccine contains no more than 200 organisms per cc and the upper limits of the antibiotics employed during processing are stated as being not more than 100 u/cc polymyxin, 200 mcg/cc dihydrostreptomycin, 200 mcg/cc chlortetracycline, and 100 mcg/cc neomycin.

Vaccine comes with or without brilliant green, and in a form intended for jet-gun use only or in one not intended for jet-gun use.

Potency is measured *in ovo* by pockforming units and is adequate and well defined for two lots.

The production method is well described in material provided by the Bureau of Biologics from its license files.

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.* a. *Efficacy.*

(1) *Animals.* Not pertinent.

(2) *Humans.* The recording of take rates (both primary and revacination) is adequate. Wyeth Laboratories, Inc., in addition, submitted the following statement:

> Wyeth was the principal supplier of vaccine to a major phase of the eradication program carried out in West and Central Africa in addition to its contributions to other parts of the global program.

b. *Safety.* (1) *Animals.* The Bureau of Biologics' requirments for sterility and animal safety are satisfied.

(2) *Humans.* Minor complications of vaccination are well detailed in the data for Wyeth's product. However, the manufacturer does not submit either marketing data or data on major complications reported to them.

c. *Benefit-risk.* See generic review.

d. *Labeling.* Labeling should conform to the FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federl Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions.* a. *Critique.* See generic review.

b. *Recommentations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

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Generic Review of Measles Virus Vaccine

Background

Live measles virus vaccine falls into two generic categories: (1) attenuated Edmonston strain, and (2) further attenuated strains derived from the Edmonston strain.

About 4 million cases of measles, almost as many as the number of births each year, occurred annually in the United States before the development and widespread utilization of live attenuated measles vaccines. There were about 450 measles-associated deaths per year. The most frequent severe complications of measles were pneumonia and acute encephalitis; the latter occurred in 1 per 1,000 cases of natural measles infection (Ref. 1). In addition to this acute neurologic complication of measles infection, a much less common chronic form of encephalitis, which is fatal, occurs in approximately 0.5–1.0 case per 100,000 cases of measles infection. This chronic encephalitis associated with measles infection is called subacute sclerosing panencephalitis (SSPE).

In the late 1950's, John F. Enders and Samuel L. Katz initiated development of a live attenuated vaccine using the Edmonston strain of measles virus. This virus was repeatedly subpassaged in a variety of laboratory hosts. Each of the currently licensed vaccines was originally derived from one of two virus passage levels designated as the Enders A and the Enders B level, respectively. The passage history is shown in Table 11.

Table II.—*Derivation of the Enders A and Enders B Lines From the Edmonston Strain of Measles Virus*

Viral substrate	Number of serial passages
Primary human embryonic kidney (HEK)	24
Primary human amnion (HA)	28
Embryonated egg (E)	6
Chick embryo cell culture (CETC)	[1]13-A
Embryonated egg (E)	6
Chick embryo cell culture (CETC)	[1]3-B

[1] Level.

Thus a pool of virus (designated as 373C) at the A passage level was HEK–24 HA–28 E–6 CETC–13. The B passage level pool (designated as 749D) was HEK–24 HA–28 E–6 CETC–13 E–6 CETC–3.

The first vaccine was licensed in 1963 and by 1965 several other manufacturers received licenses. These vaccines were commonly administered in conjunction with Measles Immune Globulin (Human) in order to decrease the rates of reactivity (febrile response and rash) seen following vaccination. In 1965 and 1968, vaccines prepared from derivatives of the Edmonston virus obtained after additional serial laboratory passage were licensed. These vaccines were less reactogenic for man and could be administered without the concomitant use of globulin. Such preparations are currently the most commonly used.

Following the widespread use of measles vaccine, there has also been a

dramatic decrease in the number of measles associated deaths. This is due in large part to the high protective effect of the vaccine, the elimination of complications such as pneumonia, and the low incidence of acute neurologic disorders following administration of measles vaccine; the latter incidence is not very different from the "background" rate of encephalitis in young children (approximately one case per 1 million children as compared to a rate of one case of acute encephalitis per 1,000 children following natural measles infection). The earliest live attenuated measles vaccines had an incidence rate of associated extensive neurologic disorders of 1.61 per 1 million doses of measles vaccine, and the further attenuated vaccines subsequently developed have a lower incidence rate of 0.78 cases of acute encephalitis per 1 million doses of vaccine. Thus, the use of measles virus vaccines has led to a marked decrease in acute encephalitis due to measles infection.

However, the effect of measles vaccines on the incidence of the chronic type of encephalitis (SSPE) associated with measles virus infection is more difficult to discern. There are two major reasons for this: (1) The incidence of SSPE prior to the introduction of measles vaccine is not well defined. Several names were applied to the clinical syndrome and their identification as a single illness was not made until the association of measles with this disorder was confirmed in the late 1960's. In the absence of intensive prospective and retrospective studies, therefore, it was difficult to determine the incidence of SSPE until the early 1970's. (2) Although the interval between infection with measles virus and the expression of the clinical disease is variable, it is usually quite long, averaging 7 years.

Recently, more complete information has been obtained by the Bureau of Biologics, the Center for Disease Control, and scientists at the University of Tennessee relative to the epidemiology of SSPE during the past 8 years (Ref. 2). Some important epidemiologic findings have been made. The annual incidence of this rare but fatal disease has been decreasing the past few years in the United States (approximately 45 cases of SSPE occurred annually between 1966–1971, but in 1975 and 1976 there were 12 and 10 new cases, respectively, in the United States). The following findings were observed in patients with SSPE who had a history of measles immunization: (1) there was no relationship between onset of SSPE and age at time of vaccination; (2) SSPE occurred a mean of 3.3 years after vaccination, and (3) the potential risk was 0.48–1.13 cases of SSPE per million estimated measles vaccine recipients.

A recent update of this carefully case-controlled study (published in "Morbidity and Mortality Weekly Report," September 23, 1977) reported as follows:

> Fifty-two children with SSPE diagnosed since January 1, 1974, were each matched by age, sex, and race with both a long-term playmate and a hospitalized child. Vaccination and disease histories, verified by medical records review, were available for all cases and for 96 controls (Table 1). Children with SSPE were significantly more likely to have had natural measles than were controls ($p > .001$). Control children were significantly more likely to have received measles vaccine than were SSPE cases ($p > .001$). There was no difference between cases and controls with regard to having received measles vaccine after having had natural measles (21.2% vs 20.8%).

Table 1.—*History of Measles Infection and Measles Vaccination in 52 Children With SSPE and 96 Control Children*

Measles disease/vaccine history	SSPE cases (percent)	Controls (percent)
Had natural measles; no measles vaccination	32 (61.5)	25 (26)
Had natural measles; received measles vaccine	11 (21.2)	20 (20.8)
Had no history of measles; received measles vaccine	6 (11.5)	43 (44.8)
Had no history of measles or measles vaccination	3 (5.8)	8 (8.3)
Total	52	96

Two SSPE cases (3.8%) and 4 control children (4.2%) had received 2 or more doses of measles vaccine. Eleven SSPE cases (21.2%) had natural measles before they were 1 year old compared to 4 control children (4.2%) ($p > .01$). Four control children but none of the SSPE cases had received measles vaccine before they were 1 year old.

In short, it appears that utilization of measles vaccine has been associated with no detectable increase in the number of new cases of SSPE in the United States. In fact, the data currently available suggest that if there is any risk of developing SSPE following measles vaccination, it would be less than that associated with the alternative, i.e., natural infection with the virus. Obviously, more data are needed concerning these relationships (Ref. 3).

The Public Health Service Advisory Committee on Immunization Practices generally recommends that all susceptible children, i.e., those who have not had measles or measles vaccine, should be vaccinated after 1 year of age (15 months) with a single dose of live measles virus vaccine (Refs. 4 and 5). If an Edmonston B strain vaccine is to be used, it is recommended that it be accompanied by measles immune globulin, 0.01 ml/lb of body weight, given with different syringes at different sites. Measles immune globulin should *not* be given with further attenuated measles vaccines.

In the face of an epidemic or in areas with high measles incidence in the first 15 months of life, it may be desirable to vaccinate infants as young as 6 months of age, in which case these children should be revaccinated after reaching 15 months of age.

It is further recommended that children vaccinated before the age of 13 months, particularly if measles immune globulin was given concomitantly, be revaccinated. Also children who received killed measles vaccine should be vaccinated with live vaccine. High risk groups in which immunization is particularly important include children with chronic illnesses such as heart disease, cystic fibrosis, and tuberculosis, and those who are malnourished or institutionalized.

It is noted that live measles vaccine can usually prevent disease if administered within 2 days of exposure. It is rarely necessary to immunize adults, but no special untoward effects have been noted when this is done.

Precautions listed include: severe febrile illness, tuberculosis not under active treatment, recent administration of immune serum globulin (within 3 months), or marked hypersensitivity to vaccine components (chicken protein, etc.).

Contraindications listed include: altered immune states (leukemia, lymphoma, generalized malignancy, chemical immunosuppression, radiation therapy) and pregnancy.

The Food and Drug regulations governing manufacture of live, attenuated measles virus vaccines include specification of a seed lot system, with appropriate testing of new seed lots for neurovirulence. Chick embryo tissue must be derived from flocks certified to be free of obvious fowl pathogens and of avian leucosis, Rous sarcoma and "other adventitious agents pathogenic for chickens" (21 CFR 630.32(b)).

Virus in the final vaccine must be no more than ten tissue culture passages beyond the passage used to perform the clinical trials which qualified the manufacturer for license of that strain. Only primary cell cultures shall be used in the manufacture of Measles Virus Vaccine, Live, Attenuated.

Additional testing for safety includes mouse inoculation (21 days' observation of adult mice, 14 days' observations of

suckling mice), inoculation of embryonated chicken eggs, and inoculation of monkey, chick, and human cell cultures. Bacteriologic and complement-fixation for avian leucosis virus (COFAL) testing are done.

The potency required is "no less than the equivalent of 1,000 $TCID_{50}$ of the U.S. reference per human dose" (21 CFR 630.34).

Labeling requirements include specification of dose and a statement of caution about inactivation by temperature and light.

Analysis

1. *Efficacy.* Experience in the use of live, attenuated measles vaccines now covers more than 12 years and some 80 million doses. In terms of seroconversion, all preparations result in at least 95 percent responses in susceptibles over the age of 13 months. In addition, in epidemic situations the protective efficacy has ranged from 83 to 98 percent. Groups of apparent vaccine failures include:

a. Those who received killed measles vaccine or followed shortly thereafter by live vaccine when it was available before 1968;

b. Those who received live attenuated measles virus vaccine, Edmonston B strain, with or without human immune serum globulin (ISG) before 13 months of age;

c. Those who received further attenuated measles virus vaccine with ISG in a dose intended for use with the more reactive Edmonston B vaccine;

d. Those who received live measles vaccine that had lost its potency because of exposure to excessive light or heat.

Duration of protection has been well evaluated in several studies. Adequate levels of antibody have been demonstrated 11 years postimmunization in nearly all vaccines with no exposure over the intervening years; thus, there is no evidence at present to suggest the need for reimmunization in general.

2. *Safety.* Both the Edmonston B and further attenuated vaccine strains have been shown to be remarkably safe in terms of major complications. In fact, the incidence of neurologic illness occurring within 4 weeks of measles vaccination is as low as, if not lower than, that in the general population, i.e., 2 per million per 4 week interval. In only one instance has isolation of a measles vaccine-like virus actually substantiated a possible association of vaccination and neurologic disease. It is noteworthy that the risk per million in the past few years has been substantially lower than in the first years of immunization with attenuated virus, which suggests that the further attenuated strains in current use may be even safer than the Edmonston B type of attenuated virus vaccine. However, this is a minor point since at no time has clear proof been addressed to indicate the vaccine as etiologically responsible for neurologic disease at or above background levels.

In terms of minor complications, the Edmonston B type vaccine must be distinguished from further attenuated strains. The former evokes a modified measles rash in 30 to 60 percent of instances, and significant percentages of recipients experience fever of 103° F or greater lasting 2 to 5 days. While these manifestations are usually not accompanied by toxicity or significant disability, they are sufficiently prominent to result in the recommendation that gamma globulin be given simultaneously. This additional procedure introduces an entirely new set of risks (e.g., second injection; dosage error resulting in failure of vaccine take, etc.). This makes this class of measles vaccine less useful in the overall balance than the further attenuated vaccines. These latter preparations evoke only mild manifestations (low grade fever and/or rash in up to 20 percent of recipients) and at a level insufficient to necessitate gamma globulin administration.

3. *Benefit/risk.* All of the above considerations result in an excellent benefit/risk ratio. The benefit of widespread, early vaccination of susceptibles against measles is clear: the prevention of approximately 95 percent of instances of measles, with a durable protective immunity. Unmodified measles is associated with a risk of numerous respiratory complications and about one instance of overt encephalitis per 1,000 cases of measles, at least 400 deaths per year, and unmeasured additional instances of minimal neurologic damage. The risk of the vaccine is, at most 2 per million doses distributed in terms of major neurologic disease, so that the benefit to risk ratio is enormously in favor of live attenuated measles virus immunization. (see Fig. 3.)

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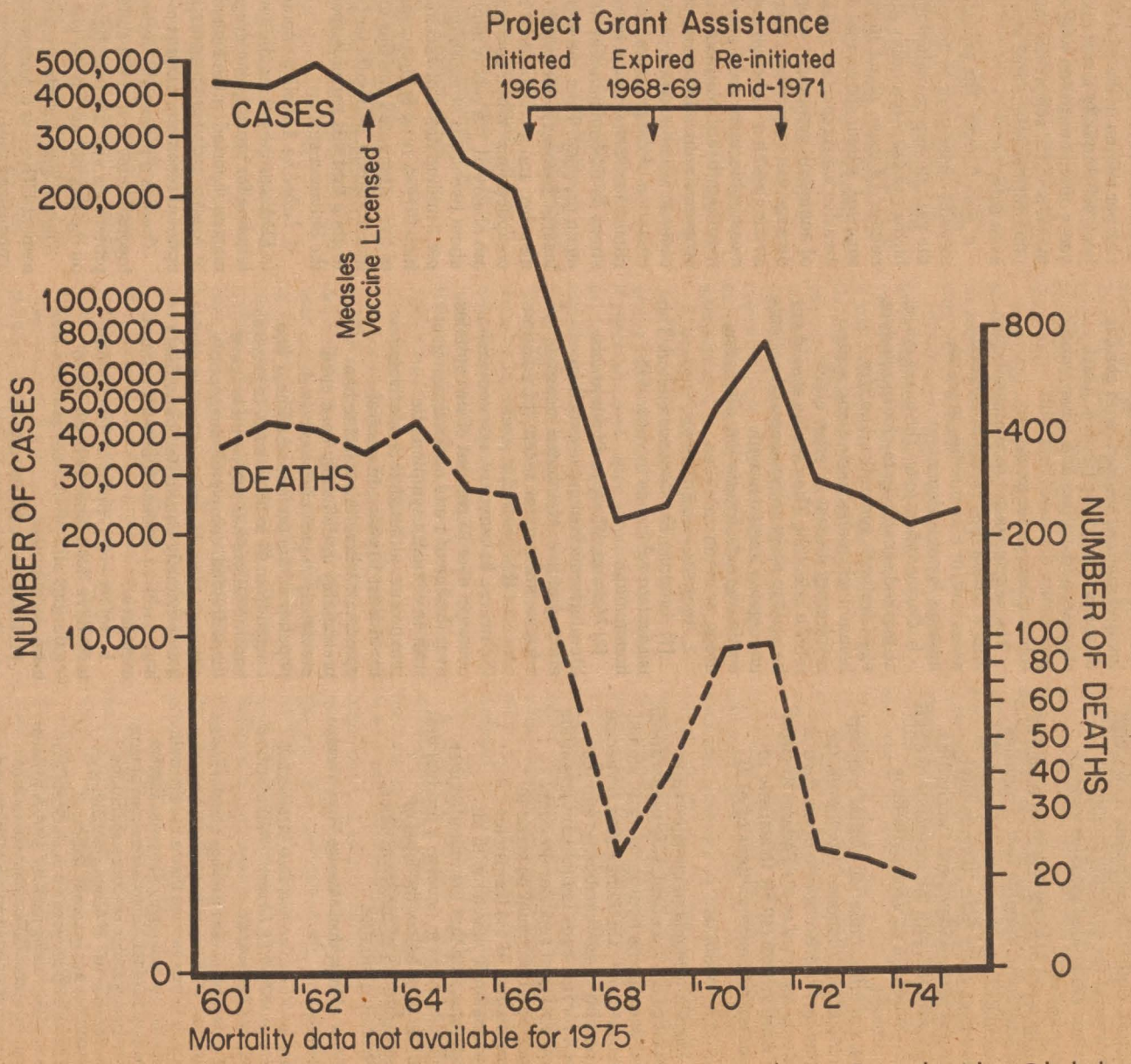
Figure 3

Reported Measles Cases and Deaths, United States - 1960-1975



Source: Center for Disease Control, Bureau of State Services, Immunization Division

The Edmonston strain clearly has a greater risk of minor complications and gamma globulin adds additional risk factors. Both of these points thus weigh in favor of the currently employed further attenuated measles vaccine preparation.

The issue of SSPE has been raised as an additional possible risk of measles vaccination, as it is of measles itself. However, more than 10 years have passed since widespread vaccination was initiated, and the incidence of SSPE has decreased as vaccination has continued.

4. *Labeling. Labeling should conform to the FDA's proposed regulations for labeling for prescription drugs used in man as reported in the* **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

Recommendations

Further attenuated measles virus vaccines are excellent, safe preparations and licensure is appropriate and should be continued. The Edmonston B vaccine is notably more reactogenic and the need for it is questionable in view of the availability of superior products. Consideration might be given to continuance of the license for Edmonston B vaccine with the understanding that the manufacturer will take steps to develop a product that will be at or below the level of reactogenicity of other vaccines currently available.

Review of Individual Measles Virus Vaccine Products

Measles Virus Vaccine, Live, Attenuated (Schwarz Strain) ("Lirugen") Manufactured by Dow Chemical Co.

1. *Description.* The package circular states that it is * * * a highly attenuated measles (rubeola) virus vaccine that is usually well tolerated but still highly antigenic. Further attenuation of the Edmonston strain of virus decreases systemic reactions so that the simultaneous use of gamma globulin with LIRUGEN is not generally indicated.

The virus is propogated in chick embryo tissue culture using medium '199'. A residual of not more than 50 micrograms each of neomycin B sulfate and stretomycin and 0.000001 micrograms of amphotericin B are present per dose * * *.

Each single dose of LIRUGEN contains no less than 1,000 $TCID_{50}$ of measles virus expressed in terms of the assigned titer of NIH reference measles virus.

a. *Recommended use.* * * * for active immunication of children against measles (rubeola). It will not immunize against German measles (rubella). The vaccine should be administered to measles-susceptible children at 12 months of age or as soon thereafter as possible to provide protection in early life. * * * may be given as early as 9 months, repeating the injection at 12–14 months of age to assure an immune repsonse.

The vaccine is particularly recommended for children in institutionalized settings, with chronic diseases (e.g., cystic fibrosis, heart disease, and asthma and other chronic pulmonary diseases) and with tuberculosis under treatment.

The vaccine is not recommended for adults unless they reside in isolated areas and/or communities in which measles is not endemic.

b. *Contraindications.* These are given as marked sensitivity to chicken protein, eggs, feathers, generalized and/or hematologic malignancies, and acute respiratory disease or other active febrile infection. The vaccine should not be used in pregnant women and patients undergoing treatment with corticosteroids, irradiation, alkylating drugs, or antimetabolites.

2. *Analysis.*—a. *Efficacy.*

(1) *Animals.* The data are limited. This is of minor relevance in view of the human data.

(2) *Humans.* There is an enormous literature concerning the excellent efficacy of live, attenuated measles vaccine; much of the recent information concerns this particular strain (Schwarz). In summary, seroconversion occurs in over 95 percent of susceptibles over the age of 1 and antibody persists with or without asymptomatic reexposure, although it is relatively low for at least 10 years. In several epidemics where this vaccine has presumably or definitely been used previously in part of the exposed population, the protective efficacy has ranged from 91 to 98 percent. In general, vaccine failure has appeared to leave the individual completely susceptible, although there is some suggestion that a few previously vaccinated individuals had modified disease following natural exposure.

b. *Safety.*—(1) *Animals.* The routine tests have been done as required by regulations and no evident problem has been encountered.

(2) *Humans.* A febrile and/or exanthematous reaction occurs in approximately 20 percent of children. Precautions in giving the vaccine to children known to have febrile convulsions, cerebral injury, etc., are well delineated. The major risk is neurologic. Data concerning the occurrence of significant neurologic disease within 4 weeks of administering any live measles vaccine assign a risk of less than 2 per million doses, which is slightly lower than the random risk. In only one instance, a measles vaccine-like virus has been isolated, which serves to support a possible association of vaccination and disease. All other evidence has been serologic and/or circumstantial. It is noteworthy that the risk per million in the past few years has been substantially lower than in the first years of immunization with attenuated measles virus, suggesting that this and other further attenuated strains may be even safer.

c. *Benefit/risk.* The annual number of measles cases prior to introduction of the vaccine approximated the number of births per year—probably about 4 million. Of these, about 10 percent were reported. About 400 annual deaths from measles were reported; 750 annual cases of nonlethal, permanent neurologic damage were reported; other less striking residua, although not measurable, were quite possibly even more significant. National vaccination programs reduced this rate of reported cases to about 20,000; with temporary cessation of the program, the rate climbed to 75,000; and with renewed stress on immunization in 1971, it has again dropped. Thus, the benefit is at least 90 percent reduction in cases of measles, and a concomitant reduction in complications. When contraindications are observed, the risk is minimal, i.e., about two cases of neurologic disease per 2 million doses of vaccine. Thus, the benefit/risk ratio is enormously in favor of live, attenuated measles virus vaccine immunization, and sufficient data exist to state that this pertains specifically to the Schwarz strain.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and the updated recommendations of ACIP.

There is a potentially serious inconsistency in that the statement to protect the vaccine from light appears on the box but not on the vial.

The package inserts are good in most respects. There is a commendably emphasized note concerning potential confusion of rubeola with rubella.

3. *Conclusions.*—a. *Critique.* This submission is extensively supported by an accompanying literature, both published and preprinted.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Measles Virus Vaccine, Live, Attenuated (M–VAC) Manufactured by Lederle Laboratories Division, American Cyanamid Co.

1. *Description.* The package circular states that M–VAC Measles Virus Vaccine, Live, Attenuated, Lederle, is a suspension of Edmonston strain measles virus, live, attenuated, propagated in chicken embryo cell culture. The virus suspension is stabilized with a protein (casein) hydrolysate and sorbitol, and then lyophilized. Each single dose vial contains not less than 1,000 $TCID_{50}$ of measles virus expressed in terms of the assigned titer of the Bureau of Biologics reference measles virus. A dose contains about 50 micrograms each of streptomycin and neomycin.

a. *Recommended use.* "* * * for immunization of all susceptible children against measles (rubeola)." The product is especially recommended for children with malnutrition, chronic illness (heart disease, cystic fibrosis, chronic pulmonary diseases), and those in institutional settings. For maximum efficacy, the vaccine "should be administered when children are at least 12 months old. When used * * * between 6 to 9 and before 12 months of age, there occurs some reduction in efficacy and repeat immunization (booster) after 1 year of age is recommended."

The live virus vaccine is recommended for all children who received inactivated measles virus vaccine. "The vaccine is not effective in the prevention of rubella (German measles)."

b. *Contraindications.* These are given as pregnancy; leukemia, lymphoma, and other generalized malignancies; during or following therapy which depresses cell-mediated immunity or resistance to disease such as steroids, irradiation, alkylating agents, and antimetabolites; severe febrile illness; active tuberculosis unless under active treatment; and known or suspected hypersensitivity to chicken egg protein. There is an added, excellent statement that if immediate protection against measles is required and vaccine is contraindicated, passive immunization should be considered and the dosage of gamma globulin is given.

2. *Analysis.*—a. *Efficacy.*

(1) *Animals.* The data are of minor relevance in view of data on man.

(2) *Humans.* The present product has the properties of Edmonston strain; 95 percent or more of susceptibles convert serologically; immunizing efficacy has been shown in community and institutional settings; and durable immunity persisting for at least 10 years has been demonstrated with or without asymptomatic reexposure. Antibody titers achieved after immunization of susceptibles with Edmonston strain attenuated measles virus have been found to be higher than those induced by further attenuated strains, but in both instances antibody persistence is of long duration.

b. *Safety.*—(1) *Animals.* The data given are appropriate, but they are not as germane as those dealing with experience in man.

(2) *Humans.* Minor complications, viz., fever and rash, are a frequent concomitant of this product; even when gamma globulin is given simultaneously, the incidence of fever over 103° F appears to be about 15 percent. Major complications have not been conclusively demonstrated, even though many millions of doses of Edmonston strain measles vaccine have been administered.

c. *Benefit/risk.* See generic review. The Edmonston strain clearly has a greater risk of minor complications (high fever, rash), and, since gamma globulin is recommended for simultaneous administration, several additional factors must be considered beyond those pertinent to the further attenuated measles vaccines. In favor of the Edmonston strain is its greater immunogenicity, as indicated by higher titers of HI antibody. However, there is no evidence of greater persistence of the antibody response elicited.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP. In addition, the label should state that the high incidence of febrile reactions can be decreased by a simultaneous inoculation of measles immune globulin.

3. *Conclusions.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product. While this product is effective and safe with respect to major complications, it is more frequently associated with minor complications than are the more attenuated measles vaccines, and it is recommended in conjunction with gamma globulin whereas the others can be given alone.

Measles Virus Vaccine, Live, Attenuated, MSD (Attenuvax) Manufactured by Merck & Dohme, Division of Merck Sharp & Co., Inc.

1. *Description.* The package circular states that Attenuvax (measles virus vaccine, live attenuated, MSD) is a measles virus vaccine prepared by using a more attenuated line of measles virus derived from Enders' attenuated Edmonston strain. The further modification of the virus in ATTENUVAX was achieved in the Merck Institute for Therapeutic Research by multiple passage of Edmonston virus in cell cultures of chick embryo at low temperature. Clinical studies have demonstrated that ATTENUVAX is highly immunogenic and well tolerated. The coadminstration of human immune globulin has not been necessary for reduction of clinical reactions. A single injection of the vaccine has induced a measles antibody response in 97 percent or more of susceptible persons.

a. *Recommended use.* The preparation is intened for active immunization of children 1 year of age or older against measles (rubeola). In high risk situations, the vaccine may be given as early as 9 months of age. It is especially recommended for children in institutions, those with inactive tuberculosis or tuberculosis under treatment, or with chronic disease (e.g., cystic fibrosis, heart disease, asthma or other chronic pulmonary disease). It is recommended for adults only if their isolated circumstances warrant, e.g., residence in nonendemic areas.

b. *Contraindications.* These are given as sensitivity to eggs, chickens, chicken feathers, or neomycin; febrile illness; active untreated tuberculosis; leukemia, lymphoma, or other generalized malignancies; patients undergoing therapy with corticosteroids, irradiation, ACTH, alkylating agents, antimetabolities, gamma globulin deficiency (i.e., agammaglobulinemia, hypogammaglobulinemia, or dysgammaglobulinemia); and pregnancy.

2. *Analysis.*—a. *Efficacy.*

(1) *Animals.* The data available are limited and are of minor relevance in view of data on man.

(2) *Humans.* The general efficacy of live attenuated measles vacines has been well established. With specific reference at Attenuvax, three studies are cited in which 96 to 100 percent of susceptibles serocoverted (N=approximately 180) as measured by the hemagglutination-inhibition test. In addition, Attenuvax was one of the vaccines represented in studies of outbreaks in 1969–1971 in which vaccination was shown to be 90 to 95 percent protective.

b. *Safety.* Routine tests have been done in animals as required by Federal regulations. No evidence is given that problems have been encountered. The major (neurologic) risks appears to be 2

per million or less and in no instance has the association of neurologic complications with vaccination been more than circumstantial. (See also the generic statement for measles vaccine.)

c. *Benefit/risk.* See generic review.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

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Generic Review of Mumps Virus Vaccines

Background

Mumps is a relatively benign disease of childhood with a low case fatality rate and usually only a moderate morbidity. Many patients do not manifest parotitis and there is a substantial incidence of asymptomatic infection. The meningoencephalitis occasionally associated with mumps is usually uncomplicated and self-limited. The greatest stimulus for prevention of mumps by vaccine comes from the feared occurrence of orchitis in postpubertal males. While this is documented to occur with a frequency as great as 20 percent (in epidemic situations as occur in the military), the incidence of subsequent sterility is very low.

While live, attenuated vaccines for mumps had been developed in other countries earlier, the only vaccine available in the United States until 1967 was a killed virus preparation, inactivated with formaldehyde and evaluated for potency by its ability to evoke an antibody response in guinea pigs. The efficacy of this preparation is very much in question (see below).

In 1967, a live, attenuated mumps virus vaccine (virus grown in chick embryo cell cultures) was introduced, and since then it has been used widely with clearly demonstrated safety and efficacy.

The Public Health Service Advisory Committee on Immunization Practices emphasizes its recommendation that mumps immunization programs should not be allowed to take priority over more essential ongoing community health activities. However, whatever resources are sufficient, incorporating live mumps vaccine into routine childhood immunization programs is desirable. The combination live virus vaccines which include mumps antigen can be particularly efficient for this purpose. Keeping this in mind, the Panel recommends that it be given at any age over 1 year, especially to children approaching puberty, to adolescents, and to adults, especially males, who have not had mumps or who have no serologic evidence of mumps immunity. Under those circumstances, a single dose subcutaneously is given, with no booster required. It is cautioned that the vaccine does not offer postexposure protection, but in the case of ineffectual exposure it will then offer immunity and will do no harm.

Precautions include severe febrile illnesses, hypersensitivity to vaccine components (egg proteins), leukemia, lymphoma and other generalized malignancies, therapeutic immunosuppression, and pregnancy. No contradictions are specifically listed.

The FDA regulations governing manufacture of live, attenuated mumps virus vaccine include a seed lot system; propagation in chick embryo cell cultures from eggs of flocks free of Rous and avian leukosis viruses as well as fowl pathogens; neurovirulence safety testing in monkeys of seed lots, and safety testing in adult and suckling mice, monkey and human cell cultures, and embryonated chicken eggs, as well as the usual bacteriologic screening; and a minimum potency of 5,000 $TCID_{50}$ per dose. The labeling should include warnings concerning photochemical deterioration as well as dose designation.

Regulations governing manufacture of formaldehyde-inactivated mumps virus vaccines date back to September 4, 1952 and will not be reviewed in detail herein. The most pertinent feature is the potency of the vaccine. As measured by a complement fixation test, at least a 1:16 dilution of test vaccine should yield 4+ fixation against 4 units of mumps immune serum.

Analysis

1. *Efficacy.*—a. *Live attenuated mumps virus vaccine.* There is wide experience with attenuated mumps virus vaccine and excellent documentation of its efficacy. An example is shown in Table 12, taken from Hilleman et al. (Ref. 1).

Table 12.—*Evaluation of Protective Efficacy of Mumps Virus Vaccine Among Initially Susceptible Children—Comparison of Attack Rates for Laboratory-Proved Cases of Natural Mumps Among Vaccinated and Controls*

Time period after vaccination to challenge	Group	Vaccinated cases/risk	Percentage	Unvaccinated cases/risk	Percentage	Efficacy percentage
0 to 10 months	Family	2/29	6.9	50/59	84.7	91.7
	Classroom	2/114	1.8	49/113	43.4	95.9
11 to 20 months	Family	1/14	7.1	22/24	91.7	92.3
	Classroom	1/28	3.6	24/40	60.0	94.1
Total	All	5/174	2.9	133/224	59.4	95.1

Neutralizing antibody was shown to persist for at least 8 years after vacinnation, and protective immunity was retained through the 8 observation years (the attack rates of children exposed to mumps were 0/18 in vaccinies and 27/35 in the unvaccinated).

B. *Mumps vaccine, killed.* Essentially no data are available to document the efficacy of this preparation in the prevention of mumps. A study by Habel in 1951 (Ref. 2), which suggested protection by a killed mumps virus vaccine, used a different preparation, one in which the vaccine was mixed with a peanut oil-beeswax adjuvant. A study by Meyer et al. in 1966 (Ref. 3) used the presently available type of preparation in parents, who were seen when their children had mumps and who themselves had not had the clinical disease. In their group of 176 vaccinees,

there were 14 clinical cases of mumps (8 percent) in comparison to six cases of the clinical disease among 153 controls (3.9 percent).

Thus, no efficacy was demonstrated by this study using two sub-cutaneous injections of 1.0 ml each approximately 1 week apart.

Sood used a current preparation (2 doses of 1 ml each at an interval of 2 weeks) in Gorkha recruits (Ref. 4). There were 51 cases of mumps among 1,000 vaccinees, and 94 among 1,040 controls, giving a coefficient of vaccine effectiveness of 1.4.

Disregarding those cases which occurred within the first 3 weeks, there was a reduction in incidence of mumps in the vaccinated group as compared to the control group (31.0 per 1,00 v. 70.1 per 1,000, or a coefficient of effectiveness of 2.2).

A study to test rapid immunization potential by Friedman et al. (Ref. 5) showed that even a large dose (10 ml) given as a single injection to children resulted in only 17 percent (4/23) seroconversion within 1 week.

2. *Safety.*—a. *Live, attenuated mumps virus vaccine.* Few, if any significant adverse reactions or complications have been associated with delivery of many millions of doses. The Center for Disease Control cites only one serious illness associated with mumps antibody rise within 2 months of immunization. The manufacturer cites, of many millions of doses, the following temporally related incidents: nine cases of encephalitis (0.7 per million), two febrile convulsions, one case each of deafness and visual disturbance.

b. *Mumps vaccine, killed.* Data are sparse. Field trials report a small percentage of febrile reactions. The producers report only one complaint, an undescribed neurological disorder, during the period 1969 through June 1973.

3. *Benefit/risk.*—a. *Live, attunuated mumps virus vaccine.* The benefit/risk ratio is favorable in that there is excellent protection against the disease with virtually no reported short-term complications of vacinnation. While the disease is usually nonfatal it may occasionally be associated with considerable morbidity and occasionally with serious complications. (see Fig. 4)

b. *Mumps vaccine, killed.* While there is apparently very little risk from vaccination with currently available inactivated mumps vaccine products, there is also no demonstrable benefit, resulting in a ratio approaching zero.

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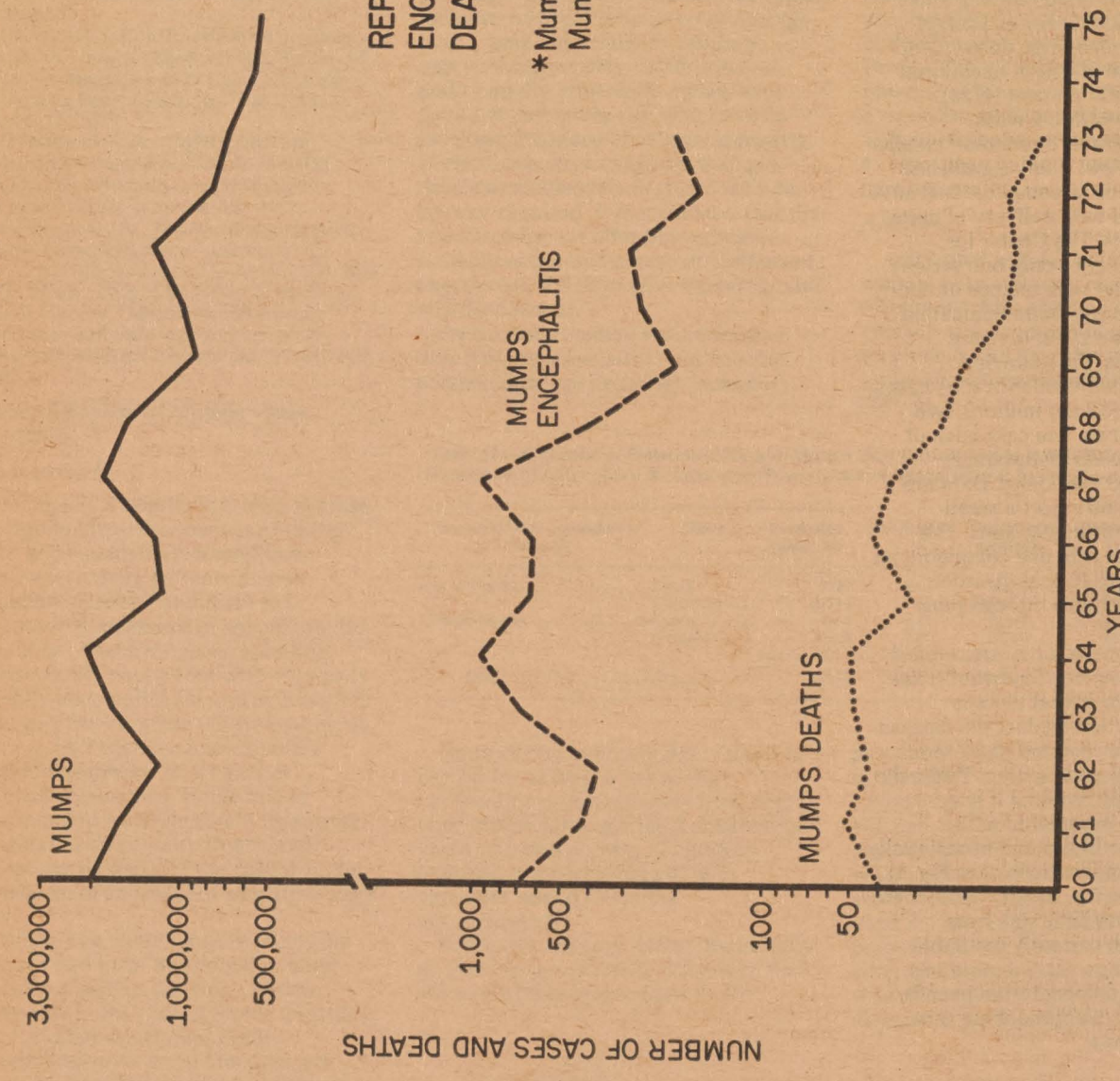
Figure 4



Source: Center for Disease Control, Bureau of State Services, Immunization Division.

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4. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

Recommendations

1. *Live, attenuated mumps virus vaccine.* This is an excellent biological product and the license should be continued.

2. *Mumps vaccine, killed.* It is recommended that licensure for manfacture of this product be withdrawn in that there is no demonstrable efficacy of the currently available inactivated mumps vaccine and no justification for its continued production.

Review of Individual Mumps Virus Vaccine Products

Mumps Virus Vaccine, Live (Mumpsvax) Manufactured by Merck Sharp & Dohme, Division of Merck & Co., Inc.

1. *Description.* Live mumps virus, Jeryl-Lynn strain, attentuated (B level) by passage in embryonated hens' eggs and in chick embryo cell culture, with the vaccine being prepared from virus grown in the latter medium. Each does of vaccine contains not less than 5,000 $TCID_{50}$ of mumps virus, as stated on the label and in the package insert, and also contains 25 mcg of neomycin per dose.

a. *Recommended use.* The vaccine is indicated for immunization against mumps in children over 1 year of age and adults.

b. *Contraindications.* (1) Pregnancy; (2) Sensitivity to eggs, chicken, chicken feathers, or neomycin; (3) Blood dyscrasias, leukemia, lymphoma, etc; (4) Therapy with ACTH, corticosteroids, irradiation, or other immunosuppressants; (5) Gamma globulin deficiency; (6) Any active infection.

2. *Analysis.—a. Efficacy.* (1) *Animals.* See section on human efficacy.

(2) *Humans.* Efficacy is clearly established both in terms of serologic response and in terms of protection (see Table 12). Neutralizing antibody has been shown to persist for at least 8 years after vaccination and protective immunity through at least 6 years (Ref. 6).

b. *Safety.* (1) *Animals.* Routine tests are done as required by Federal Regulations.

(2) *Humans.* There have been few, if any, significant adverse reactions or complications following the administration of the many million doses given thus far. The rate of temporally associated neurologic disease occurring within 30 days after vaccination is less than 1 per million, which is similar to or less than the expected rate in unimmunized children of a similar age.

c. *Benefit/risk.* See generic review.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions.*—a. *Critique.* This is a safe and effective product in children. There are inadequate data regarding protective effectiveness in susceptible adults (e.g., military recruits) but safety and antigenicity have been established in adults.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Mumps Virus Vaccine (Inactivated) Manufactured by Eli Lilly & Co.

1. *Description.* This preparation is a suspension of killed mumps virus derived from the extra-embryonic fluids of virus infected chick embryos. The virus is concentrated and purified by differential centrifugation inactivated with formaldehyde solution, 1:2,000, and suspended in isotonic saline containing 0.05 molar glycine. Thimerosal solution, 1:10,000, is used as the preservative.

a. *Recommended use.* The vaccine is intended for active immunization against mumps. The primary immunization consists of two injections given 1 to 4 weeks apart, and a booster injection is given 6 months to 1 year later. Emphasis is on prevention of mumps in young adults, particularly those in segregated populations (e.g., military recruits, medical students, and nurses). Routine administration of vaccine to all susceptible individuals is recommended, with susceptibility being determined by use of skin test antigen. Its use is also recommended to abort epidemics. Use of the vaccine for routine immunization before adolescence is not recommended.

b. *Contraindications.* (1) A history of egg sensitivity;

(2) Immune individuals;

(3) Therapy with ACTH, corticosteroids or other immunosuppressants.

2. *Analysis.*—a. *Efficacy.* (1) *Animal.* The minimum acceptable antigen concentration is that which will give complete (4+) fixation of complement at a 1:16 dilution against 4 units of a FDA reference antiserum. One batch in this submission is shown to have a titer of 1:64. The submission also includes data on a recent (1973) lot tested in guinea pigs (1 ml given intraperitoneally); pooled sera from 10 such guinea pigs had a CF titer of 1:32 against the 4 units of antigen required.

(2) *Human.* The manufacturer submitted no data concerning the effectiveness of his current product; the literature cited as pertaining to effectiveness dealt with a different product, incorporated into a peanut oil-beeswax adjuvant.

b. *Safety.* (1) *Animal.* The submission states that the product passes all safety tests.

(2) *Human.* The product is safe with less than 1 complaint per 100,000 doses of vaccine distributed.

c. *Benefit/risk ratio.* While there is no evidence of direct, substantial risk, there is also no evidence that the vaccine is of benefit, since it is poorly antigenic and offers no sustained protection.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP. The labeling in the submission to the Panel is considered inappropriate because one must read the fine print to discover that this is inactivated mumps vaccine, whereas the label should clearly indicate inactivation.

3. *Conclusions.*—a. *Critique.* Use of this vaccine requires prior determination of susceptibility in the recipient, but with the currently available antigens, the present skin test is not a reliable indicator of immunity as reported in the **Federal Register** of September 30, 1977 (42 FR 52674).

It seems highly unlikely that use of serological tests to determine susceptibility in exposed adults would be appropriate or timely, and the expense, even if such tests are available, would not be justified to attain the minimal protection that might be offered by inactivated vaccine.

The Panel concludes that the indications, as given, are inappropriate. Inactivated mumps virus vaccine is only marginally effective, and is of very limited usefulness.

b. *Recommendation.* Given the availability of live mumps virus vaccine, there seems to be no good justification for the continued production of inactivated mumps vaccine. Consequently, the Panel recommends that this product be placed in Category II and that appropriate license(s) be revoked because there are compelling reasons to assume a lack of

effectiveness and an unsatisfactory benefit-risk ratio for this product.

The Panel is aware that inactivated mumps virus vaccine is used to hyperimmunize donors as a source of immune plasma for the production of mumps immune globulin (human). This vaccine usage is discussed in the section dealing with mumps immune globulin.

Mumps Vaccine (Killed) Manufactured by Lederle Laboratories Division, American Cyanamid Co.

1. *Description.* The vaccine is prepared from the allantoic fluid of embryonated hens' eggs infected with mumps virus. The virus is concentrated, inactivated with formaldehyde and ethylene oxide, and suspended in a 0.1 M sodium phosphate buffered solution with 1:10,000 thimerosal added as a perservative. The actual viral content is not stated.

a. *Recommended use.* To protect susceptible individuals who have been exposed to infection, the vaccine should be given 2 to 3 days after such exposure.

The recommended immunizing dose for children and adults is two injections of 1.0 ml each, administered either subcutaneously or intramuscularly. The interval for optimal immunizations is not known, but 1 to 4 weeks between injections is suggested.

b. *Contraindications.* (1) Presence of tuberculosis, debilitating disease, latent or active infections;

(2) Sensitivity to eggs, chicken, or chicken feathers.

2. *Analysis.*—a. *Efficacy.* (1) *Animals.* Potency is measured by a compliment fixation test. At least a 1:16 dilution of the test vaccine should give complete (4+) fixation of complement against four units of a FDA Reference Antiserum Seven guinea pigs were each given 1 ml of vaccine intraperitoneally, bled 3 weeks later and the sera tested for antibody by complement fixation; a serum CF titer of 1:32 against 4 units of antigen (equal to minimum requirements) was shown in protocols provided for a recent batch.

(2) *Humans.* The submission incorporates references pertinent to the efficacy of killed mumps vaccine. These are discussed with pertinent data, under the generic review. The Panel knows of no evidence that effective protection can be induced within 2 to 3 days after exposure as is implied by the recommended use of the product within this interval. Sood's data (Ref. 4) suggest that a 3 to 6 week interval is necessary and show that absolutely no protection is afforded within 3 weeks postvaccination, evidently even after the second dose.

No procedure for determining susceptibility is given. It does not seem justified to recommend general vaccination of children except where special conditions exist (e.g., large groups housed in institutions, summer camps, orphanages, etc.) and vaccination is repeated at annual intervals to keep the antibody titer at an adequate level.

b. *Safety.* (1) *Animals.* The tests reported in the submission were satisfactory.

(2) *Humans.* Field trials report the occurence of a small percentage of febrile reactions; the producer reports only one complaint, an undescribed neurological disorder during the period 1969 thru June 1973.

c. *Benefit/risk.* While there is no evidence of a substantial direct risk, there is also no evidence of benefit, since the vaccine is poorly antigenic and offers no sustained protection.

d. *Labeling.* The labeling is inappropriate because it is not immediately obvious that the product is an inactivated mumps virus vaccine. The Panel also considers the indications to be inappropriate (see Recommendation). Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and the updated recommendations of ACIP.

3. *Conclusions.* a. *Critique.* This product is not recommended by ACIP. As detailed above, there is no evidence that this product is efficacious. In view of the availability of an effective attentuated mumps virus vaccine, there seems little or no need for this product.

b. *Recommendation.* There is no good justification for the continued production of inactivated mumps virus vaccine, and the Panel recommends that this product be placed in Category II and that appropriate license(s) be revoked because there are compelling reasons to assume lack of effectiveness and an unsatisfactory benefit-risk ratio for this product. The Panel is aware that inactivated mumps virus vaccine is used to hyperimmunize donors as a source of plasma for the production of mumps immune globulin (human). This vaccine usage is discussed in the section dealing with mumps immune globulin.

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(6) Weibel, R. E., E. B. Buynak, A. A. McLean, and M. R. Hilleman, "Long-Term Follow-up for Immunity After Monovalent or Combined Live Measles, Mumps, and Rubella Virus Vaccines," *Pediatrics*, 56:380–387, 1975.

Generic Review of Rubella Virus Vaccine

Background

Infection with rubella virus is generally a benign self-limiting illness of childhood. However, infection of a susceptible woman during the first trimester of pregnancy may give rise to transplacental infection of fetal tissues and result in serious congenital abnormalities. The recognition of this association between rubella infection and congenital disease was first made in Australia by Gregg in 1941. (See Ref. 1 for one discussion of this association.) Since then, his observations have been confirmed during the course of several rubella epidemics, including the United States epidemic of 1964 which resulted in a large number of infants with congential rubella syndrome. The prevention of rubella epidemics and their sequelae became possible with the development of attenuated live rubella virus vaccine. The vaccine was licensed in June 1969 and more than 70 million doses have been administered. The data in Table 13 indicate that as many as 80 percent of children 5 to 9 years old have natural or vaccine-acquired immunity.

Table 13.—*Rubella Immunization Status of Children in Age Groups 1–4 and 5–9; United States 1965–72*

[Population in thousands]

Year	Net dosage of vaccine [1] distributed	1–4 year age group percent with			5–9 year age group percent with		
		Population	Vaccine	Infection	Vaccine/infected	Population	Vaccine	Infection	Vaccine/infected
1965		16,502		26.5		20,361		56.0	
1966		16,091		25.1		20,436		51.8	
1967		15,552		20.2		20,862		46.8	
1968		14,994		18.5		20,856		44.2	

Table 13.—*Rubella Immunization Status of Children in Age Groups 1–4 and 5–9; United States 1965–72*—Continued

[Population in thousands]

Year	Net dosage of vaccine [1] distributed	1–4 year age group				5–9 year age group			
		Population	percent with Vaccine	Infection	Vaccine/infected	Population	percent with Vaccine	Infection	Vaccine/infected
1969		14,393		16.7		20,773		40.4	
1970	[2]29.3	14,123	37.2	14.4	47.3	20,421	46.5	31.8	67.3
1971	8.6	14,112	51.2	13.9	59.4	19,799	63.2	28.0	77.8
1972	7.0	13,905	56.9	12.3	63.3	18,552	66.8	25.7	79.5

[1] Biologics Surveillance (million).
[2] Total doses (not) distributed from June 1969 through December 1970.
Source: CDC, Bureau of Epidemiology.

The purpose of rubella vaccination is primarily to prevent rubella embryopathy. The direct approach to this goal would be to immunize all women before they become pregnant. The impossibility of insuring that any given women was not pregnant and an increased rate of side effects (joint symptons) in women rendered this direct approach impractical on a public health level. Because children, on the basis of serologic and epidemiologic studies, were an important primary source of virus excretion to infect pregnant women, rubella vaccine policy was initially to immunize children of all ages. Women of child-bearing age, if not pregnant, are of equal importance and all others are of significantly lower priority to receive vaccine.

The Public Health Service Advisory Committee on Immunization Practices for rubella vaccine recommends live rubella virus vaccine for all children between the age of 1 year and puberty. It should not be administered to infants less than 1 year of age because of their possible failure to respond to vaccination.

Priority for immunization should be given to children in kindergarten and elementary school because they are a major source of virus dissemination in the community. For optimum program effectiveness, it is essential that immunization activities be developed to ensure ongoing, routine immunization of preschool children as well. A history of rubella is not reliable; therefore, all children should receive vaccine.

It is desirable for rubella vaccination programs to include adolescent girls and adult women. Because of the precautions which must apply, potential vaccinees in these groups should be considered individually. They should receive vaccine only if they are shown to be susceptible by serologic testing and if they agree to prevent pregnancy for 2 months after immunization.

To accomplish such extended use of rubella vaccine, accurate serologic testing capabilities should be improved. With sufficient laboratory services available, there is merit in undertaking prenatal or antepartum screening for rubella susceptibility and, if appropriate, immunization in the immediate postpartum period. *Pregnant women should not under any circumstances be given vaccine.*

Immunization of adolescent or adult males is of lower priority; however, it may be a useful practice in the prevention or control of outbreaks of rubella in circumscribed population groups.

There is no evidence that live rubella virus vaccine given after exposure will prevent illness. There is, however, no contraindication to immunizing children already exposed to natural rubella. Similarly, there is no harm in vaccinating persons who have had rubella.

The contraindications are as follows:

1. *Pregnancy.* Live rubella virus vaccine is contraindicated.

2. *Altered immune states.* Attenuated rubella virus infection might be potentiated by severe underlying disease such as leukemia, lymphoma, or generalized malignancy, and when the immunologic response has been suppressed with steriods, alkylating drugs, antimetabolities, or radiation. Such patients should not be given live rubella virus vaccine.

3. *Febrile illness.* Immunization should be postponed until the patient has recovered.

4. *Hypersensitivity to vaccine components.* Theoretically, rubella vaccine should not be given to children clearly hypersensitive to the animals from which cells are derived for use in vaccine production or to other components of the vaccine. To date, there have been no documented reports of serious reactions to rubella vaccine clearly attributable to hypersensitivity.

Now that the vaccine is in general use, accurate diagnosis and reporting of congenital rubella syndrome and vaccine complications have become more important than ever. All cases of birth defects suspected of being related to rubella should be thoroughly investigated and reported. There should also be continuing followup of women inadvertently vaccinated during pregnancy.

A number of aspects of FDA regulations for manufacture of Rubella Virus Vaccine, Live, warrant emphasis or comment. (See 21 CFR 630.60).

1. *Strains.* Vaccine strains must be identified by historical records and antigenic specificity. Field studies must document that the strain is safe, potent, and noncommunicable to susceptible, unvaccinated persons.

2. *Cell substrate.* There are some aspects of testing cell substrates for extraneous agents or indigenous viruses, especially in the duck embryo system, which should be updated.

3. *Potency.* Potency requirements are regularly met by the manufacturer. Photoinactivation is applicable to this vaccine as well as to other viral vaccines and is a factor in storage of the products.

4. *Production procedures.* A defined seed-lot system is in effect; five passages from the master seed are permitted.

5. *Safety tests.* Tests in monkey kidney cell cultures for cytopathic viruses are probably not as important as tests employing human cells. The inoculation of embryonated eggs should specify incubation period and subpassage requirement of tests to be employed.

Analysis

1. *Efficacy.*—a. *Animals.* Not applicable.

b. *Humans.* Immunization against rubella is directed toward prevention of infection in the pregnant woman since, during the early months of pregnancy, the virus may cross the transplacental barrier to infect the fetus, with the risk of embryopathy. The effectiveness of the vaccine has been evaluated in a number of ways. First, in early experimental studies high passage level virus was shown to produce a modified infection and to be immunogenic in the rhesus monkey. The antibody response produced by such an infection protected animals against subsequent challenge with the natural virus. Second, the vaccine has been shown to protect vaccinees exposed to wild virus under natural conditions; i.e., in rubella epidemics, vaccinees did not develop clinical disease whereas cases of rubella were observed in seronegative, previously unvaccinated persons.

The most direct evidence of effectiveness would be through epidemiologic analysis of the incidence of the disease and on the ability of the vaccine to reduce the incidence of congenital defects associated with the rubella syndrome. The following is

based on data extracted from CDC reports (Ref. 1) and a review of the current literature on rubella. This epidemiological approach to an evaluation of the effectiveness of rubella vaccine in the United States is complicated by several variables: (1) surveillance is inadequate for both the clinical disease and the congenital rubella syndrome; (2) spread of the virus and the development of epidemics are somewhat unpredictable; and (3) the increasing use of serological screening, followed by abortion for proven rubella infection in the first trimester of pregnancy, could be responsible for the decreased number of infants born with congenital rubella.

Figure 5 shows reported cases of rubella by year from 1966 through 1973 and Figure 6 shows the reported cases by 4-week periods 1969 through 1975.

Although the accuracy and completeness of reporting of rubella vary considerably in different areas of the country, the data available do appear sufficient to permit analysis of disease patterns and trends in the United States. Thus, despite yearly and regional variations, the great preponderance of States reported (see Fig. 5) a decline in rubella from 1971 to 1972, with the total number of cases showing a decline of 43 percent (from 45,086 to 25,507) over this 1 year and a decline of 50 percent from the average number of cases reported in each of the years 1967 to 1971. From 1969, when rubella vaccine was first licensed (see Fig. 6A), the incidence of rubella has decreased steadily through 1975 with only slight upward fluctuations in 1973 and 1975.

The appearance of epidemic rubella every 6 to 9 years had led to predictions that another significant epidemic would occur in the early 1970's. No such epidemic occurred, and the incidence of rubella over the last 46 years (shown in Fig. 7) suggests that use of the vaccine since 1969 has affected the 7- to 9-year cycling of rubella epidemics in this country.

Data on the age incidence of rubella collected from four areas, viz., Illinois (exclusive of Chicago), Chicago, Massachusetts, and New York City for the 4-year interval 1969 to 1972 have been compared with similar data from the same areas for the 5-year period 1963 to 1967. The observed decrease in incidence was found to give a generally symmetrical pattern in each age group; also, the accumulated percentages of rubella cases by age for the pre- and postvaccination periods showed no significant difference. While absence of a displacement in the age-specific incidence curve may represent an unusual situation in these four study aeas, a more likely interpretation is that immunization of school-age children has lead to a diminished activity of rubella virus in all age groups.

While the information available on the congenital rubella syndrome is not entirely satisfactory, the data suggest that there has been a decline in this syndrome coincident with widespread immunization and with the concomitant decline in the incidence of reported rubella.

The Center for Disease Control, in 1969, established a National Registry for the Congenital Rubella Syndrome, but the reporting of cases has been less than satisfactory. Of some 284 case reports received by the Registry by July 1974, only 237 represent children born in 1969 or later. Eleven of the 50 States have reported no cases and certain States (California, Colorado, and Louisiana) account for a disproportionately large number of cases in the Registry (Ref. 3). In figure 8 the reported incidence of rubella is given by 4-week periods from 1969 to 1975 in order to provide a background for the lower graph which depicts the cases of congenital rubella syndrome (CRS) reported to the Registry by date of birth since 1969.

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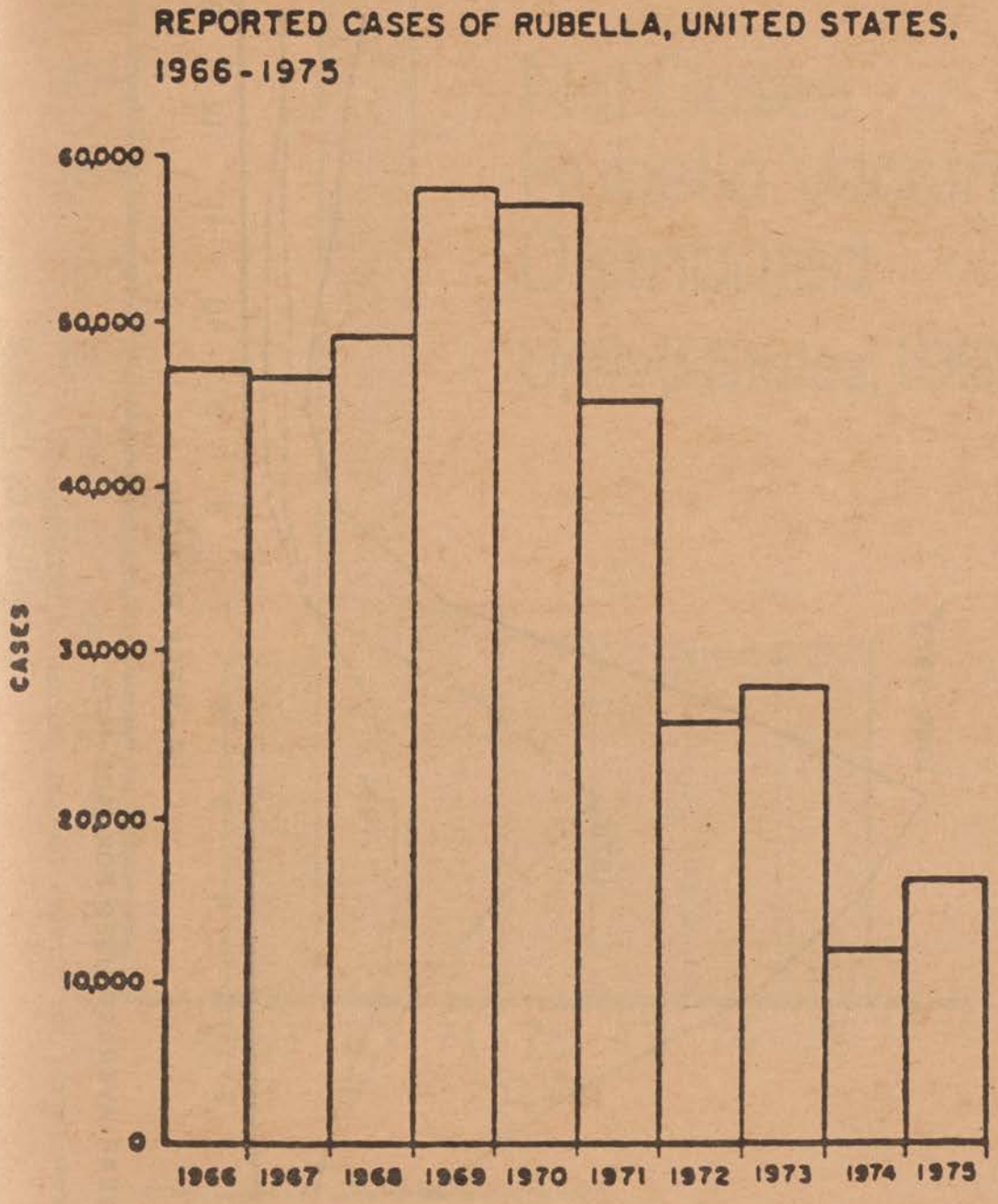
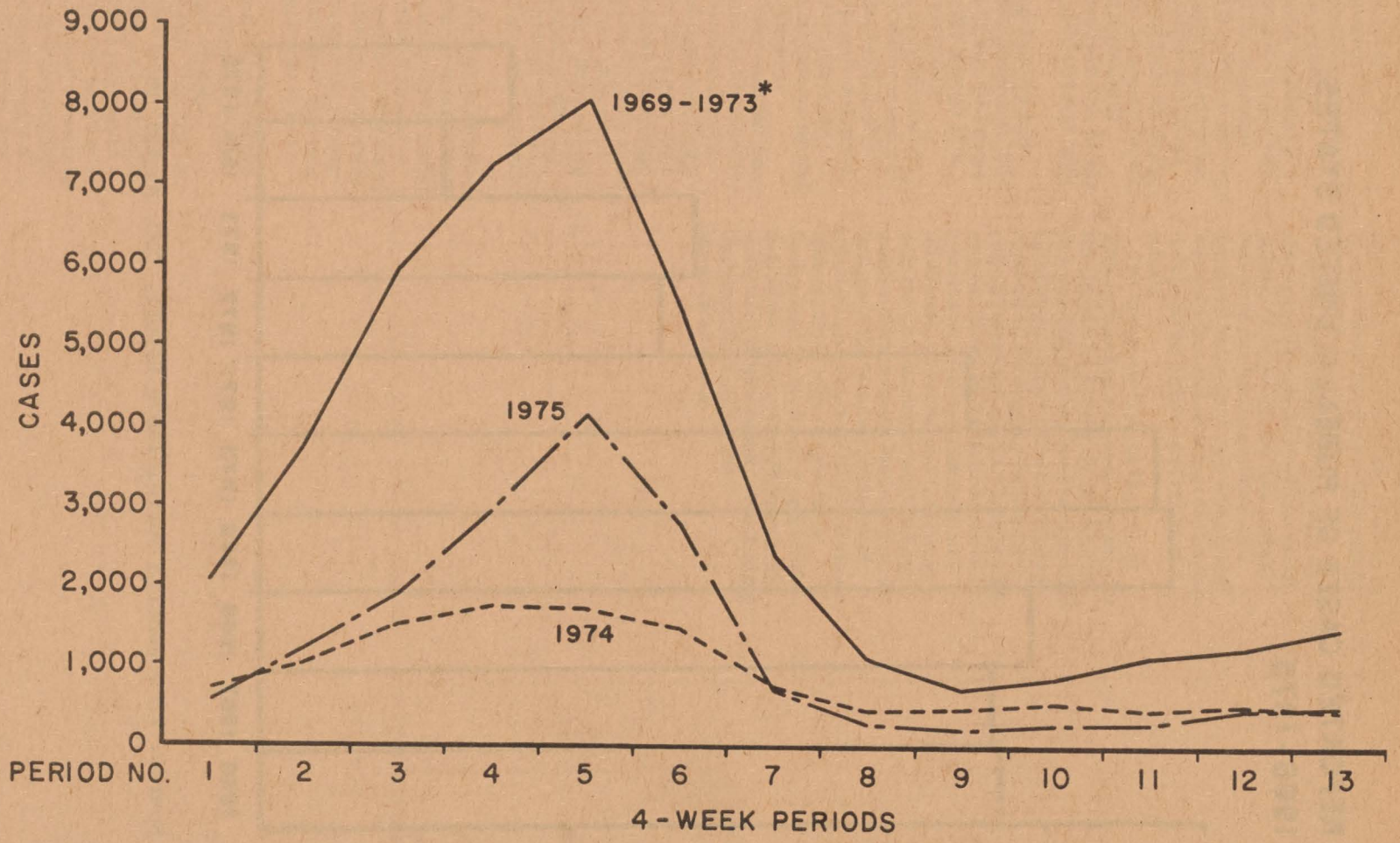
Figure 5



Source: From Rubella Surveillance Report, CDC, August 1976

Figure 6

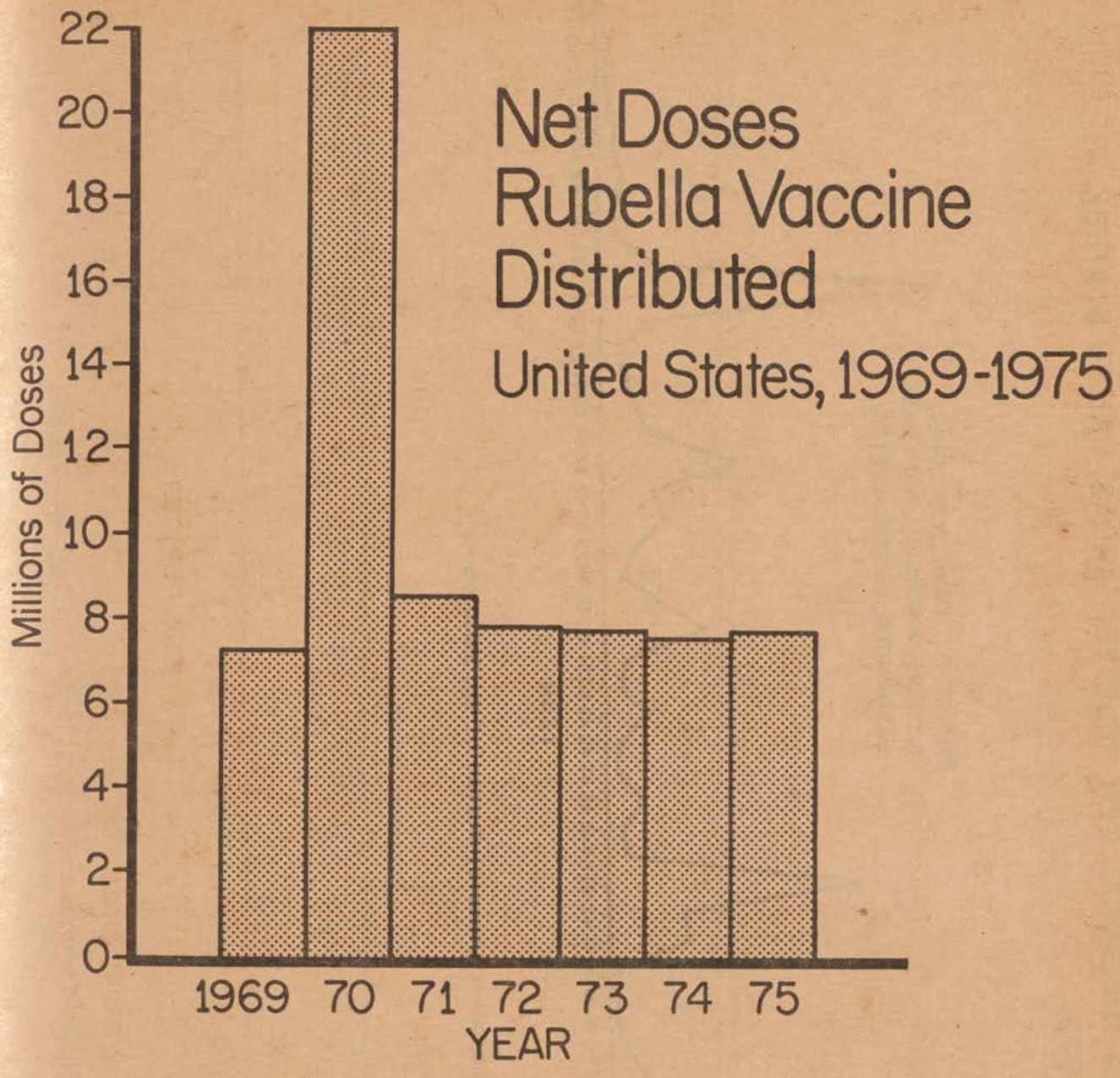
REPORTED CASES OF RUBELLA, BY 4-WEEK PERIODS, UNITED STATES, 1969*-1975



*5-YEAR AVERAGE USED FOR 1969-1973

Source: Center for Disease Control, Bureau of Epidemiology.

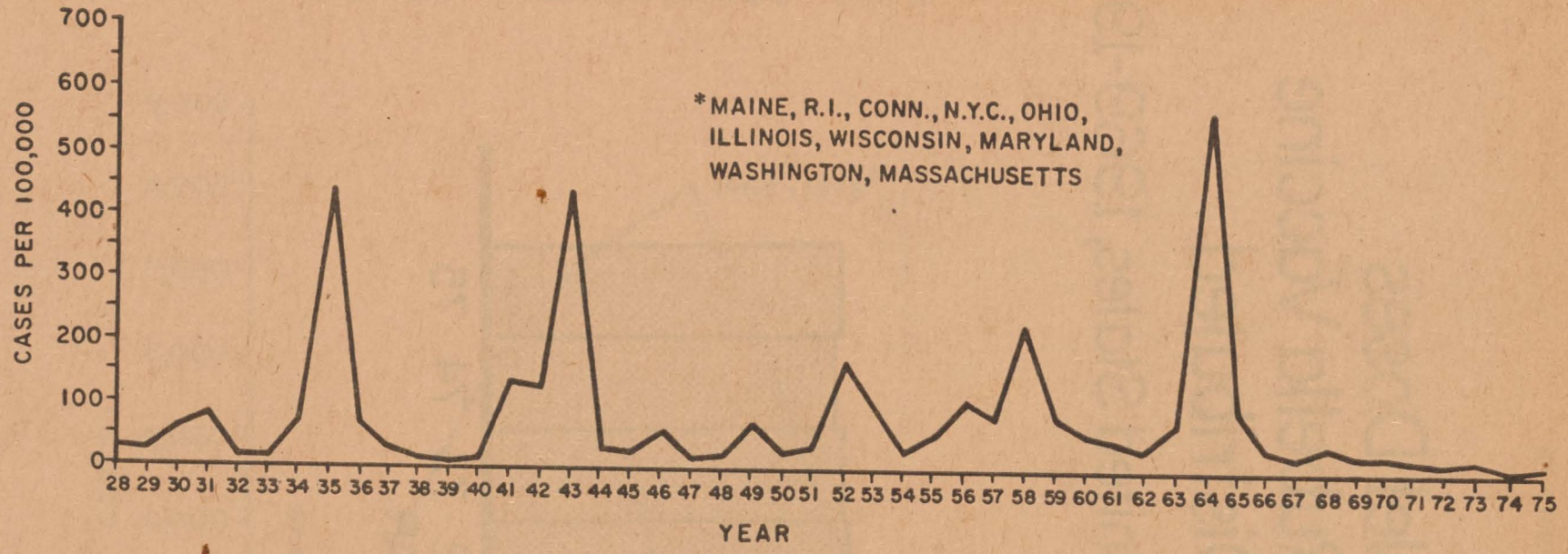
Figure 6A



Source: Center for Disease Control

Figure 7

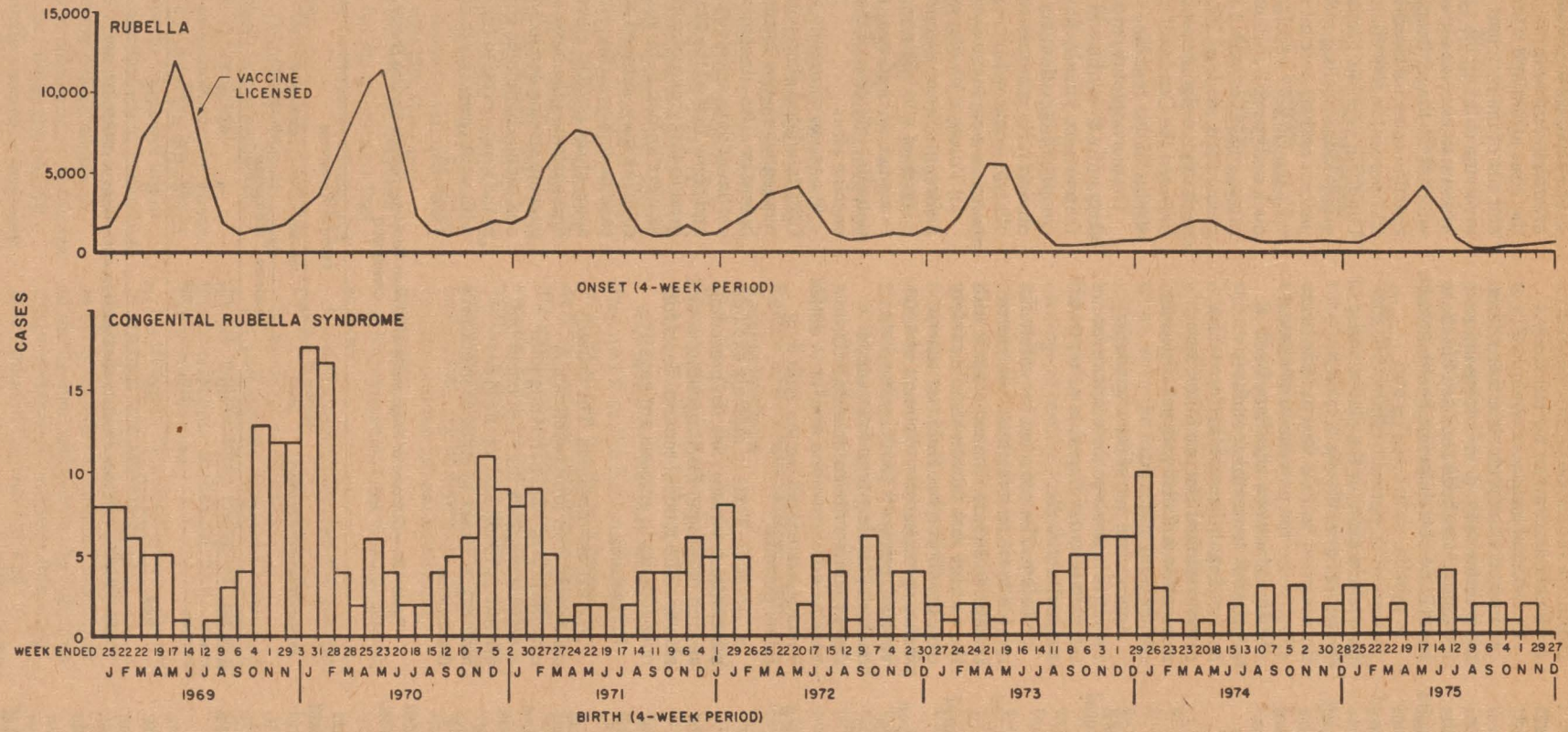
RUBELLA INCIDENCE, TEN SELECTED AREAS*, UNITED STATES, 1928–1975



Source: Center for Disease Control, Bureau of Epidemiology.

Figure 8

CASES OF RUBELLA,* BY PERIOD OF ONSET, AND OF CONGENITAL RUBELLA SYNDROME, BY PERIOD OF BIRTH,** USA, 1969-1975



* OFFICIAL TELEGRAPHIC REPORTS FROM STATES AND AREAS

** FROM CRS REGISTRY

Source: Center for Disease Control, Bureau of Epidemiology.

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Peaks in the number of births with CRS are evident at 7 to 9 months after the peaks in rubella virus activity and the number of CRS cases appears to have declined since 1969. It is obvious that reporting of the congenital rubella syndrome must be improved, but despite this, Figure 8 suggests that there has been a decline in the number of cases of congenital rubella syndrome.

The overall evidence presented by all of the studies published thus far on the persistence of antibodies indicates that rubella HAI antibody titers are stable for at least the first 2 to 4 years after vaccination, and that the pattern of antibody decline is the same as that observed after the natural disease.

Subclinical reinfection following exposure to wild-type rubella virus has been reported to occur both after natural immunity and after vaccine-induced immunity. Studies in small groups of institutionalized children or young adults (military recruits) have shown the occurrence of a rise in antibody titer in 2.5 to 10 percent of children with natural immunity, compared with antibody increases in 3.5 to 80 percent of children and young adults exposed to wild-type rubella virus at varying intervals after vaccination. Thus far, the only study concerned with an urban community which experienced a rubella outbreak 9 months after a vaccination campaign reported rises in antibody titer in 12.7 percent of the population vaccinated with HPV–77 DE–5, and in 11.6 percent of susceptibles over the same time period, thus showing that rubella virus had circulated through this community.

The major concern regarding reinfection is related to its significance during pregnancy. Would the fetus of a reinfected women be at risk of infection by the natural virus? The evidence thus far does not support the probability of such an occurrence. Thus, in one study (Ref. 4) it was found that vaccinated children exposed in an epidemic did not become viremic, and the titer of virus in the pharynx and the duration of shedding were both markedly less than that seen in susceptible children studied under the same conditions. Hence, it seem unlikely that in a comparable situation in a reinfected pregnant woman, virus would reach the fetus. To date, there are no published data concerning reinfection of pregnant women vaccinated earlier. Reinfection of women with naturally acquired immunity has been reported, but the number of cases involved is small and the diagnosis has been subject to debate. On balance, it seems that protection of the fetus will be assured if circulating antibodies are present. Definitive resolution of this question obviously must await further study.

Occasional instances of clinical reinfection in individuals either with a natural immunity or a vaccine-induced immunity have been reported but these seem to be of little public health impact.

In rubella, as in measles and poliomyelitis, periodic reinfection may be a mechanism for the maintenance of high titers of antibody. It is well documented that the vaccine has been effective for the prevention of clinical disease in persons who have been adequately immunized, and it is assumed that the same factors which prevent clinical disease following reinfection will also prevent or greatly reduce fetal infection.

Appropriate use of the vaccine is essential to achieve the purpose for which it was developed, viz., to prevent congenital rubella.

2. *Safety.* The concerns for safety are related to toxic, infectious, allergic, or oncogenic factors. The experience with the vaccine thus far attests to its safety over the short term. Field test criteria include prospective enlistment of 5,000 vaccine recipients (with appropriate controls) for long-term followup to detect rare events associated with vaccine administration and/or to detect vaccine-associated events with long latent periods.

a. *Animals.* Tests in animals exclude adventitious viruses. See the preceding section refering to FDA regulations, and also specific product reports. Tests for oncogenicity in animals are negative.

b. *Humans.*

(1) *Adverse reactions.* The primary concern is with joint reactions. A compilation of long persisting joint reactions suggests they can occur but are not common and, in the great majority of cases, symptoms eventually disappear.

The capacity to produce transient arthralgia and arthritis is a property of the virus strain and varies with the age and sex of the recipient. In studies involving children the rates were as follows: the canine kidney vaccine, which is no longer licensed, produced reaction rates between 8.1 percent and 20.7 percent in five clinical studies; the Cendehill vaccine, prepared in primary rabbit kidney cells, produced rates of 5.1 percent and 8.9 percent in two studies; with the HPV–77 vaccine prepared in duck embryo cell cultures, the reaction rates ranged between 1.8 percent and 7.6 percent (six studies). Thus, there is probably no significant difference between the Cendehill and HPV–77 strains in this regard.

These symptoms occur more frequently in adults and more in women than in men, thereby further complicating patient acceptance of these products. No other reactions, including allergic, occur with enough frequency to permit a meaningful evaluation.

(2) *Vaccination of women shortly before or after conception.* One of the hazards of administering rubella vaccine to women of child-bearing age is the potential infection of the fetus by the vaccine virus.

In a report of rubella surveillance the CDC tabulated observations on 343 women who were vaccinated shortly before or after conception (Ref. 4). The pertinent data are given in Table 13a, and show that of the 172 live infants born to this group of mothers (of whom 38 were known to be susceptible to rubella), none showed evidence of rubella embryopathy. However, this same study at CDC clearly demonstrated (as have others) that the vaccine strains can infect fetal tissues and induce histologic changes analagous to those observed to follow infection with wild virus; this is illustrated in Table 14.

Table 13a.—*Outcome of Pregnancies in Women Receiving Rubella Vaccine Shortly Before or After Conception*

Prevaccination immunity status	Number of cases	Outcome of pregnancy			Unborn	Virus isolate
		Abortion		Delivery of live infants		
		Therapeutic	Spontaneous			
Susceptible	70	28	3	38	1	6
Immune	14	1	0	13	0	0
Unknown	259	116	13	121	8	3
Total	343	145	16	172	9	9

Source: Modlin, J. F., K. Hermann, et al., *New England Journal of Medicine, 294:972-974, 1976.*

Table 14.—*Characteristics of Patients With Rubella Vaccine-Like Virus Isolated From Therapeutic Abortion Specimens*

Pre-vaccination immunity status	Gestation at abortion (weeks)	Interval between vaccination and abortion (weeks)	Tissues positive for rubella virus
Unknown	14	16	Fetal eye, placenta.
Unknown	13	2	Fetal kidney, placenta.
Susceptible	6	8	Placenta.
Susceptible	8	5	Decidua.
Unknown	10½	9½	Decidua, placenta.
Susceptible	13½	4	Placenta.
Susceptible	13	20	Fetal eye.
Susceptible	18	12	Fetal bone marrow.

Source: Rubella Surveillance Report, CDC, November 1973.

It should be noted that no differences between the licensed strains were detected in these studies. The actual risk of vaccine virus-induced congenital disease is still unknown. While the recovery of virus from the products of conception suggests a pathogenic potential, the absence of such disease in live born infants of vaccinated susceptible mothers suggests that the risk is at least an order or magnitude less than that associated with wild disease. Continued surveillance in this area is needed.

3. *Benefit/risk.* The cost of providing the necessary health care for, and the support of, 4,000 blind/deaf children with rubella syndrome in the New York City area from the 1964 epidemic is estimated to be $30 million per year for at least another 20 years. This is only a partial cost, since, nationwide, as many as 20,000 infants were recorded to have congenital rubella as an aftermath of that epidemic. The absence of a major epidemic since 1964, the decline in the incidence of rubella, and the decrease in reported cases of rubella empryopathy are clear evidence of the benefits; while the exact contribution of the licensed vaccine to this benefit is not quite as clear as one would like, the Panel concludes that the vaccine deserves primary credit for the alterations that have been noted in the epidemiology of rubella.

The risk of rubella vaccine is limited to two areas: (1) transient arthralgia and arthritis, especially in postpubertal recipients, and (2) accidental vaccination of pregnant women. These factors tend to increase the difficulties of administration to adults but are of little practical significance in vacination of children. All other risks are theoretical and there is no means of including them in calculations which are already imprecise. While the benefit-risk ratio of rubella vaccine is probably not as high as that of measles or poliovirus vaccine, it is already great enough to more than justify its continued licensure.

4. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and the updated recommendations of ACIP.

Recommendations

1. The labeling and package inserts of rubella vaccines should be continuously updated to reflect ACIP recommendations.

2. The Panel suggests that the ACIP recommendations for use of the vaccine in women of child-bearing age be phrased positively, and that specific conditions for their immunization be given, as in the following example: "A high priority adult group for immunization are postpartum women shown to be susceptible to rubella by serological testing. Postpartum females who have not been tested can also be immunized; in either case, women should agree to prevent pregnancy for 2 months after immunization. Any nonpregnant woman of child-bearing age who agrees to prevent pregnancy for 2 months also should be given vaccine."

3. Encourage support of continued and more complete rubella surveillance by CDC.

Review of Individual Rubella Virus Vaccine Products

Rubella Virus Vaccine, Live (Meruvax) Manufactured by Merck Sharp & Dohme, Division of Merck & Co., Inc.

1. *Description.* The vaccine is prepared from the duck-cell adapted HPV–77 strain; the virus is grown in duck embryo cell cultures. Each dose (0.5 milliliters) of the reconstituted vaccine contains not less than 1,000 $TCID_{50}$ of rubella virus in terms of FDA reference rubella vaccine, and each also contains 25 mcg of neomycin. The vaccine and the diluent contain no preservative.

a. *Recommended use.* See the generic review.

b. *Contraindications.* See the generic review.

2. *Analysis.* a. *Efficacy.*

(1) *Animals.* No data were submitted by the manufacturer. However, this is of minor relevance in view of the experience in man.

(2) *Humans.* This vaccine was shown to produce seroconversion in approximately 95 percent of vaccinees in clinical trials performend in support of the license application. As concerns the persistence of antibody following inoculation of the vaccine, and specifically with respect to HPV–77 DE–5, i.e., Meruvax vaccine, Weibel et al. (Ref. 5) reported in 1972 on the hemagglutination-inhibiting antibody determinations in a group of 79 children; there was a slight decline in antibody level 2½ years after vaccination and none of the children had become seronegative. Weibel et al. (Ref. 6) reporting on a 5½ year followup the longest to date, found that the titer patterns in children given live attenuated HPV–77 virus were similar to those noted after natural infection, a good indication that the vaccine produces a durable immunity in terms of the humoral antibody response.

b. *Safety.*

(1) *Animals.* The tests employed to ensure the safety of the vaccine for man from the standpoint of adventitious agents, viral or other, are the usual ones demanded by the Bureau of Biologics. However, although precautions are taken to utilize eggs free of avian leukosis virus, the reviewers did not find any mention of the duck infectious anemia virus (DIAV) either as to its recognition that this agent may occur in duck eggs or its possible significance.

(2) *Humans.* From the standpoint of adverse reactions, it is recommended, as mentioned above, that live attenuated rubella virus vaccine not be administered to persons with sensitivities to duck or chicken tissues or feathers, that it not be administered to persons with malignancies or those under treatment with immunosuppressive drugs, nor to individuals with acute febrile illnesses, such as acute respiratory disease. Above all, it should not be administered to pregnant women because of the potential, but as yet unknown, teratogenicity of the attenuated virus.

Although rubella virus has been recovered from the pharynx of institutionalized children who were reinfected, titers of the virus that was shed were very low and a viremia was not demonstrated. The significance of subclinical reinfection in terms of viral transmission, either person-to-person in an epidemic or from the reinfected mother to the unborn child, remains to be determined; however, the low titers of virus involved and the apparent absence of viremia suggest that the hazards of transmission are minimal.

With respect to Meruvax live attenuated rubella virus vaccine, many million doses were distributed over the period June 1969 through December 1972. The most significant of the reported experiences are those involving the nervous system and the most frequently reported reactions were arthralgia and arthritis, as indicated in the following tabulation:

Types of disorder	Number of patients	Reports per million
Polyneuritis	3	0.125
Convulsion	1	<0.1
Febrile convulsion	1	<0.1
Encephalitis	4	0.17
Myelitis	3	0.125
Arthralgia	22	0.9
Arthritis	13	0.54

According to Merck Sharp & Dohme, the above tabulation lists reported reactions which were temporally associated with vaccination, but a relationship between the vaccination and the reaction has not been established. This method of surveillance for adverse reactions, i.e., reports to the manufacturer, obviously grossly underestimates the true incidence of certain adverse reactions, e.g., arthralgia. Occasionally, mild fever may be encountered as may such local reactions as erythema, induration, tenderness, and regional adenopathy.

Transient arthralgia and arthritis, which are common occurrences in natural natural rubella in adult women, have been noted 2 to 4 weeks after vaccination in up to 40 percent of susceptible women. Such reactions are fewer (7 percent) and milder in females between 13 and 21 years of age. Rarely, a more severe arthritis with joint effusion has occurred. Transient arthralgia and arthritis may occur in nonimmune males, but the incidence is lower than in women.

c. *Benefit/risk.* Transient arthralgia and arthritis, both common occurrences in adult women with naturally acquired rubella, have been reported in up to 40 percent of susceptible women who received the vaccine. These are the major reactions encountered; the others, as tabulated earlier in this report are of comparatively infrequent occurrence. The vaccine, although associated with troublesome and painful arthralgias and arthritis, is essentially free of serious complications, such as those of the central nervous system, so that in weighing benefit against risk, the vaccine in the judgment of the Panel is acceptable. More importantly, there is accumulating evidence that the vaccine is reducing the incidence of natural rubella and there is, at the present time, suggestive evidence that the congenital rubella syndrome is also declining.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription durgs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions—recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Rubella Virus Vaccine, Live (Cendehill Strain) (Cendevax) Manufactured by Recherche et Industrie Therapeutiques, S.A.

1. *Description.* According to the package insert:

When reconstituted, 'Cendevax' is a suspension of the 'Cendehill' strain of live, attenuated rubella virus. The vaccine in prepared by propagation in primary cultures of rabbit kidney cells. Each dose (0.5 ml) of 'Cendevax' contains the equivalent of not less than 1,000 $TCID_{50}$ (tissue culture infectious doses) of the NIH reference rubella vaccine, and not more than 25 mcg of neomycin sulfate. The vaccine and diluent contain no preservative.

a. *Recommended use.* See the generic review.

b. *Contraindications.* See the generic review.

2. *Analysis.*

a. *Efficacy.*

(1) *Animals.* No data submitted by the manufacturer. However, animal data are of minor relevance in view of the human data available.

(2) *Humans.* This vaccine was shown to produce seroconversion in 95 to 100 percent of vaccinees in the clinical trials performed to support licensure. There is considerable evidence to show that the presence of detectable HAI antibodies is correlated with protection against disease, and also a body of literature attesting to the capacity of live attenuated rubella virus vaccine to protect against attacks of the disease (see the generic review).

b. *Safety.*

(1) *Laboratory testing.* Comprehensive testing, utilizing bacteriologic media and a variety of animal species, e.g., monkeys, adult mice, sucking mice, guinea pigs, rabbits, and several cell culture host systems is done to detect the potential presence of adventitious agents and the methods employed, representing standard approaches, are acceptable.

(2) *Humans.* The safety of Cendevax rubella vaccine in man has been established through both controlled and uncontrolled clinical trials in the United States and elsewhere. Adverse reactions such as fever, rash, and lymphadenopathy have been reported but the incidence has been very low. Arthralgia appears to be the most troublesome reaction to the vaccine, especially in women. Transmission of the Cendehill strain of rubella virus through the placenta can occur. The virus has been isolated from the placenta on several occasions and, less often, from the decidua from women who have undergone therapeutic abortion following inoculation of vaccine. However, as the manufacturer points out, there has been only one instance in which rubella virus has been isolated from the fetus following maternal vaccination and this was from the femoral bone marrow and the virus was considered to have the characteristics of the Cendehill strain.

c. *Benefit/risk.* See generic review.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions—recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

(1) Gregg, N., "Further Observations on Congential Defects in Infants Following Maternal Rebella" *Transactions of the Opthal Society of Australia,* 4:119–131, 1944.

(2) Center for Disease Control, "Rubella Surveillance, January 1972—July 1973," Center for Disease Control, Atlanta, Ga., 1973.

(3) Modlin, J. F., A. D. Brandling-Bennett, J. J. Witte, C. C. Campbell and J. D. Meyers, "A Review of Five Years' Experience With Rubella Vaccine in the United States," *Pediatrics,* 55:20–29, 1975.

(4) Modlin, J. F., K. Herrman, et al., "Risk of Congential Abnormality After Inadvertant Rubella Vaccination of Pregnant Women," *The New England Journal of Medicine,* 294:972–974, 1976.

(5) Weibel, R. E., E. B. Buynak, J. Stokes, Jr., and M. R. Hilleman, "Measurement of Immunity Following Live Mumps (5 years), Measles (3 years), and Rubella (2½ years) Virus Vaccines," *Pediatrics,* 49:334–341, 1972.

(6) Weibel, R. E., E. B. Buynak, A. A. McLean, and M. R. Hilleman, "Long-term Follow-up For Immunity After Monavalent or Combined Live Measles, Mumps and Rubella Virus Vaccines," *Pediatrics,* 56:380–387, 1975.

Review of Combinations of Generically Different Vaccines

The Panel notes that those generically different viral vaccines that have been found to be safe and effective as single viral products continue to be safe and effective single-component vaccines, when combined into the products reviewed below, are found to meet the following requirements:

1. Each active component makes a contribution to the claimed effect or effects;

2. Combining of the active ingredients does not decrease the purity, potency, safety, or effectiveness of any of the individual active components;

3. If administered according to adequate directions for use, and with heed to warnings against unsafe use, the combined vaccine provides a rational preventive method for a significant proportion of the target population.

The individual vaccine reviews contain information on the safety and effectiveness of each of the active components of the combination products.

No individual product review for Measles and Mumps Virus Vaccine, Live, is included here as this vaccine is not marketed in the United States. It is intended for use in those countries wher routine immunization against rubella is not recommended for young children.

Table 15, compiled by the Bureau of Biologics staff, presents data on seroconversion rates obtained with combinations of measles, mumps, and rubella virus vaccines documenting their effectiveness as antigens.

Table 15.—*Seroconversion Rates in Relation to Vaccine Titer for Combinations of Live Measles, Mumps, and Rubella*

Virus mixture and vaccine lot	Virus titer (Log 10) Per human dose			Seroconversion rates of double and triple negatives					
	measles	mumps	rubella	Measles		Mumps		Rubella	
					Percent		Percent		Percent
Mumps and rubella:									
a		3.9	2.9			30/31	96.8	31/31	1.0
b		4.5	3.8			133/140	95.0	133/140	95.0
c		4.6	3.9			95/100	95.0	94/100	94.0
d		4.7	3.1			139/144	96.5	132/144	91.7
e[1]		4.2	3.5			131/138	94.9	126/138	91.3
f[1]		4.3	3.6			145/159	91.2	142/159	89.3
g[1]		4.4	2.8			119/122	97.5	114/122	93.4
Group		[2]4.4	[2]3.4			792/834	95.0	772/834	92.6
Totals		[3]3.9–4.7	[3]2.8–3.9						
Measles, mumps and rubella:									
h	3.4	3.7	2.8	30/30	100	29/30	96.7	30/30	100
i	2.8	4.4	3.6	223/237	94.1	224/237	94.5	222/237	93.7
j	2.8	4.0	4.0	209/221	94.6	207/221	93.7	209/221	94.6
k	3.2	4.5	3.2	222/227	97.8	220/227	96.9	209/227	92.1
Field mix	l,m,n 4.1	3.8	2.8	28/28	100	26/28	92.8	26/28	100
Group	[2]3.3	[2]4.1	[2]3.3	712/743	95.8	706/743	95.0	698/743	93.9
Totals	[3]2.8–4.1	[3]3.7	[3]2.8–4.0						
Measles and rubella:									
o	3.0		3.6	92/95	96.8			89/95	93.7
p	3.2		3.5	110/110	100			106/110	96.4
q	3.1		3.4	127/128	99.2			122/128	95.3
r	3.2		3.6	42/42	100			41/42	97.6
Group	[2]3.1		[2]3.5	371/375	98.9			338/375	95.5
Totals	[3]3.0–3.2		[3]3.4–3.6						
Measles and mumps: s	3.9	3.8		37/38	97.8	37/38	97.4		
All groups	[2]3.3	[2]4.2	[2]3.4	1120/1156	96.9	1535/1615	95.0	1828/1952	93.6
All groups	[3]2.4–4.1	[3]3.7–4.0	[3]2.8–4.0						

[1] 0.5 ml dose rather than 1.0 ml of these lots reduced virus delivered to recipient by 100:3.
[2] Mean.
[3] Range.

Measles, Mumps, and Rubella Virus Vaccine, Live ("M-M-R") and Measles and Rubella Virus Vaccine, Live (M-R-Vax) Manufactured by Merck Sharp & Dohme, Division of Merck & Co., Inc.

1. *Description.* Each of the two products contains, in addition to its other components, further attenuated measles virus vaccine which is identical to Attenuvax. For rubella, the HPV–77 strain is used, and for mumps, the Jeryl Lynn strain is used.

2. *Analysis.*

a. *Efficacy.* The efficacy of further attenuated measles virus vaccines has been specifically tested (Ref. 1). In summary, it was found that in any combination tested of measles, mumps, and rubella, the measles component evoked serologic response in 95 percent or more of recipients, which is equal to its efficacy when given alone. Each viral component of the combined vaccine evokes a serologic response in 89 percent or more of the recipients (Ref. 1), comparable to the seroconversion rates noted when each of the vaccine components is used alone. (See also Ref. 6, p. 227.)

b. *Safety.* See generic reviews and appropriate monovalent product reviews.

c. *Benefit/risk.* The benefit/risk ratio for combinations of measles, rubella, and mumps virus vaccines or measles and rubella vaccines appears to be excellent in view of the obvious potential for such an approach in public health and mass immunization programs.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions—recommendations.* The Panel recommends that these products be placed in Category I and that the appropriate licenses be continued because there is substantial evidence of safety and effectiveness for these products.

Measles-Smallpox Vaccine, Live (Attenuvax-Smallpox) Manufactured by Merck Sharp & Dohme, Division of Merck & Co., Inc.

1. *Description.* The vaccine contains sufficient measles virus to give a final product concentration of at least 1,000 $TCID_{50}$/dose; sufficient smallpox vaccine to give a final product concentration of at least 50,000 pfu/dose; meomycin in approximately 25 mcg/dose; and trace amounts of other antibiotics and phenol which is introduced during the processing of the smallpox component since the regulations prescribe that this combined product be bacteriologically sterile (21 CFR 630.86(a)). The label indicates that the measles virus component derives from a more attenuated strain of the Edmonston measles virus (Attenuvax) grown at low temperatures in cell cultures of chick embryo. The vaccinia virus component is prepared from calf lymph which is produced and supplied by Wyeth Laboratories, Inc. The

lyophilized product is accompanied by a vial of sterile diluent for reconstitution.

a. *Recommended use.* The labeling indicates that the combined vaccine is "recommended for single dose jet gun primary immunization of children one year of age or older against measles (rubeola) and smallpox." The recommended dose of vaccine is 0.3 ml. It is pointed out that infants less than 12 months of age may fail to respond to one or both components of the vaccine due to the presence in the circulation of residual measles and/or vaccinial antibody of maternal origin. Smallpox vaccine alone is recommended for children already immune to measles or for revaccination against smallpox.

The indicated precautions include a prohibition against giving vaccine intravenously; the necessity for burning, boiling or autoclaving the vial and stopper before disposal and sterilizing parts of jet injector; having epinephrine available for immediate use in case of an anaphylactoid reaction; admonition against giving the combined vaccine less than 1 month before or after immunization with other live virus vaccines; deferral of vaccination for 3 months following receipt of whole human blood, ISG, or human plasma; use of due caution in giving vaccine to children with a history of febrile convulsions, cerebral injury, or any other conditions in which stress due to fever should be avoided; and finally, to avoid possible false negative responses, scheduling of any contemplated tuberculin test before giving measles vaccine. Both label and package insert mention how the lyophilized vaccine should be stored and state that unused, reconstituted vaccine should be discarded after 8 hours.

Mention of fever, rash, or both occurring 5 to 12 days after vaccination or at other times during the month following vaccination, the statement that moderate fever occurs occasionally and high fever (over 103° F) less commonly; and that encephalitis and other nervous system reactions have occurred very rarely in vaccinees given the individual vaccines are included under the heading "Adverse reactions." Additionally under the same heading the label mentions thrombocytopenia, purpura, regional lymphadenopathy, febrile convulsions, conjunctivitis, headache, and mild local reactions such as erythema, induration, and tenderness. Local reactions at the site of vaccination in children who have previously received killed measles vaccine are described. A variety of systemic symptoms associated with primary vaccinia are described which may occasionally be severe and include secondary bacterial infection with enlargement of the local lesion, lymphangitis, lymphadenitis, and accessory vesicles around the vaccination site, secondary lesions due to autoinoculation, and the occasional occurrence during or shortly after the height of reaction of vacuolar or papular erythematous skin eruptions which are transient and require no treatment. Also mentioned are the more serious complications including generalized vaccinia, progressive necrotizing vaccinia, and encephalitis.

Labeling contains a section headed "Action of vaccine" which notes that fever and/or rash may develop approximately 5 to 12 days after vaccination, presumably, although not so stated, due to the measles vaccine component. The remainder of this section deals with the usual response to vaccinia virus on primary vaccination. This description conforms to the current definitions of the WHO Expert Committee on Smallpox.

b. *Contraindications.* These are given as (a) sensitivity to egg, chicken, chicken feathers, neomycin, dihydrostreptomycin, polymyxin B, sulfate or chlortetracycline; (b) active untreated tuberculosis; (c) patients receiving therapy with ACTH, corticosteroids, irradiation, alkylating agents or antimetabolites; (d) individuals with blood dyscrasias, leukemia, lymphomas, or other malignant neoplasms affecting the bone marrow or lymphatic systems; (e) various gammaglobulin deficiencies; (f) individuals of any age suffering from eczema, skin conditions, wounds, or burns, or siblings or other household contacts of such individuals; (g) pregnancy; and (h) any febrile respiratory illness or other active febrile infection. No mention is made of the possible use of vaccinia immune globulin (VIG).

2. *Analysis.*

a. *Efficacy.* In the submission, items IV through VI, which deal with efficacy data, animal safety data, and human safety data are handled by reference to: (1) prior submissions for live measles virus vaccine or for combined live measles-smallpox vaccine dried; (2) license applications for Rubeovax and Attenuvax plus the supporting submissions and agenda of various dates; and (3) the license application and clinical data in support of smallpox vaccine-dried, product #72–12 Wyeth Laboratories, Incorporated. In addition, reference is made to attachments which consist of reference lists, a statement of marketing experience with Attenuvax together with summary tables of adverse reactions, and a detailed individual tabulation of serious neurologic disorders and of deaths associated with Attenuvax. The combined product has not been marketed in this country.

b. *Safety.* See above.

c. *Benefit/risk.* This product is a combination of two generically distinct live virus vaccines, which is for administration only by automatic jet injection for primary vaccination against smallpox and simultaneous immunization against measles. Its use is therefore currently limited to those areas of the world where simultaneous measles and smallpox immunization is a routine practice. Both vaccines are well established as effective individually, but they differ with respect to safety. In the case of the vaccinia component, the degree of risk in this country is currently judged to outweigh the potential benefit. In areas of the world where smallpox is, or has recently been endemic, vaccination is a significant benefit. With respect to the measles component, the risk is extremely small and is far outweighed by the benefits provided by protection against the naturally occurring disease.

d. *Labeling.* In the contraindications section of the labeling, the prohibition against vaccination in the presence of febrile respiratory illness or other active infection might be modified by the reasonable provision, "Unless contracting measles or smallpox involves greater risk." The list of contraindications is relatively complete, but the portion dealing with eczema and other skin conditions with special reference to household contacts of persons so afflicted should be in boldfact type or otherwise given special prominence. Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions—recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Rubella and Mumps Virus Vaccine, Live (Biavax) Manufactured by Merck Sharp & Dohme, Division of Merck & Co., Inc.

1. *Description.* This is a combination of mumps virus vaccine, live (Mumpsvax) and of rubella virus vaccine, live (Meruvax) (see the descriptions given in reviews of these two vaccines). Each dose of this combined vaccine contains not less than 5,000 $TCID_{50}$ of the Jeryl Lynn strain of

mumps virus (grown in chick cell tissue culture) and not less than 1,000 $TCID_{50}$ of the HPV-77 strain of rubella virus (grown in duck cell tissue culture). Each dose also contains 50 mcg of neomycin.

a. *Recommended use.* This product is designed to permit simultaneous immunization of children, age 1 to puberty, against rubella and mumps.

b. *Contraindications.* These are listed as pregnancy or prospect of pregnancy within 3 months; sensitivity to vaccine components, viz, chick or duck egg proteins or feathers, or neomycin; any febrile illness; blood dyscrasis (leukemia, lymphoma, generalized malignancies); and altered resistance from therapy (ACTH, corticosteroid, irradiation, alkylating agents, and antimetabolites).

2. *Anaylsis.* a. *Efficacy.*

(1) *Animals.* Not applicable.

(2) *Humans.* Four lots were administered to 415 children, 7 months to 7 years of age, who were initially without antibody against either mumps or rubella virus. Overall, 94.7 percent developed rubella hemagglutination inhibiting antibodies and 96 percent developed mumps neutralizing antibodies. The antibody responses elicited approximated those induced by either vaccine component given alone, and the pattern of antibody persistence, as measured at 2 years postvaccination was the same as that observed with the monovalent vaccines.

The combined vaccine is presumed to have the protective effectiveness equivalent to that provided by the monovalent vaccines.

b. *Safety.*

(1) *Animals.* The vaccine passed all the required safety tests.

(2) *Humans.* Clinical reactions, including joint involvement and fever, were notably absent among the children during the 28-day follow-up.

c. *Benefit/risk.* The ratio is good; vaccine associated reactions are assumed to occur at the same rate as those observed following the use of monovalent vaccine components.

d. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

3. *Conclusions—recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Reference

(1) J. J. Witte, "Simultaneous Administration of Live or Killed Vaccines," *in* "Symposia Series in Immunobiological Standardization," Vol. 22, Edited by F. T. Perkins, S. Karger, London, pp. 163–171, 1973.

Generic Review of Influenza Vaccines

Background

Unlike smallpox and poliomyelitis, influenza continues to plague man with periodic outbreaks of variable severity. Pandemics, affecting hundreds of millions of persons, may still be expected to occur.

Technologic advances have been contravened by biologic factors which are peculiar to influenza; foremost among these are the genetic instability of the causal viruses, which results in frequent major antigenic changes, and the short-lived immune responses which follow the natural disease as well as vaccination.

Nevertheless, vaccines prepared with virus strains responsible for current influenza have resulted in a significant reduction of cases of disease. A review of the benefit-risk factors clearly indicates that influenza vaccine has prevented thousands of cases of influenza, with most of the well-controlled trials having been conducted in young adults. It is believed that mass use of influenza vaccine will prevent a significant number of deaths, especially in high-risk groups.

Influenza virus vaccine is prepared from the extra-embryonic fluids of influenza virus-infected chick embryos. Whole virus is separated from nonviral egg proteins and debris by several purification steps, and concentrated by density gradient centrifugation and/or ultrafiltration. The virus is inactivated by formaldehyde and suspended in a sodium chloride solution with various buffers. These monovalent aqueous suspensions are titrated, adjusted to give the chick cell agglutination (CCA) unit content desired prior to combination, and pooled with the appropriate A or B strains in proper proportions to give the required CCA unitage per dose. Some producers employ viral disruption procedures utilizing polysorbate and ethyl ether or tri-n-butyl phosphate to prepare "subunit" vaccines.

In interpandemic years the ACIP policy emphasizes prevention of the most serious effect of the disease, i.e., excess mortality, by routine, annual immunization of individuals at high risk. The high-risk population is comprised of persons aged 65 and over, plus younger persons affected with chronic diseases, especially cardiopulmonary, which are believed to heighten vulnerability to a fatal outcome of influenzal infection.

Other groups on which special attention is focused are children and persons in essential positions, such as hospital employees or military personnel. Arguments have been advanced in support of the strategy of immunizing children, especially school children in order to limit, through herd immunity, the spread of the virus. While current interpandemic year recommendations do not emphasize this approach, vaccine formulations and dosage schedules should allow for such usage in the future.

Current evidence indicates that protection against the homologous virus strain persists for at least 1 year and in one study as many as 3 years. However, the present recommendation is for annual vaccination of high-risk groups.

Both monovalent and multivalent vaccines have been used in the past. The 1973 to 1974 formulation, which was submitted for review, was a bivalent one, with unequal amounts of influenza A (700 CCA) and B (300 CCA) viruses. Just how much total antigen should be included in a single dose is still the subject of debate. Experience accumulated during the clinical trials conducted in support of the National Immunization Program of 1976, suggests that the proper dose depends on the previous influenza experience of the vaccinee. (See Addendum following this section.)

Route of immunization has been another topic of debate. Intradermal injection appears to be inferior to either intramuscular or subcutaneous vaccination. While immunization by jet injection induces a high rate of local reactions, these are not of sufficient import to preclude the use of jet injection in mass immunization campaigns, and the resultant antibody responses are equivalent to those induced by intramuscular or subcutaneous vaccination. Intranasal immunization is still considered experimental.

None of the presently available influenza vaccines contains alum or other adjuvants. One product, the ether-tween split vaccine of Parke, Davis & Co. at one time contained aluminum phosphate; this was subsequently deleted from the vaccine when evidence was adduced that the aqueous vaccine was adequate in itself to stimulate antibody formation in adults.

Contraindications are given as follows:

1. The presence of acute respiratory or other active infections.

2. A history of hypersensitivity to chicken, chicken feathers, egg or egg products.

Analysis

1. *Efficacy.*

a. *Animals.* Many studies in animals, particularly the mouse and ferret, have demonstrated that killed virus vaccines protect against challenge with homotypic live viruses. The antibodies directed against the viral hemagglutinin neutralize infectivity and are responsible for protection against infection. The antibodies against the neuraminidase are believed to inhibit multicycle viral replication and spread of infection within the host and may serve to modify disease if infection does occur. Such models, adapted to the measurement of vaccine immunogencity, can provide basic information useful to the regulatory field. However, no animal model so far developed yields data which correlate consistently with observations in man.

b. *Human.* Inactivated, aqueous, whole virus influenza vaccines of adequate potency have been shown to provide substantial protection during epidemics caused by virus strains identical to or closely related to those contained in the vaccine. More data in support of this statement are available from well-controlled field trials for the Type A virus vaccines than for B vaccines, since the efficacy of the B component in any of the currently formulated vaccines has not been proven. Only a few well-controlled trials have involved the high-risk populations for which the vaccine is particularly recommended.

The protective efficacy of commercially prepared subunit vaccines is not clearly demonstrated. The problem is a two-part one. First is the question whether HI antibody induced by subunit vaccine is as preventive of disease as antibody induced by either whole virus vaccines or natural infection. This question, which is addressed in detail in the product reviews, has been only partially resolved in controlled vaccine, trials; the evidence from experimental animal models and inconclusive trials in humans favors the view that protective of vaccinees is correlated with the level of postvaccination HI antibody without regard to the type of vaccine administered.

The second issue is the capacity of subunit vaccines to stimulate antibody in human subjects. The preponderance of evidence from comparative studies of H_3N_2 subunit and whole virus vaccines suggests that subunit products are equally antigenic in adults but less antigenic in children. Results from 1976 trials of vaccines containing antigens in the A/Swine family indicate clearly that young recipients (those 3 to 10 years old) respond poorly to a single injection of subunit vaccine, when whole virus vaccines at the same or lesser dosage (in CCA units) often stimulate measurable HI antibody. It is likely that the poor response of children, especially to subunit vaccine reflects a lack of prior experience with related antigens. This is supported by the fact that older individuals (over 24 years) respond as well to subunit as whole virus vaccines. It is probable that the satisfactory response of seronegative school-age children and young adults to H_3N_2 subunit vaccines reflects prior experience with the same or related antigens, despite the absense of detectrable homologous HI antibody.

Efficacy data for vaccines prepared by current production methods are provided in the section on Reviews of Individual Influenza Virus Vaccine Products.

In the case of influenza, there are two compelling factors which lead to changes in vaccine formulation. First, the manufacturer regularly changes the component strains as directed by the PHS to conform with shifts in the antigenic makeup of epidemic strains. Evidence of the protective efficacy of current formulation is therefore difficult or impossible to obtain before the vaccine must be released for use. This poses special problems which are addressed under the heading Recommendations below. Second, the manufacturer may change the basic production process as acquisition of basic information and technical knowledge makes a superior or more economic product possible.

Nevertheless, the accumulation of certain data is desirable. For example, this information includes the history of the virus strain or strains to be used, as well as subsequent passage history and evidence of consistency in quality.

2. *Safety.* Local and systemic reactions to influenza vaccines do occur. The most commonly reported reactions are soreness, redness, and swelling at the site of injection and fever, malaise, and headache during the 24 hours following vaccination. These reactions may be briefly disabling and have been reported, on an episodic basis, with undesirable frequency. Such reactions have adversely influenced vaccine acceptance. While there is evidence to support claims that purified whole virus or subunit vaccine as currently produced are less reactogenic than earlier, conventional vaccines, this is now a less relevant factor in recommending one vaccine over another, inasmuch as no licensed products are any longer conventional. However, while major systemic reactions are now rarely reported, there is evidence that, at least in children, subunit vaccines are appreciably less reactogenic than whole virus products.

Febrile reactions are more common in children than in adults. These, as well as other systemic reactions, are in part related to preexisting immunity. Thus, there is an inverse correlation between incidence of systemic reactions and HI antibody against the vaccine strain or history of a recent homologous immunization. In children under 3 years of age, administration of large (adult) doses of whole virus vaccine has been associated with a rapid rise in temperature 6 to 9 hours later and, in a few instances, convulsions. Dosages in this age group which are both immunogenic and of acceptable reactogenicity remain to be established.

Information has accumulated recently on the extraneous, nonviral content of influenza vaccines. The stimulus for this data gathering has been the limited understanding of the factors underlying the variable systemic reactogenicity of the more purified present-day vaccines, and the lethality of some recent formulations for guinea pigs after parenteral injection (done as part of the routine, final safety test). This lethal effect for guinea pigs has been attributed to both the endotoxin and the viral content of the vaccine. Vaccine lots containing less than 0.8 microgram/milliliter (mcg/ml) of endotoxin have not killed guinea pigs, and those containing more were lethal in proportion to the amount of endotoxin present. Endotoxin alone, however, is not entirely responsible.

In the process of these investigations, information was also obtained on the content of diffusable egg protein, total protein, residual formalin, and particulate contaminants visible by electron microscopy. The characteristics (contaminating diffusable chick protein, endotoxin, total protein, and formalin content) of six recent influenza vaccine lots in this respect, as determined by the Bureau of Biologics, are illustrated in Table 16.

Table 16.—*Chemical and Biological Characteristics of Six Lots of Bivalent Influenza Vaccine*

Manufacturer	Vaccine		Total protein [1]	Chick cell [1] protein	Limulus [1] endotoxin	Rabbit pyrogen [2]	Formalin
	Type	CCA					
A	ZPWV	990	239	0.5	0.06	UNDIL.	3.0
B	ZPWV	1150	442	0.5	0.06	1.10	0.9
C	ZPWV	1440	243	<.01	<.001	0	3.0
D	CPWV	1050	1480	0.02	0.20	1.100	4.4
E	TBP	1120	206	10.55	0.02	1.10	16.8
F	ET	1240	114	<.01	0.11	0	6.2

[1] Microgram/dose.
[2] Last dilution which induced a mean temperature elevation of >.5° C.

Key.—ZPWV: Zonally purified whole virus.; CPWV: Chromatograph purified whole virus; TBP: Tri-batyl phosphate; ET: Ether treated.

The reactogenicity and antigenicity of these six vaccines were carefully compared by the Bureau of Biologics and a recent clinical trial. There was no demonstrable association of any contaminant or combination of contaminants with adverse systemic reactions. Further studies which compared vaccines with widely differing endotoxin concentration have confirmed this conclusion. Nevertheless, since endotoxin was considered undesirable in itself, the Bureau of Biologics took steps in the fall of 1974 to limit the permissible content in the following year's vaccines. At the same time, the guinea pig safety test was altered by the stipulation that the vaccine may be inoculated subcutaneously to avoid deaths believed more attributable to inherent properties of the viral antigens than to adventitious toxic compnents.

The extensive experience in the clinical trials of "swine influenza" vaccines in 1976 corroborated these conclusions. Endotoxin content was not related to systemic reactogenicity. Rather, it was clear that split virus vaccines were of low reactogenicity and that the toxicity of whole virus vaccine was related to the viral mass then contained. An additional risk of influenza vaccination became evident in the National Immunization Program in the fall of 1976, namely the excess occurrence of Guillain-Barre-Syndrome (GBS) in persons who had recently received vaccine.

3. *Benefit/risk.* Epidemic influenza is associated with a considerable morbidity and, in certain groups, an excess mortality. Prevention of such disease and death is highly desirable. The risk associated with present vaccines is small, even including the risk of GBS. (See Addendum following this section.) Their efficacy, when they are properly matched against the infecting strains, is between 60 and 90 percent. Thus, the benefit-risk ratio is, from the data available, acceptable. There is, however, a compelling need for efficacy studies in high risk populations so that the true benefit/risk ratio in these target groups can be more precisely assessed.

4. *Labeling.* Labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP.

Recommendations

Since influenza vaccines must, of necessity, be produced with continuous changes in formulation, a review of effectiveness prior to release of a current lot must focus more on the process of manufacture than on specific viral strains. Assumptions regarding a given process must be based on knowledge of safety, antigenicity, and effectiveness of vaccines produced by that process. In addition, recently acquired information on vaccine contaminants raises a number of questions which cannot be answered at this time.

1. *Potency of licensed vaccines.* The present method for standardizing vaccine potency (by CCA units) does not take into account fragmentation and aggregation of viral particles and other possible factors which are clearly of importance in determining the antigenicity and reactogenicity of a vaccine in man. For this reason, the Bureau of Biologics should be encouraged to continue its investigations on the possible supplementary use, or even substitution, of other tests of potency, in particular, suitable animal test models and in vitro measurement for antigenic mass. (See Addendum following this section.)

2. *Presence of nonviral components.* The Bureau of Biologics should establish standards of the maximal acceptable level of nonviral components in influenza vaccines. Regulations cover the endotoxin content, and if adequate quantitative measurements can be developed, the content of nonviral protein and of diffusible chick protein should be similarly covered by regulations.

In addition, efforts should continue by the Bureau of Biologics, National Institutes of Allergy and Infectious Diseases (NIAID), and the Center for Disease Control (CDC) to determine what components of present-day vaccines are responsible for local and systemic reactions in man. An important aspect of such efforts would be prospective studies of representative recipients of a suitable number of consecutive vaccine lots to identify the most reactogenic lots for further study and to determine the reason for the lesser reactogenicity of split-virus vaccines.

3. *Vaccine antigenicity, safety, and efficacy.* It is a characteristic of influenza vaccines that component virus strains need to be changed frequently. It is also probable that manufacturers will from time to time introduce changes in the manufacturing process. Control of the vaccines for changes in the component viral strains and in the manufacturing process is the responsibility of the Bureau of Biologics. The extent and nature of testing in vitro, and in animals and man, necessary with each change to demonstrate the safety and potency of each new vaccine should be, as far as possible, prescribed in detail. The following guidelines are submitted by the Panel to aid the Bureau in its delineation of rules and regulations.

A major change in process is defined as (1) one which alters the nature of the virus so that whole particles are no longer the major antigenic units; (2) one which changes the ratio of the mass of component virus parts (such as hemagglutinin, neuraminidase, etc.) to each other; (3) one which introduces major extraneous components into the vaccine (such as adjuvants, detergents, etc.); or (4) any other change which the Bureau deems is sufficiently significant to require extensive proof of safety and efficacy. A change of this nature will necessitate carefully controlled tests of safety and antigenicity in adults and children. The new product also should be shown to be comparable or superior to vaccines prepared by acceptable earlier processes. In addition, evidence should be presented that a well-designed trial of the efficacy of the vaccine in man is in process. The trial should be expected to provide data concerning the efficacy of at least one of the several antigenic components. The requirements concerning major changes should be enforced retroactively, if the requirements have not been satisfied in relation to a prior major change. In this regard, currently available whole virus vaccines are similar enough to one another that trials of protective efficacy (but not of antigenicity or of safety) carried out with one such vaccine may be considered to apply to all whole-virus vaccines of similar or greater

potency as established by appropriate laboratory testing.

Minor changes in manufacturing process which would not reasonably be expected to alter either the safety or antigenicity, would necessitate lesser amounts of safety and antigenicity testing, confined to adults. Such requirements would likewise be enforced retroactively, if necessary, for prior minor changes.

Changes in component virus strains, dictated by the Bureau, do not require efficacy tests for protective effect of each vaccine in human subjects. However, particularly in view of the recent experience with A/Swine vaccine, new strains ideally should receive antigenicity testing in a small number of human subjects of a suitably wide age range so that there is assurance of potency in the age groups for which the vaccine is recommended. Antigens of new strains should also be investigated for their immunogenicity, i.e., ability to induce protective immunity, in animal models. Perhaps the Bureau may find it of advantage to have each manufacturer conduct animal immunogenicity trials with his own vaccine and compare it in potency with a standard vaccine.

4. *Special studies.* There are a number of other issues which the Panel believes should be examined by the Bureau, in collaboration with NIAID, CDC, and the ACIP.

a. Vaccine trials in high-risk adult groups are needed, since, although these are the priority target populations, information on efficacy is scanty. The construction of placebo or unvaccinated control groups must take into account the fact that vaccine is recommended in such individuals; hence, only persons refusing offered vaccine would be eligible as controls.

b. Studies should be undertaken of the safey, antigenicity, and protective effect of vaccines in children under 6 years including, in particular, those with no prior influenza infection experience. The problems of dose, vaccination schedule, and toxicity require special investigation. Monovalent vaccines will be required to examine differences in toxicity of Type A and Type B viral components. On epidemiological grounds, prevention of infection among young children would be desirable. Further, the ability to immunize effectively and safely those who have never experienced influenza infection may be of greater importance when the next major antigenic variant emerges and a much larger proportion of the population will fall into this category. As noted in previous sections, in the young age group the advantage lies with subunit vaccines for reactogenicity but with the whole virus product for immunogenicity. The Panel believes resolution of this dilemma is of critical importance. As noted in the Addendum (following this section), the results of the 1976 nationwide clinical trials have provided one solution to this problem, i.e., a two-dose regimen of subunit vaccine.

c. Particularly emphasis should be placed on investigating the protective efficacy of the B component in current vaccines. Although B vaccines have been shown to induce sufficient protection in both civilian and military populations, these formulations contained less antigen than presently recommended, sometimes with an adjuvant. In comparison with A vaccines, B vaccine field trials have been few in number, a fact attributable to the different epidemiology of B infections (Ref. 13). Further, data from one study suggests that natural infection with Type B affords negligible protection against reinfection and associated disease. In addition to well-controlled field trials, consideration needs to be given to volunteer challenge studies to support continued inclusion of B virus, and its amount, in future vaccines.

D. The bureau should periodically review the status of adsorbants and adjuvants in experimental influenza vaccnes, as more data are collected on their safety and efficacy in human subjects.

e. Recent experience with swine influenza vaccines underlines the importance of rare but severe vaccination sequellae. In this particular case, the disease was GBS, but other diseases may also occur with other latent periods and enter into the calculation of benefit-risk ratios. The Bureau, in cooperation with CDC and NIAID, should remain on the outlook for such rare events, following influenza and other vaccines, both live and inactivated. These problems are discussed more fully in the Introductory comments section of this document.

Addendum to Generic Review of Influenza Virus Vaccines

The foregoing review was essentially completed in late 1975 and modified slightly in June 1976 in light of the early results of the nationwide clinical trials of influenza vaccines, sponsored by NIAID in relation to the National Influenza Immunization Program. On January 20, and 21, 1977, the many investigators participating in these trials made formal presentations of their data at a meeting at National Institutes of Health (NIH) in Bethesda. The more than 50 separate presentations and, presumably, the related discussions are to be published in a special supplement of "The Journal of Infectious Diseases." At the same meeting the significant data relating to the possible association between influenza vaccination and GBS were presented by a representative of CDC. The following is a summary of the most important findings and conclusions resulting from the clinical trails and of the problem posed by GBS. Their documentation can be found in "The Journal of Infestious Diseases" supplement and/or (for GBS) contemporary issues of the "Morbidity and Mortality Weekly Report."

The clinical trials had as their objective determination of the dose (or doses) of monovalent (A/Swine) and bivalent (A/Swine plus A/Victoria) influenza vaccines produced by four manufacturers which would induce satisfactory immune response with an acceptably low level of reactions. These trials involved nearly 8,000 volunteers ranging in age from 6 months of 65 years and older and were conducted by over 20 teams of investigators, all of whom followed a common basic protocol. This protocol called for inoculation of healthy or high-risk volunteers in prescribed age groups with randomly assigned, coded preparations, each representing a particular dose of vaccine produced by one of the four manufacturers or an inert placebo. Also required was completion of careful records concerning local and systemic reactions during the 48 hours postinoculation and collection of appropriate blood specimens to determine antibody response. All antibody assays were done—still under code—in the laboratories of CDC.

Reactions to vaccines were related to type and dose of vaccine, the method of inoculation, and the age and immune status of the vaccinees. Method of inoculation (intramuscularly, by needle, or jetgun) was related only to local reactions; these were more common and somewhat more extensive when the jetgun was used. Whole virus vaccines tended to induce more frequent and more serve systemic reactions (fever, headache, malaise, etc.) than did split virus or subunit vaccines. Moreover, there was no evidence that, in persons 3 years of age and older, subunit vaccines had any significant systematic toxicity in the dosage levels tested. The incidence and intensity of systemic reactions with a particular whole virus vaccine tended to increase with vaccine dose especially in the younger age groups. A history of a recent previous homologous vaccine injection or a level of preexisting vaccine-strain specific HI

antibody appeared to mitigate reactivity. Within the range of vaccines tested no other factor, e.g., endotoxin content, was related to reactions. The inescapable conclusion is that the principal cause of immediate systemic reactions is something within the virus itself, which is largely lost or masked during the manufacture of split virus vaccines and which is obstructed by viral antibody.

Immune response (measured by HI antibody titer) also was related to type and dose of vaccine and to age vaccinee. For persons 25 years and older, the smallest single doses tested (200 CCA) of vaccines produced by each manufacturer (two whole virus, two split virus) induced acceptable responses to both A/Swine and A/Victoria antigens. In younger individuals, the results were different, especially for response to the A/Swine antigen. Response to whole virus vaccines tended to exceed that to subunit vaccines but no dose tested, even of the more potent whole virus vaccine, induced satisfactory response (HI titer of 1:40 or higher) in seronegative volunteers with acceptable frequency. This outcome suggested that the prior infection experience of persons 25 years and older, i.e., experience with influenza A strains prevalent prior to 1957, had conditioned or primed them immunologically to respond anamnestically to the A/Swine antigen. An obvious general conclusion is that the dose of any specific vaccine needed to induce satisfactory immune response is in large part dependent on the previous influenza antigen experience of the vaccinees.

The relative failure of vaccines in younger person meant that futher trials were necessary. The frequency of systemic reactions to the largest doses of whole virus vaccines tested was unacceptably high, especially in those under 18 years of age. This made it clear that simply increasing the dose of vaccine was not the answer and led to trails of regimens involving two doses of vaccine. The importnat outcome of these trials was that subunit vaccines, in adult doses (200 CCA of monovalent A/Swine or bivalent with 200 CCA of each antigen) proved nonreactogenic and satisfactorily immunogenic in ages as young as 3 years. Trials in still younger children (down to 6 months) were conducted in too few subjects to justify firm conclusions, but the results suggested that, in reduced dose (100 CCA), the two-dose regimen of subunit vaccine also may be successful. Two small doses of whole virus vaccines, while still reactogenic, also proved highly immunogenic. Thus, it appears that influenza vaccine can be used effectively and safely in young children if a two-dose regimen of subunit (and possibly even of whole virus) vaccine is employed. Such a regimen, although not ideal, would be acceptable in the interpandemic period. However, in the face of a threatened pandemic posed by a major influenza A variant, time would be a critical factor and a one-dose vaccination would be highly desirable.

A possible way to achieve this is suggested by studies with highly purified preparations of hemagglutinin and neuraminidase. Although these proved poorly immunogenic alone, combining these with small amounts of whole virus greatly enhanced their immunogenicity. This suggests that a similar addition of small amounts of whole virus to standard subunit vaccines might have a similar enhancing effect.

A further important byproduct of the trials was the result of efforts to quantitate the hemagglutinins and neuraminidase content of vaccines. Methods of measuring hemagglutinin content of vaccines, based on immunodiffusion in antibody-containing agar, show great promise as prospective regulatory tools which may substitute for the CCA test (Ref. 1). In the trials, hemagglutinin levels, although still not precisely predictive, correlated better than CCA content with both the reactogenicity of whole virus vaccines and the antigenicity of all vaccines in some age groups. The methods for neuraminidase measurement are still in development and further research should be encouraged.

The National Immunization Program was initiated effectively as of October 1, 1976. By mid-December some 45 million doses of vaccine, monovalent A/Swine or bivalent A/Swine plus A/Victoria, had been given, almost exclusively to adults (18 years and older). Use in younger persons (other than high-risk) was effectively prevented by lack of the recommended subunit type of monovalent vaccine. As of December 16, 1976 a moratorium on the further use of influenza vaccine was declared because of a possible association between vaccination and occurrence of GBS. As of January 12, 1977, 582 cases had been recognized in the United States with onsets on or after October 1, 1976, nearly 300 of which had received influenza vaccine within 4 weeks prior to onset. Analysis of the available information, including age distribution and age-specific rates, suggests that vaccination was associated with a 10-fold increase in the risk of developing GBS within the month following vaccination. (This increase in risk is estimated at 1 in 110,000 vaccinations.)

The fundamental cause of GBS remains unknown. A widely accepted hypothesis is that it is a form of autoimmune disease which may be triggered in peculiarly vulnerable persons by immune response. Prior reviews implicate naturally occurring acute infections of many types as the most common triggers. The experience in fall, 1976, makes it clear that vaccination, at least influenza vaccination, also can serve as a trigger. Thus, in describing the possible risks associated with influenza vaccine, GBS must be included. This risk of developing the syndrome is estimated at one in 110,000 vaccinations. Although most cases of GBS recover fully, respiratory paralysis results in death in about 3.5 percent of cases. This is an extremely small risk which is far outweighed by the potential benefits of successful immunization.

Reviews of Individual Influenza Virus Vaccine Products

Influenza Virus Vaccine, Bivalent (Flu-Immune) Manufactured by Lederle Laboratories Division, American Cyanamid Co.

1. *Description.* The package circular states that:

Influenza Virus Vaccine, Bivalent Flu-Immune, Lederle is prepared from the allantoic fluid of embryonated chicken eggs infected with influenza virus. The virus is inactivated with formaldehyde and ethylene oxide. The concentrated virus is suspended in a buffered diluent containing sodium citrate, sodium phosphate monobasic and sodium phosphate dibasic. Thimerosal (1:10,000) is added as a preservative and the preparation is further purified by a chromatographic process.

In chromatographic purification the conventionally prepared Influenza Virus Vaccine is passed through a molecular sieve composed of chemically inert, porous, borosilicate spheres. These spheres have controlled size pores which entrap extraneous protein.

Chromatographically purified Influenza Virus Vaccine has significantly less extreneous protein content than conventionally prepared Influenza Virus Vaccine, as measured by protein determinations and electron micrographs. . . .

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.*

a. *Efficacy.*

(1) *Animals.* Potency data were not submitted.

(2) *Humans.* Data have been submitted on an antigenicity study which may be summarized as follows:

(i) *Investigator.* Peninsular Testing Corporation, North Miami, FL (Annual Progress Report, September 1973).

(ii) *Vaccine.* Flu-Immune-Bivalent. Each 0.5 ml dose contains:

A2/Aichi/2/68–X–31—700 CCA units.
B/Mass/1/71—300 CCA units

(iii) *Population:* Adult volunteers, 17–69 years.

(iv) *Dosage.* Group I—0.5 ml intramuscularly (100 subjects); Group II—0.5 ml subcutaneously (100 subjects); Group III—two 0.5 ml doses, intramuscularly, 6 weeks apart (46 subjects); Group IV—two 0.5 ml doses, subcutaneously 6 weeks apart (43 subjects).

(v) *Results.* Two 0.5 cc vaccine doses spaced 6 weeks apart stimulated a fourfold increase in HI antibody titer in approximately 70 percent of individuals given the vaccine intramuscularly and approximately 64 percent of those given the vaccine subcutaneously. Details of the serologic responses are presented in Tables 17 and 17a.

Table 17.—*Summary of Results Obtained in Antigenicity Study of Flu-Immune, Bivalent*

Vaccine group	Geometric mean titers					
	MASS-B			X-31		
	Preinoculation	6 weeks	12 weeks	Preinoculation	6 weeks	12 weeks
Intramuscular, 1 dose	17.7	141.4	103.1	23.7	214.4	130.6
Intramuscular, 2 doses	18.6	95.5	102.4	25.0	185.4	201.6
Intramuscular, all	18.1	115.7	102.7	24.3	199.0	163.9
Subcutaneous, 1 dose	20.3	83.9	89.0	27.8	138.8	138.8
Subcutaneous, 2 doses	17.9	108.7	88.1	23.1	128.6	129.8
Subcutaneous, all	19.0	95.4	88.5	25.4	148.1	134.0
Combined	18.5	105.4	95.5	24.8	167.0	148.5

Table 17a.—*Summary of Results Obtained in Antigenicity Study of Flu-Immune, Bivalent—Individuals Showing a Fourfold Rise in Titer*

Vaccine group	MASS-B		X-31	
	6 weeks	12 weeks	6 weeks	12 weeks
Intramuscular, 1 dose	30/45 (67%)	28/41 (68%)	32/45 (71%)	23/41 (56%)
Intramuscular, 2 doses	30/47 (64%)	34/45 (76%)	30/47 (64%)	34/45 (76%)
Intramuscular, all	60/92 (65%)	62/86 (72%)	62/92 (67%)	57/86 (66%)
Subcutaneous, 1 dose	30/44 (68%)	27/39 (69%)	32/44 (73%)	23/39 (59%)
Subcutaneous, 2 doses	28/43 (65%)	26/43 (60%)	25/43 (58%)	29/43 (67%)
Subcutaneous, all	58/87 (67%)	53/82 (65%)	57/87 (66%)	52/82 (63%)
Combined	118/179 (66%)	115/168 (68%)	119/179 (66%)	109/168 (65%)

It is assumed that vaccines of this antigenicity will induce a significant degree of protection. However, no studies are mentioned in the submission nor were any found in the recent literature which demonstrate the protective efficacy of Lederle Laboratories vaccine as last prepared. One study employed a Lederle Laboratories vaccine presumably prepared by older methods and demonstrated a protective effect (Ref. 2). Likewise, the X–31 recombinant vaccine described by Kilbourne has been shown to be effective in volunteer challenge experiments.

b. *Safety.* (1) *Animals.* See generic statement. Data on COFAL testing were not given in the producers submission.

(2) *Humans.* In the study cited above, "there were no significant differences (subcutaneous vs intramuscular) in the local or systemic reactivity immediately following vaccine administration. However, there were statistically significant differences observed in the local reactivity at 24 hours post-inoculation. Individuals who were administered vaccine intramuscularly had fewer incidences of erythema (8/95) and induration than the subjects who received the vaccine by subcutaneous administration (34/93)." There were no significant differences in systemic reactivity (e.g., chills=4/95 vs 3/93).

The producer has received 35 written complaints for the many millions of doses marketed.

c. *Benefit/risk.* See generic review.

d. *Labeling.* See generic review.

3. *Conclusions—Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license be continued because there is substantial evidence of safety and effectiveness for this product.

Influenza Virus Vaccine, Bivalent (Zonomune) Manufactured by Eli Lilly & Co.

1. *Description.* The package circular states:

Influenza Virus Vaccine, Bivalent, U.S.P., Zonomune(R) (zonal centrifuged vaccine, Lilly) is composed of the recommended contemporary strains of influenza viruses. The vaccine virus is grown in embryonated chicken eggs but is not processed by the usual differential centrifugation technics. Instead, the virus is purified and concentrated in a sucrose density-gradient solution by means of a continuous-flow isopycnic centrifugation process. By this procedure, the virus can be removed selectively from the nonviral components of the egg fluid. Amorphous and cellular residue usually found in conventionally produced vaccine (as demonstrated by electron micrographs) is discarded. Furthermore, laboratory studies utilizing gel-diffusion technics have demonstrated a significant reduction in specific soluble chicken-protein components in vaccine manufactured by the Zonomune process as compared with conventionally produced vaccine. As a result of these new production methods, the adult dosage volume has been decreased by half, to 0.5 ml., while retaining full antigenic potency * * *.

* * * Neomycin has been added to the virus inoculum, and negligible amounts remain after processing. The virus is inactivated with formaldehyde solution (no more than 1:10,000 in the final product) and preserved with Merthiolate(R) (thimerosal, Lilly), 1:10,000. Iodoacetic acid was used as a preservative during the processing and does not exceed 0.15 mcg./ml. in the final vaccine. The preparation also contains Gelatin, U.S.P., 0.2 percent, and sucrose, less than 10 percent, in the final product.

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.* a. *Efficacy.*

(1) *Animals.* See generic statement.

(2) *Humans.* Since Zonomune manufactured by Eli Lilly & Co. was the first zonal centrifuge purified vaccine available, it was extensively tested during the 1968 to 1969 Hong Kong influenza epidemic. There are several studies showing that immunization at that time conferred protection both in adults and in children.

(i) *Antigenicity.* Data adduced in 1967 are provided comparing human reactivity to vaccine (containing Taiwan and Maryland B strains) produced by isopycnic and by Sharples centrifugation. On the basis of

equivalent populations in regard to prior immunization status, four lots of isopycnic vaccine produced a rise in HI antibody titer equivalent to that found in Sharples vaccine.

(ii) *Protection.* The following studies have been excerpted from the literature:

(*a*) *Study I.*

Investigator. Knight et al. (Ref. 3).

Vaccine. A_2/Aichi/2/68 Monovalent. Prepared by continuous flow zonal ultracentrifugation; formol inactivated.

Population. Prisoners, November 1968.

Challenge. Natural epidemic caused by Hong Kong virus strains.

Results. Conclusion based on occurrence of illness in relation to dose. (See Table 18).

There was significantly less illness (5.6 percent) among men who received the three higher doses of vaccine than among nonimmunized men (11.7 percent) ($X^2=5.46$; $P<0.03$). When only febrile cases were considered, the difference between the occurrence of illness among all immunized and nonimmunized men was significant ($X^2=4.46$; $P<0.05$), with even greater differences for higher doses.

Table 18.—*Illness in Vaccinated Volunteers Exposed to Natural Challenge*

Dose of vaccine CCA units	Number vaccinated	Acute respiratory illness	
		Febrile	Afebrile (>99°F)
1265	78	3	1
535	39	1	3
332	59	2	1
137	60	7	2
54	14	2	1
Immunized group	270	15	8
No vaccine	755	76	12

(b) *Study II.*

Investigator. Gwaltney et al. (Ref. 4).

Population. Elderly psychiatric patients, November 1968.

Vaccine. (*1*) Zonomune, monovalent A_2 (400 CCA Hong Kong virus in 0.5 ml); (*2*) Control-B/Mass/3/66 (Lilly), 400 CCA units in 0.5 ml; (*3*) Booster Vaccine (Lilly) 1965–70 bivalent formulation.

Dosage. (*1*) Jet injector, 0.5 ml, 400 CCA A_2/HK; (*2*) Jet injector (control) 0.5 ml, 400 CCA, B/Mass; (*3*) Spray: 0.125 cc (100 CCA) nebulized into each nostril and 0.25 cc (200 CCA) into orophraynx during inspiration. The groups are described in Tables 19 and 20.

Results. There was a significant reduction in the influenza attack rate in the group receiving vaccine by jet gun (5.5 percent) or by gun spray combined (5.4 percent) as compared to the controls (14.7 percent) or those receiving vaccine by spray alone (12.2 percent).

(c) *Study III.*

Investigator. Couch et al. (Ref. 5).

Vaccine. A_2/Aichi/2/68; 503 CCA units/ml; 1.0 ml given intra-muscularly. (This vaccine was compared with the A_2/X–31 vaccine (556 CCA units/ml), which is not made by Eli Lilly and Co.)

Population. Adult volunteers (prisoners).

Challenger. A_2/Aichi live virus; first passage HEK 1,000 $TCID_{50}$/0.5 ml; 8 HID_{50} estimated.

Table 19.—*Vaccine Groups and Route of Inoculation of Vaccine*

Vaccine group	Route of inoculation [1]	
	Subcutaneous	Naso-pharyngeal
Jetgun	A_2/HK	B/Mass/3/66.
Spray	B/Mass/3/66	A_2/HK.
Combined (jetgun and spray).	A_2/HK	A_2/HK.
Control	B/Mass/3/66	B/Mass/3/66.

[1] 400 CCA units of each vaccine administered by route shown.

Table 20.—*Influenza Illness Rates in Vaccinated Psychiatric Patients Exposed to Infection During Naturally Occurring A_2/HK Influenza Epidemic*

Vaccine group	Number of persons	Reported	Number of patients		Influenza attack rate/100
			Tested	Positive	
Control	87	14	14	11	14.7
Spray	89	12	12	10	12.2
Jetgun	90	5	4	4	5.5
Combine (jetgun and spray)	88	6	5	4	5.4

Results. When frequency of illness in the vaccinated groups was compared to that in the control group saline, a significant reduction was noted in the group receiving the X–31 vaccine ($p=0.02$) and a borderline reduction in the group receiving the Aichi strain vaccine ($p=0.06$). This is summarized in Table 21.

Table 21.—*Occurrence of Illness in Vaccinated Volunteers Challenged With Live A_2/Aichi Strain Vaccine*

Vaccine group	Number of volunteers	Virus isolated	Results of challenge inoculation		
			4-fold antibody rise	Number ill	Number febrile
Saline Control	14	11	11	6	4
A_2/Aichi	15	5	4	1	1
A_2/X–31	14	2	0	0	

b. *Safety.*

(1) *Animals.* See generic review. COFAL test are described.

(2) *Humans.* The submission contains an excellent summary of studies performed by Eli Lilly and Co. staff in 1967 which indicates that Zonomune produce fewer local and systemic adverse reactions than the previous product. Comparisons of Zonomune with other purified vaccines have been submitted by other drug companies which confirm these results.

Data on serious adverse reactions are not submitted. There is at least one report (not mentioned in the submission) of meningoencephalitis following Zonomune (Ref. 6).

c. *Benefit/risk.* See generic review.

d. *Labeling.* See generic review.

3. *Conclusions—recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Influenza Virus Vaccine, Bivalent (Fluax) Manufactured by Merck Sharp & Dohme, Division of Merck & Co., Inc.

1. *Description.* The package circular states FLUAX—(Influenza Virus Vaccine, MSD). Bivalent Types A & B, Filter and Zonal Centrifuge Purified, is an aqueous suspension containing the recommended contemporary strains of influenza viruses. The vaccine virus is grown in embroynated chicken eggs and purified by a series of physical separation steps. Cellular residues and other extraneous particulate contaminants are removed by means of sedimentation-clarification of the extra-embryonic fluid. The resultant fluid is further freed of undesirable (non-viral) materials by selective filtration through controlled pore size filters. The final purification step consists of isopycnic banding of the virus in sucrose in a flow zonal centrifuge with selective recovery of influenza virus. Sedimentation analysis of the zonally fractionated vaccine demonstrates the absence of impurities. Formalin is the inactivating agent. Thimerosal 1:10,000 is added as preservative.

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.*

a. *Efficacy.*

(1) *Animals.* Potency data are provided, with specific reference to stability of vaccines.

(2) *Humans.* Only one study of antigenicity and reactogenicity was presented by the manufacturer for the product as presently prepared.

Study 234 (1969) involved two lots of

zonal centrifuge-filter purified aqueous vaccine containing A_2/Aichi/2/68, 400 CCA/ml and B/Mass/3/66 and 300 CCA/ml.

Two 0.5 ml doses were given subcutaneously at a 1-month interval to males 17 to 69 years of age. The serologic responses observed are summarized in Table 22.

Table 22.—*Serologic Responses to Vaccine*

	Number with 4-fold greater response/total number texted (by month)								GM titer of HI antibody by month					
	Initially seronegative				All vaccinees									
	A_2/Aichi		B/Mass		A_2/Aichi		B/Mass		A_2/Aichi			B/Mass		
	Months													
	1	2	1	2	1	2	1	2	0	1	2	0	1	2
Lot number of vaccine:														
1121	13/21	13/20	5/5	4/5	14/33	19/31	8/33	6/31	3	16	20	16	42	31
4/98450	(62%)	(65%)	(100%)	(80%)	(42%)	(61%)	(24%)	(19%)						
1121	16/22	16/23	2/3	1/3	17/33	18/34	5/33	3/34	3	22	22	19	37	30
598451	(73%)	(70%)	(67%)	(33%)	(52%)	(53%)	(15%)	(9%)						

In addition to this study, the following statement is made in a Merck Sharp & Dohme supplemental submission:

There are no data to indicate the protective capacity of the specific product in response to natural infection or artificial challenge. However, it is fairly well accepted among influenza virus experts that a level of circulating hemagglutination-inhibition antibody of 1:40 or greater generally correlates with protection. In a series of 6 clinical studies which incorporated zonal centrifuge-purified aqueous type influenza virus vaccine as control, and which involved about 450 persons, approximately 80 percent of the subjects had a 1:40 or greater titer of HI antibody to the A_2 influenza virus strain and about 50 percent had similar activity to the B strain. It would be expected that the same general level of protective antibodies would be generated in the population at large.

The data from these six clinical studies mentioned are not available. However, there is recent information obtained by the Bureau of Biologics that influenza vaccine produced by this manufacturer is similar in antigenicity to other whole virus influenza vaccines.

In spite of the claim in the submission that "there are no data to indicate the protective capacity of the specific product," there is one published report where a Merck Sharp & Dohme vaccine was used in April 1969 to prevent Hong Kong influenza (Ref. 7). This vaccine, which was not prepared by the current process (Zonal centrifugation), contained the A_2/Aichi/2/68 strain (CCA unitage unknown) and was administered subcutaneously in 1.0 ml doses.

Some 1,254 Bantu subjects received the vaccine and 413 received placebo; all worked in the same factory. An outbreak of influenza-like disease was observed in May 1969, some cases of which were proved to be Hong Kong influenza. The incidence of clinical influenza in the control group was 31/1,000 and in the vaccinated group was 5/1,000.

b. *Safety.* (1) *Animals.* The released vaccines meet Federal requirements.

(2) *Humans.* In the study summarized in Table 22 above, there were only two cases of local erythema and essentially no febrile or other adverse reactions greater than those noted in controls. It is disturbing, however, that local swelling or induration, and malaise, headache, chills, etc. were apparently not looked for in this study. Additional information on human safety is, however, provided in recent studies performed by the Bureau of Biologics and the manufacturer. In these trials the rates of reactogenicity of this vaccine were similar to those of other whole virus vaccines.

c. *Benefit/risk.* See generic review.

d. *Labeling.* See generic review. One suggested change is that the reduction in volume (from 1.0 to 0.5 ml) should not be claimed to be an unusual feature of the vaccine, since this has been achieved by all companies presently marketing influenza vaccines.

3. *Conclusions.* a. *Critique.* This Merck Sharp & Dohme submission suffers from the defects seen in others from the same manufacturer. No protective data were submitted by the manufacturer. The matter of protection is dismissed with the statement, "Influenza virus vaccines have been studied so thoroughly through the years that essentially all published efficacy data have a direct or indirect influence on all available commercial vaccines.".

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Influenza Virus Vaccine, Bivalent (Fluzone) Manufactured by Merrell-National Laboratories, Division of Richardson-Merrell, Inc.

1. *Description.* The package circular states:

Influenza Virus Vaccine (Zonal Purified) is prepared from the allantoic fluid of chick embryos infected with Types A_2 and B influenza viruses. Each virus is inactivated with formaldehyde, and concentrated and purified in a linear sucrose density-gradient solution using a continuous flow ultracentrifuge. The virus is then further purified by chemical means. The resulting vaccine is more highly purified than vaccine processed by the usual differential centrifugation method as determined by total nitrogen content and electron microscopic studies * * *. Thimerosal 1:10,000 is added as a preservative. The final product contains less than two percent sucrose.

A. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.* a. *Efficacy.* (1) *Animals.* No potency data submitted. See generic review.

(2) Humans. Most of the references cited regarding zonal purified vaccines report studies which used vaccines produced by other companies. Two of the citations in the submission refer to data regarding the antigenicity of the A component present in formulations produced by Merrell-National, and a third citation is to a paper on the protective capacity of the A component. No data of any kind were submitted for the B component.

(i) *Antigenicity.* Monovalent vaccines were administered to recruits at the Great Lakes Naval Training Station by Dr. Nicola Tauraso, and the antibody reponse measured 30 days later. The results are summarized in Table 23.

Table 23.—*Antibody Reponse to Two Lots of Zonally Cetrifuged A_2/Aichi/2/68 Vaccine, 0.5 ml per Subcutaneous Dose*

Vaccine lot No.	CCA dose[1]	Initially geometric mean titer		Seronegative converting		Initially geometric mean titer		Seropositive converting	
		Pre	Post	Number	Percent	Pre	Post	Number	Percent 4-fold
7145 Z	787	1.0	64	10/10	100	64	256		2/5 40
7151 Z	772	1.0	208	8/8	100	23	418	7/7	
	100								

[1] These data are from the producer's submission (Table D of attachment 4). An addendum to the attachment stated: "Lots #7145 and 7151 were prepared by zonal purification and contained 400 CCA units per dose (0.5 ml)."

In a second study bivalent vaccine containing 700 CCA units of A/Aichi/2/68 (H_3N_2) and 300 CCA units B/Mass/1/71 per 0.5 ml dose was given subcutaneously to 100 males 24 to 93 years of age, 91 of whom had serologic specimens tested (median age 51) (Ref. 8). Serum antibody responses after 3 weeks were as follows: 62 percent of men with initial serum HI titers of ≤ 160 showed a four-fold or greater antibody response, and the GMT of the entire group rose from 65 prior to vaccination to ≥ 212 following vaccination. Hemagglutination inhibition responses occurred in all seven men with undetectable preexisting antibody (< 10). This group had a final GMT of 83. Antibody rises were seen in 24 of 27 (89 percent) men with prevaccination titers of ≤ 20. Of 48 volunteers with initial HI titers less than a "protective" level (80), 36 (75 percent) reached ≥ 80 in the serum after vaccination.

Nasal antibody was measured in 18 men. One-half showed a four-fold or greater antibody rise.

(ii) *Efficacy.* Stiver et al. administered bivalent vaccine containing 600 CCA units of A_2/Aichi/2/68 antigen and 400 CCA units of B/Mass/3/66 antigen to Air Force recruits during the first 6 months of 1972 (Ref. 9). An outbreak of A_2/Denver/1/72($=A_2$/England/72) infection occurred several months after the vaccine was administered. The overall attack rate of influenza was 46.0 per 1,000 in 2,955 unvaccinated men, and 18.4 per 1,000 in 979 vaccinees, a reduction of 60 percent.

b. *Safety.* (1) *Animals.* No data submitted; the product meets FDA requirements. See generic review.

(2) *Humans.* Data available for the two antigenicity trials cited above indicate acceptable percentage of mild to moderate local and systemic reactions. Only six medical complaints were reported for 2 distribution years during which 5 million doses were distributed. COFAL testing is described.

c. *Benefit/risk.* See generic review.

d. *Labeling.* See generic review.

3. *Conclusions.* a. *Critique.* The study by Stiver et al. provided efficacy data which show a 60 percent reduction in illness even when the epidemic strain was not homologous to the vaccine strain (Ref. 9). There is recent information obtained by the Bureau of Biologics that influenza vaccine produced by this manufacturer is similar in antigenicity to other whole virus influenza vaccines.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product.

Influenza Virus Vaccine, Bivalent (Fluogen) Manufactured by Parke, Davis & Co.

1. *Description.* The package circular states:

FLUOGEN (Influenza Virus Vaccine, Bivalent, Ether-Extracted Antigen) (Types A and B) is composed of the antigen of the strains of influenza viruses recommended* * *. In addition to initial virus purification steps by filtration, ultracentrifugation, and zonal centrifugation, treatment of the influenza virus vaccine concentrate with ethyl ether disrupts the virus, removes a high proportion of egg protein, ribonucleic acid, lipids, and other pyrogenic substances. From this process, the active immunizing antigens are retained at full potency.

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.* a. *Efficacy.* (1) *Animals.* Potency data were not provided by the manufacturer. Data obtained by the staff of the Bureau of Biologics showed clearly that the Parke-Davis & Co. vaccine, in equivalent CCA content, produced lower mean antibody levels in mice than did whole virus vaccines (refs. 10 and 15). It was estimated that 10 to 100 times the quantity of antigen in terms of CCA units, was required to produce the same effect with ether-split as with whole virus vaccine.

(2) *Humans.* Limited data were provided in the original submission concerning the antigenicity of the product as currently prepared (including the zonal purification step). One supplementary submission included an analysis of a study in children 5 to 14 years of age who, in December 1972, received one or two inoculations (0.5 milliliters each) of bivalent vaccine containing either the X–31 recombinant of A2/Aichi (700 CCA) or the X–37 recombinant of A2/England (700 CCA) plus B/Mass (300 CCA). Diphtheria-tetanus controls were included. The 1-week geometric mean (GM) antibody titers of this group of children are listed in Table 24.

Table 24.—*Antigenicity in Children of X–31 Recombinant of A_2/Aichi and the X–37 Recombinant of A_2/England Viruses*

Vaccine group	Nunber of children	Serum spec.	GMT of HI antibody to virus strain				
			X-31	Aichi	X-37	England	B/Mass
X-31	219	Pre-vacc.	55	57	41	26	16
and B		1 wk	213 (3.89)	218 (3.86)	158 (3.86)	114 (4.34)	53 (3.27)
X-37	228	Pre-vacc.	51	54	37	25	18
and B		1 wk	276 (5.37)	307 (5.65)	293 (7.85)	219 (8.92)	66 (3.61)
Diph.-tet	213	Pre-vacc.	57	57	40	25	18
		1 wk	53 (0.94)	57 (1.00)	38 (0.98)	28 (1.10)	18 (1.00)

[1] Figures in parentheses show the fold-rise in antibody titer.

The FDA material contains data on a comparative trial of the antigenicity of a nonzonal ether-extracted vaccine with the present vaccine (protocol 150 to 152). The two types of vaccine, either with our without aluminum phosphate adjuvant, were found to be of equivalent antigenicity. Table 25 illustrates the findings on the antigenicity of a nonadjuvanted, zonal centrifugation product, an A2/Aichi/X–31 vaccine.

Table 25.—*Antibody Response to a Nonadjuvanted, Zonally Centrifuged A_2/Aichi/X–31 Vaccine*

Number of volunteers [2]	Route of inoc. (0.5 ml)	HI antibody response [1] to:					
		A_2/Aichi/X–31 (400 CCA units)			B/Mass (300 CCA units)		
		Pre-vacc.	Post-vacc.	Fold-rise	Pre-vacc.	Post-vacc.	Fold-rise
31	Subcutaneous	32.05	178.75	5.58	7.85	21.45	2.73
27	Intramuscular	44.40	304.85	6.87	7.55	46.60	6.17

[1] Expressed as geometric mean titer.
[2] Prisoners, aged 21–65 years.

The superiority of the intramuscular route shown in Table 25 above is reflected in all vaccines (nonzonal and aluminum phosphate absorbed) used in this study and is significant when all the data are pooled ($p<0.05$). Considerable data are available concerning the antigenicity of earlier ether-split vaccines, but the details are not included here. In one trial comparing Fluogen with Merck Sharp & Dohme and National Drug zonal purified vaccines, the fold-rise with Fluogen (A_2/Aichi) was 7.84 vs 3.36 and 3.97, respectively, and the fold-rise with Fluogen (B/Mass) was 4.63 vs 3.51 and 2.41. The CAA content in the bivalent Fluogen was greater than that of the two whole virus vaccines (849 vs 743 and 481 for Merck Sharp & Dohme and National products, respectively). This fact might have had some influence on the comparative antibody responses, but it would certainly not have entirely accounted for the differences observed.

Because of the inferior antigenicity of nonadjuvanted ether-tween and other subunit vaccines in mice, there is considerable interest in the response to such vaccines of human subjects without previous influenza experience. As noted in the generic statement, seronegative individuals may or may not have had previous influenza infection. Few adults, or even school aged children, have escaped previous infection with both A and B strains of influenza, and most are, therefore, primed for an anamnestic response to any influenze vaccine they may receive. Several studies of such seronegative subjects have been provided both by the Bureau of Biologics and in supplementary submissions by the manufacturer. The results of these are summarized in Tables 26D through 26G.

A comparative trial of licensed influenza vaccines was performed by the Bureau of Biologics at the Arkansas Children's Colony (Ref. 12). The subjects were mentally retarded children and adults, 6 to 33 years of age and normal adults, ages 18 to 88. The vaccines were the bivalent A/England/72-B/Mass/71 (700 and 300 CCA units/0.5 ml claimed, 1240/0.5 ml total measured) and B/Hong Kong (500 CCA units/0.5 ml claimed, 576/0.5 ml measured). Dosage was 0.5 ml for those over 12 years and 0.25 ml for those 6 to 12 years. Bivalent vaccine was administered subcutaneously on day zero and the B/HK vaccine at 6 weeks. It should be noted that it is recommended on the package circular that Parke-Davis' product be administered intramuscularly, and that the superiority of the intramuscular route had been previously demonstrated from Fluogen (R) (see above).

In those individuals with measurable pre-existing HI antibody (≥1:8), there was no difference between the response to ether-tween split vaccine and the whole virus products. In those with prevaccination levels <1:8, the Parke-Davis products stimulated antibody levels which were, in most cases, lower than those induced by whole virus vaccines (the results are shown in Table 26 below).

Table 26.—*Antibody Response to Whole Virus Vaccine and the Ether-Tween Split Vaccine in Individuals With Prevaccination HI Antibody Titers of <1:8*

Vaccine	Seroconversion rates and HI antibody response at postvaccination intervals and vaccine components shown					
	A[2] England		B/Mass		B/Hong Kong	
	6 wks	12 wks	6 wks	12 wks	6 wks	12 wks
Seroconversion						
Whole Virus	86/100	87/100	66/84	77/84	69/169	130/169
P–D ether-split	19/23	[1]16/23	12/16	11/16	[1]12/48	39/48
Geometric mean antibody titers (reciprocal)						
Whole virus	22.8	20.4	17.4	22.3	6.5	13.4
p–D ether-split	17.5	13.3	16.6	[2]13.9	6.0	16.2

[1] $0.05<p<0.1$.
[2] $p<0.01$

More recently a double-blind controlled trial of influenza vaccines containing monovalent A/Swine strains ws carried out in multiple centers throughout the country. Subjects were divided into the following age groups for pusposes of analyses: those over 23 years of age (and thus born before 1953 and likely to have experienced prior infection with influenza viruses preceding the Asian strains); those 17 to 23 years old; and children 6 to 10 years old. Vaccines were adjusted so that potency, as measured by the CCA test, was comparable in the four preparations tested. Two whole virus preparations (Merrell-National and Merck Sharp & Dohme) and two submits vaccines (Wyeth and Parke-Davis) were tested. Vaccine was administered in most individuals by intramuscular injection and in some by jet injection. The results, shown in Tables 26A, 26B, and 26C,

demonstrate clearly that a single inoculation of subunit vaccines in the dosages tested was highly antigenic in the oldest group, inferior to whole virus preparations in young adults, and almost totally ineffective in children. Subsequently, it was demonstrated that a booster dose of subunit vaccine administered 4 or more weeks after the first does stimulated antibody production approximately equivalent to that induced by two doses of whole virus vaccine, even in children as young as 3 years of age.

Table 26A.—*Response to A/NJ Vaccine in Children Ages 6 to 10*

Manufacturer	Dose	No. subjects	Percent with HI antibody titers		
			≥10	≥20	≥40
Wyeth	100	38	31	5	0
	200	43	33	11	3
	400	44	48	23	5
Parke-Davis	100	44	7	5	2
	200	42	14	12	9
	400	43	14	5	2
Merrell-National	100	39	82	69	44
	200	42	85	74	50
	400	34	85	82	59
Merck Sharp & Dohme	100	35	91	86	77
	200	2	100	100	50
	400	0			
Placebo		40	5	3	0

Table 26B.—*Post Vaccination Antibody Status of All Participants 23 Years and Under*

Manufacturer	Dose	No. subjects	Percent with HI antibody titers		
			≥10	≥20	≥40
Wyeth	200	43	44	35	28
	400	42	74	64	41
	800	40	80	50	33
Parke-Davis	200	41	46	44	37
	400	41	54	32	22
	800	38	71	50	45
Merrell-National	200	46	80	54	46
	400	32	91	75	56
	800	42	91	67	48
Merck Sharp & Dohme	200	38	92	74	58
	400	49	100	96	86
	800	29	100	93	90

Table 26C.—*Postvaccination Antibody Status of All Participants 24 Years and Older*

Manufacturer	Dose	No. subjects	Percent with HI antibody titers		
			≥10	≥20	≥40
Wyeth	200	111	93	85	74
	400	106	94	90	85
	800	98	97	94	91
Parke-Davis	200	109	97	96	92
	400	100	96	93	90
	800	116	95	95	93
Merrell-National	200	96	89	84	71
	400	115	97	89	83
	800	99	97	95	87
Merck Sharp & Dohme	200	119	99	98	90
	400	106	99	98	92
	800	108	99	97	93

Comparative studies in seronegative children and adults immunized with H_3N_2 antigens have demonstrated the equivalence of this product, as presently manufactured, to whole virus vaccines. The results of one such trial performed by the manufacturer are shown in Tables 26D and 26E (from Parke-Davis Protocol 150–66). The subjects were healthy hospital employees. Another trial, this one in children is summarized in Tables 26F and 26G. The children were 4 to 13 years of age, and the average age of those receiving Fluogen (R) or whole virus vaccines was 8.25 or 8.09, respectively (Parke-Davis Protocol 150–73). In addition, several other trials have been performed in children, young adults, and, in one instance, elderly subjects.

Table 26D.—*Distribution of 3-Week Postvaccination HI Titers Versus A/Port Chalmers Virus of Seronegative Subjects Given Fluogen or Whole Virus Vaccines: 1974–75 Formulae*

Vaccine	Postvaccination A/P.C. HI titer					Geometric mean	Percent with ≥4X increase
	<10	10–20	40–80	160–320	>640		
Parke-Davis (16) [1]	1	1	3	9	2	129	94
Merck Sharp and Dohme (20)	0	2	8	8	2	113	90
Merrell-National (17)	0	0	7	7	3	189	100
Lilly (21)	0	3	7	6	5	131	95

[1] Number of seronegative subjects.

Source: Final Report, P–D Protocol 150–66. Subjects were adults all of whom received 0.5 ml of intramuscular vaccine containing approximately 700 CCA units of A/PC/1/73 and 500 CCA units of B/HK/5/72 per 0.5 ml. Measured potency not reported.

Table 26E.—*Distribution of 3-Week Postvaccination HI Titers Versus B/Hong Kong Virus of Seronegative Subjects Given Fluogen or Whole Virus Vaccines: 1974–75 Formula*

Vaccine	Postvaccination, B/HK HI titer					Geometric mean	Percent with ≥4X increase
	<10	10–20	40–80	160–320	≥640		
Parke-Davis (25)*	1	5	8	8	3	92	88
Merck Sharp and Dohme (30)	0	1	15	10	4	139	100
Merrell-National (29)	3	3	14	8	1	57	90
Lilly (25)	2	3	9	7	4	82	88

[1] Number of seronegative subjects.

Source: Final Report, P–D Protocol 150–66. See source note, Table 26D.

Table 26F.—*Distribution of 4-Week Postvaccination HI Titers Versus A/Scotland Virus of Seronegative Children Given Fluogen or Whole Virus Vaccines: 1975–76 Formula*

Vaccine	Postvaccination A/Scot HI titer					Geometric mean	Percent with ≥4X increase
	<10	10–20	40–80	≥160–320	640		
Fluogen (21) [1]	2	4	2	9	4	104	86
Whole virus [2] (32)	0	3	5	20	4	171	94

[1] Number of seronegative subjects.
[2] Merck Sharp & Dohme and Merrell-National.

Source: Final Report, P–D Protocol 150–73. Children were 4–13 years of age and received 0.5 ml (>10 years old) or 0.25 ml (<10 years old) of intramuscular vaccine containing approximately 350 CCA units A/PC/1/73, 350 CCA units A/Scotland/840/74, and 500 CCA units B/HK/5/72 per 0.5 ml. Measured potency of the vaccine was not reported. Bleeding before and 4 weeks after immunization.

Table 26G.—*Distribution of 4-Week Postvaccination HI Titers Versus B/Hong Kong Virus of Seronegative Children Given Fluogen or Whole Virus Vaccines: 1975–76 Formula*

Vaccine	Postvaccination B/HK HI titer					Geometric mean	Percent with ≥4X increase
	<10	10–20	40–80	160–320	≥640		
Fluogen (54) [1]	1	9	20	21	3	80	94
Whole virus [2] (71)	1	8	28	29	5	105	96

[1] Number of seronegative subjects.
[2] Merck Sharp & Dohme and Merrell-National.

Source: Final Report, Parke-Davis. Protocol 150–73. See source note, Table 26F.

There are efficacy data for the present product derived from the school study described above. In this study, influenza vaccines or diphtheria tetanus toxoid

vaccined as a placebo were administered on December 4, 1972, and a booster to those available on January 8, 1973. A small outbreak of A2/England influenza occurred in the school during early January, detected by influenza virus recovery in 10 of 23 cases and rises in HI antibody during this period in 19 percent of the placebo control children. The outbreak, and the efficacy of the vaccine, were measured primarily by school absenteeism. Comparison was made between (1) children who received either of the two influenza vaccines, and (2) those who received a diphtheria-tetanus vaccine plus (3) a larger "control" group of children who attended another school in the same community and received no vaccine. The following is from the discussion section of the manufacturer's submission:

Average total days of absence/100 children/ 15 day observation interval (1500 child-school days) are collected below [presented here in Table 26H], for the influenza vaccinee and nonvaccinee groups respectively, as a function of observation interval. Using these values, various estimates of vaccine efficacy can be derived.

Table 26H.—*Protective Efficacy of Vaccine Evaluated on Basis of School Absenteeism*

Vaccine group (observation interval)	Total number children	Days of absence/1,500 child-days of school		
		1 and 2 [1]	3 [2]	4 and 5 [3]
X-31 plus X-37 vacinees.	458	68.7	127.3	92.1
Placebo plus controls	612	61.4	192.9	91.1

[1] Nov. 8, 1972 to Dec 19, 1972.
[2] Jan. 3, 1973 to Jan 23, 1973.
[3] Jan. 24, 1973 to Apr. 7, 1973.

1. From the interval 3 data alone, one obtains (192.9–127.3)/192.9=34.0%, as the protection ratio without correction for noninfluenza associated background absenteeism.

2. Subtraction of the average, pre-Christmas absentee rates from the interval 3 data gives a protection ratio of (131.5–58.6)/131.5=55.4%, corrected for pre-Christmas absentee levels.

3. However, since background absentee rates differed significantly between the first two and last two intervals [see Table 26H], and since the latter period was closest to and continuous with the third, or epidemic interval, post-Christmas absenteeism (intervals 4 and 5) seems the most realistic backgound against which to judge the superimposed, influenza-associated, effect. Correction of the interval 3 data for the post-Christmas background yields (101.8–35.2)/101.8=65.4% as the most reasonable estimate of vaccine efficacy (against absenteeism) in this student population.

Thus, depending on the choice of background, efficacy estimates from a low of 34.0% (without correction from backgound absenteeism), to a high of 65.4% (correcting from immediately adjacent backgound absenteeism) are possible; with the latter seeming to provide the most reasonable value.

This study appears to show a protective effect of Fluogen(R) on epidemic influenza in school children. However, because school absenteeism, rather than true infection and illness rates, was used as an index of vaccine efficacy, and because the control group was diluted with a large number of children from a different school who were not true controls, the Panel considers that further efficacy trials are necessary to corroborate this finding.

Other protection data available refer to older either-split vaccines but the studies were not very well controlled (Refs. 16 and 17).

b. *Safety.*

(1) *Animals.* The vacine is said to be free of live virus and to have passed the general safety tests.

(2) *Humans.* At a time when vaccines were made from Sharples concentrated virus and when local and systemic reactogenicity posed a serious barrier to their general acceptance, ether-Tween treatement clearly reduced the number of febrile response, particularly in children (Ref. 18). More recently, further data have been submitted (Parke-Davis Protocols 150–66 and 150–73) to support the contention that febrile responses, and probably other systemic reactions as well, are less frequent following Fluogen (R) than after present zonally purified vaccines. This difference appears to be particularly clear in children. The results of Protocol 150–66, where Fluogen (R) was compared with three commercial zonally purified whole virus vaccine in healthy hospital employees are shown in Table 26I. Similar results in school children (Protocal 150–73) are shown in Table 26J.

Table 26I.—*Distribution of Subjects With a Local or Systemic Reaction 24 Hours After Vaccination*

	Number of subjects with local reaction			Number of subjects with systemic reaction		
	Yes	No	Total	Yes	No	Total
Fluogen	60	26	86	19	67	86
Whole virus	207	50	257	88	169	257
Total	267	76	343	107	236	343
Chi squared	3.7			3.9		
p	=.053 (1)			>.05 (2)		

[1] Not significant.
[2] Significant.
Source: See source note to Table 26D.

Table 26J.—*Distribution of Children With a Local or Systemic Reaction 24 Hours After Vaccination*

	Number of children with local reaction			Number of children with systemic reaction		
	Yes	No	Total	Yes	No	Total
Fluogen	37 [1](31)	83	120	14 (12)	106	120
Whole virus	55 (43)	73	128	36 (28)	92	128
Total	92	156	248	50	198	248
Chi squared	3.4			9.4		
p	=.065 (2)			>.01 (3)		

[1] Numbers in parentheses are percent showing reaction.
[2] Not significant.
[3] Significant.
Source: See source note to Table 26F.

The producer has received 45 written complaints concerning reactions for over 22.8 million doses distributed (of earlier formulations).

c. *Benefit/risk.* See generic review.

d. *Labeling.* See generic review.

3. *Conclusions.* a. *Critique.* This vaccine is antigenic in individuals who have had prior experience with related influenza strains. This statement appears to hold true whether or not there is measurable preimmunization homologous HI antibody. In those without such experience, the use of this vaccine requires several doses to stimulate protective levels of HI antibody.

One study of protective efficacy has been reported for the vaccine as presently manufactured. A significant protective effect, measured in school absenteeism, was shown in children who, as a group, had responded with the development of antibody. The findings require corroboration in further efficacy trials. The Panel recognizes the difficulty of proving efficacy for influenza vaccines, particularly in interepidemic years, but such proof is clearly needed.

Evidence supports the opinion that this vaccine is less reactogenic than whole virus products.

b. *Recommendation.* (1) The total body of evidence, including that recently developed in tha national dose-response trial of A/swine vaccines, indicates that split virus vaccines are adequately antigenic in persons with appropriate prior immunologic experience. In the case of H_3N_2 and, presumably B/HK antigens, these include most school-age children and older persons. In the case of the A/swine antigen, adequate response in persons under 24 years of age requires more than one dose.

The Panel recommends that this product be placed in Category I and that the license be continued, subject to labeling which clearly indicates the necessity for more than one dose in immunologically inexperienced persons.

(2) Further efficacy trials should be designed and implemented by the manufacturer.

Influenza Virus Vaccine, Bivalent (Chromatograph and Filter Purified Subvirion Antigen) Manufactured by Wyeth Laboratories, Inc.

1. *Description.* The package circular states:

Influenza Virus Vaccine, Bivalent, (Chromatograph and Filter Purified Subvirion Antigen) Wyeth, contains the immunizing antigens of the contemporary influenza virus strains recommended by the U.S.P.H.S. . . . The vaccine virus is grown in the extraembryonic fluids of embryonated chicken eggs and then processed to final vaccine by an improved method different from the usual differential centrifugation techniques yielding whole-virion vaccines. The harvested virus is concentrated and refined by a column chromatographic procedure, retaining full antigenicity while losing large amounts of contaminating egg proteins, lipids, nucleic acids and other amorphous and cellular residues arising in the egg fluids. At the same time, addition of tri(n)butyl phosphate and Polysorbate 80 U.S.P. to the column-eluting fluids effects disruption of the virus to smaller, fully antigenic sub-unit particles. The recovered sub-virion suspension is freed of substantial portions of the disrupting agents by dialysis, and of other undesirable materials by selective filtration through membranes of controlled pore size. In the course of preparation, formaldehyde solution (no more than 1:10,000 in the final product) is used, and thimerosal, 0.01 %, is added as a preservative.

a. *Recommended use.* See generic review.

b. *Contraindications.* See generic review.

2. *Analysis.* a. *Efficacy.*

(1) *Animals.* Data obtained by the staff of the Bureau of Biologics and published in an article by D. W. Barry et al. (Ref. 10) showed clearly that the Wyeth Laboratories vaccine, in equivalent CCA content, produced lower mean antibody levels in mice than whole virus vaccines. Data subsequently submitted by Wyeth Laboratories, with the caveat that the mouse can not be equated with man, showed that the antibody response in mice (both neutralizing and HI) was slower with subvirion vaccine than with whole virus vaccine, but that antibody levels at 4 to 8 weeks, although still lower, were more nearly comparable.

(2) *Humans.* Tables 26A, 26B, and 26C (see review of Parke-Davis influenza virus vaccine) present antigenicity data from recent A/swine vaccine clinical trials. Tables 27 through 34 summarize data from earlier antigenicity studies with A and B antigens. Tables 35 and 36 summarize two studies of protection, one in young adults and one in the elderly. In addition, two studies have noted that this product stimulated neuraminidase-inhibiting antibody, and that among persons lacking prevaccination serum antibody to the hemagglutinin antigen in whole virus or subvirion vaccines, the numbers of responders to the neuraminidase antigen were comparable in each vaccine group (approximately 50 percent) (Refs. 19 and 20).

Table 27.—*Antigenicity Study by Wyeth of a TNBP Purified Bivalent Vaccine* [1]

Vaccine lot No.	Route of innoculation (0.5 ml)	Serum pairs	Virus type	Results initial GMT	Responses		
					Number	Percentage	Fold-rise
78BIV	Subcutaneous	12	A	53	11	92	7.1
00701			B	40	11	92	10.0
78BIV	Intramuscular	10	A	41	8	80	13.2
00702			B	71	10	100	15.1

[1] Study units were 400 CCA units A_2/Aichi/2/68 and 300 CCA units B/Mass/3/66 in 0.5 ml. Subjects were male and female students, 18 to 26 years of age.

Table 28.—*Results of 3 Combined Antigenicity Studies, 1 Including Controls, by Wyeth Laboratories* [1]

Vaccine lot number	Serum pairs	Antibody responses to					
		A_2/Aichi/2/68			B/Mass/3/66		
		No. and percent ≥ 4-fold rise	GMT		No. and percent ≥ 4-fold rise	GMT	
			Initial titer	Rise in titer		Initial titer	Rise in titer
78BIV-005	73	71 (97)	57	35.5	67 (92)	104	21.9
78BIV-006	73	67 (92)	37	24.8	67 (92)	70	27.8
78BIV-007	85	78 (91)	53	18.1	82 (95)	98	25.6
Placebo	69	3 (4.3)	36	1.5	16 (23)	89	2.5

[1] Vaccines, dosage, and strains were as in Table 27. The population was male and female students and recruits, 17-26 years of age.

NOTE.—Figures in parenthesis are present.

Table 29.—*Antigenicity Studies by Phillips et al. (Ref. 21) of a Bivalent Vaccine in Children* [1]

	Virus type	Antibody response		
		No. and percent ≥4-fold rises	GMT	
			Pre-vaccination	4 weeks post-vaccination
Number of children:				
33	A	31 (94)	6.6	112.2
33	B	21 (64)	1.2	19.9

[1] The Vaccine used was as in table 27, given in varying doses from 350 to 1400 CCA units. Subjects were Children 5–9 years of age.

NOTE.—Figures in parenthesis are percent.

Table 30.—*Antibody Response Elicited by Varying Doses of a Bivalent Vaccine in Adults From Studies by Ruben et al. (Refs. 22 and 23)* [1]

Number of CCA units given, virus type A/B	Route	Antibody response			
		Number with ≥4-fold rises to virus type		Initial/final HI antibody titer	
				Virus type	
		A	B	A	B
40/30	Intradermal	9/9	7/9	16/167	25/239
400/300	Subcutaneous	11/14	13/14	36/247	89/1,178
400/300	Intramuscular	9/10	9/10	25/513	200/1,590
800/600	do	10/10	8/10	20/289	250/1,820
1,600/1,200	do	10/10	4/5	16/390	150/2,400
3,200/2,400	do	10/11	8/11	6/86	25/303
6,400/4,800	do	9/9	8/9	4/258	25/698

[1] The vaccine used was the same as in Table 27. The population was male and female students and recruits, 18 to 25 years of age.

Table 31.—*Comparative Antigenicity Studies in Children and Adults of a Whole Virus and Split Virus Vaccine From a Study by Barry et al. (Ref. 10)* [1]

Vaccine administered	Response of seronegative individual to					
	A/England		B/Mass		B/Hong Kong	
	6 weeks	12 weeks	6 weeks	12 weeks	6 weeks	12 weeks
Seroconversion						
Whole virus	86/100	87/100	66/84	77/84	69/169	130/169
Wyeth split	[2] 15/23	[3] 14/23	14/21	16/21	19/52	40/52
Geometric mean titers (reciprocals)						
Whole virus	22.8	20.4	17.4	22.3	6.5	13.0
Wyeth split	17.0	[3] 12.6	14.0	[3] 13.5	6.6	13.0

[1] The vaccine used were A/England—B/Mass bivalent (700 and 300 CCA units claimed per 0.5 ml, 1,120 total measured at zero time) and B/Hong Kong (500 CCA units claimed per 0.5 ml, 785 measured at 6 weeks). The population was mentally retarded subjects 6 to 33 years old and normal adults 18 to 88 years old.

[2] $p = 0.05$ in comparison to whole virus vaccines.

[3] $p = 0.01$ in comparison to whole virus vaccines.

Table 32.—*Antigenicity of Bivalent Subunit Vaccines in Naval Recruits with Varying Levels of Pre-existing Antibody From a Study by Rosenbaum, Data Submitted by Wyeth* [1]

Initial titer	HI Ab increases			
	None	≥2-fold	≥4-fold	GM increase (fold)
A_2/Aichi				
<lowest dilution (<1:10)	0/30	30/30 [2](100)	28/30 [2](93)	40.4x
Placebo group (<1:10)	5/9	4/9	2/9	1.7x
=lowest dilution (1:10)	0/24	24/24 [2](100)	24/24 [2](100)	28.2x
Placebo group	9/18	9/18	3/18	1.8x
≥lowest dilution (≥1:97.8)	3/94	91/94 [2](97)	97/94 [2](93)	27.5x
Placebo group (<1:95.8)	25/40	15/40	1/40	1.3x
B/Mass				
≥lowest dilution (1:127.7)	3/144	141/144 [2](98)	130/144 [2](91)	30.8x
Placebo group (1:98.6)	32/67	35/67	22/67	3.5x

[1] The vaccine, dosage, and strains used were as in Table 27.
[2] Percent.

Table 33.—*Antigenicity of Whole Virus and Subunit Vaccines in Adults* [1]

	Subunit						Whole virus				
	Conversion		Titer		Fold-rise	Number	Conversion		Titer		Fold-rise
	≥2-fold number	≥4-fold number	Initial	Post			≥2-fold number	≥4-fold number	Initial	Post	
Influenza A_2/Aichi											
Number:											
9	8 (88.9)	7 (77.8)	<10	37.0	≥7.4	12	11 (91.7)	10 (83.3)	<10	33.6	≥6.7
6	6 (100.0)	6 (100.0)	10	179.6	17.9	3	3 (100.0)	9 (33.3)	10	31.8	3.2
18	17 (94.4)	16 (88.9)	44.9	527.8	19.2	21	19 (90.5)	12 (57.1)	48.8	195.0	4.0
33	31 (93.9)	29 (87.9)	≥18.8	210.1	≥11.2	36	33 (91.7)	23 (63.9)	≥19.9	93.3	≥4.7
Influenza B/Mass											
Number:											
13	13 (100.0)	12 (92.3)	<10	75.8	≥15.2	17	16 (94.9)	15 (88.2)	10	40.0	≥8.0
6	6 (100.0)	6 (100.0)	10	226.2	22.6	4	4 (100.0)	4 (100.0)	10	56.6	5.7
14	12 (85.7)	9 (64.3)	34.5	215.4	6.2	15	7 (46.7)	5 (33.3)	46.0	105.5	2.3
33	31 (93.9)	27 (81.8)	≥12.9	144.0	≥11.2	36	27 (75.0)	24 (66.7)	≥12.6	62.3	≥4.9

[1] The vaccines used were subunit, Wyeth lot 75, 0.5 ml intramuscularly and whole, Wyeth Sharples, 1.0 ml subcutaneously; Spring, 1971.

NOTE.—Figures in parentheses are percent.

Table 34—*Antigenicity of Whole Virus and Subunit Vaccines in Adults From (Kasal, J. A., Progress Report to Bureau of Biologics)*[1]

Initial titer[2]	Lilly vaccine (whole)				Wyeth vaccine (subunit)			
	Seroconversion[3]		GM fold-rise		Seroconversion[3]		GM fold-rise	
	14 d	60 d	14 d	60 d	14 d	60 d	14 d	60 d
A$_2$/England/72								
10	39/60 (65)	43/60 (72)	7.4	10.0	30/46 (65)	30/46 (65)	11.3	10.0
10	14/15 (94)	13/15 (87)	8.8	11.1	17/25 (68)	18/25 (72)	8.2	9.2
10 [32.4]	6/22 (27)	6/22 (27)	≥2.1	2.6	[30.5] 16/28 (57)	17/28 (61)	≥4.7	≥4.6
Total [8.6]	59/97 (61)	62/97 (64)	≥5.7	≥7.5	[9.9] 63/99 (64)	65/99 (66)	≥8.1	≥7.9
B/Mass/71								
10	47/57 (82)	46/51 (81)	7.5	2.6	28/34 (82)	25/34 (74)	7.8	6.3
10	14/18 (78)	13/18 (72)	5.2	1.7	23/32 (72)	21/32 (66)	4.8	3.8
10 [28.2]	13/22 (59)	9/22 (41)	2.9	2.1	[29.8] 14/33 (42)	9/33 (27)	2.2	2.2
Total [8.4]	74/97 (76)	68/97 (70)	5.8	4.6	[11.3] 65/99 (66)	55/99 (56)	4.4	3.8

[1] The vaccines used were 700 CCA/Eng/72 and 300 CCA B/man/71; 0.5 ml intramuscularly; 2 weeks later, 500 CCA B/HK/72.
[2] [ ] GM titer ≥10.
[3] No. 4 fold or ≥rise/No. subjects (%).

Table 35.—*Protective Capacity of Whole Virus and Split Virus Vaccines Against Natural Challenge by an Epidemic of A2/Hong Kong Influenza From a Study of Ruben et al. (Ref. 24)*

Study population [1]		Clinical influenza			
Group	Number	Number observed	Number expected	Percent reduction	Significance
Unvaccinated	22,819	168			
Whole virus vaccinated	1,312	2	10	80	$p<0.05$
TNBP (split virus) vaccinated	1,791	6	13	54	$p=0.05$
All vaccines	3,103	8	23	65	$p \geq 0.01$

[1] The Study population was students, age 17 to 22 years. It is clear that when those individuals who received the whole virus (conventional) vaccine are removed from consideration, the protective effect of TNBP vaccine is only marginally significant.

Table 36.—*Protective Capacity of a Bivalent Vaccine in an Elderly Population Against Natural Challenge by an Epidemic of A/England/72 Influenza From a Study by Ruben et al. (Ref. 25)*

	Number of cases	Cases of influenza in		Attack rate, percent [3]	
		Vaccinees [2]	Nonvaccinees	Vaccinees	Nonvaccinees
Floor of home: [1]					
1	7	4 (2)	3 (0)	11	12
2	9	4 (0)	5 (2)	9	15
3	15	8 (3)	7 (1)	14	24
5	25	20 (2)	5 (2)	31	24
All	56	36 (7)	20 (5)	18	19
4	52	2 (1)	50 (9)	67	59

[1] Fourth floor not included in study. Since, through error, vaccine, was administered to only a small number of patients on that floor.
[2] Number in parentheses indicates number from whom influenza virus recovered.
[3] The number of days of fever (had no other symptoms) was significantly reduced ($p < 0.001$) in vaccinees as compared to controls, whether or not influenza.

The data in the studies cited indicate that this subunit or split-virus vaccine is adequately antigenic in persons with prior experience with influenza antigens or related antigens in the vaccine. As with the Parke-Davis vaccine, persons without such prior immunologic experience appear to require more than a single dose.

b. *Safety.* (1) *Animals.* Tests meet requirements; no data were presented.

(2) *Humans.* Several lots of Wyeth Laboratories vaccine as presently produced have been tested at the standard dose level, and at least one vaccine has been tested at a level of 6,400 CCA units of A and 4,800 CCA units of B. All these tests have shown an acceptably low (10 percent) rate of local and systemic reactions in adults. In a comparative trial of commercial vaccines by Barry et al. (Ref. 11), the Wyeth Laboratories product was demonstrated to produce a rate of local and systemic reactions similar to that of whole virus vaccines. Phillips et al. (Ref. 20) noted no local or systemic reactions in 33 children aged 5 to 9 years given varying intramuscular doses (0.25 ml, 0.5 ml, 1.0 ml) of bivalent vaccine containing 700 CCA units of antigen in 0.5 ml.

No severe reactions were reported in an addendum to the inital submission. Avian leukosis viruses have been tested for by the COFAL test.

Considerable information on the safety of Polysorbate 80 is included in the material from the Bureau of Biologics

c. *Benefit/risk.* See generic review.

d. *Labeling.* See generic review.

3. *Conclusions.* a. *Critique.* This vaccine has many characteristics in common with another subunit vaccine produced by Parke, Davis & Co. Antigenicity in seropositive subjects is adequate; the predominance of evidence indicates antigenicity comparable to that of whole virus vaccines in seronegative subjects. Most of the latter have been adults. A study conducted by the Bureau concluded that individuals without previous exposure to influenza virus or with low preinoculation antibody titers responded significantly

less will to this vaccine than to licensed whole virus vaccines. A number of the subjects in this study were children.

Because this product has been used for fewer years than whole virus vaccines, field experience and controlled studies coincident with natural challenge are limited. Although several efficacy trials have been completed, this vaccine has not yet been shown clearly to protect against disease. In one instance a marginally significant degree of protection against a homologous strain was shown, and in the other fever was shortened but illness not prevented by vaccine against a related but heterologous strain. It should be pointed out, however, that in the first study the attack rate was less than 1 percent, and in the second elderly subjects were studied, for whom there are few comparable data available for zonally purified whole virus vaccines. Thus, assumption of efficacy is largely based on the antigenicity of the vaccine.

b. *Recommendations.* (1) The total body of evidence, including that recently developed in the national dose-response trial of A/swine vaccines, indicates that split-virus vaccines are adequately antigenic in persons with appropriate prior immunologic experience. In the case of H_3N_2, and presumably B/HK antigens, these include most school-age children and older persons. In the case of the A/swine antigen, adequate response in persons under 24 years of age requires more than one dose.

The Panel recommends that this product be placed in Category I and that the license be continued, subject to labeling which clearly indicates the necessity for more than one dose under certain circumstances.

(2) Further efficacy trials should be designed and implemented by the manufacturer.

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Review of Adenovirus Vaccines

Adenovirus Vaccine Manufactured by Parke, Davis & Co.

1. *Description.* Two adenovirus vaccines were at one time marketed by Parke, Davis and Company: (1) a bivalent vaccine containing adenovirus Types 3 and 7; and (2) a trivalent vaccine containing Types 3, 4, and 7. Neither has been produced for many years, although both are still licensed (the manufacturer makes the comment that "this product formulation has not been marketed for many years"). Most of the comments in this review apply equally to the bivalent and trivalent vaccines.

The manufacturer's description of the bivalent vaccine is as follows:

> Adenovirus Vaccine is an aqueous combination of inactivated adenoviruses, types 3 and 7, combined in approximately equal proportions. The viruses are propagated in tissue cultures of monkey kidney cells in a special nutrient medium (Synthetic Mixture No. 199). Inactivation of the viruses is accomplished by treatment with formaldehyde under controlled conditions, supplemented with ultraviolet irradiation and betapropiolactone. Phermerol (benzethonium chloride, Parke, Davis and Company) 1:40,000, is included as a preservative.

Further description of the bivalent vaccine is provided, but it does not

include any details on the manufacturing method. The basis for selection of the virus strain, and the methods for clarification or purification of the virus, for testing of preinactivation infectivity and potency testing are not given.

a. *Recommended use.* These vaccines, according to the package insert, are for prophylaxis of infection produced by adenoviruses Types 3 and 7, and a single injection of 1.0 cm ^{3}, administered intramuscularly or subcutaneously, is recommended for adults. The dosage for children has not yet been established, nor has the need for booster injections been determined.

b. *Contraindications.* The package insert states: "It is recommended that immunization be deferred in the presence of cerebral damage, active infections, or acute respiratory disease."

2. *Analysis.*

a. *Efficacy.*

(1) *Animals.* No data concerning tests of this product in animals were submitted. The literature records that the antigenicity of experimental adenovirus vaccines in guinea pigs is low (Ref. 1). Potency tests are required under 21 CFR 630.24. These necessitate testing each lot in comparison to a standard National Institutes of Health (Bureau of Biologics) vaccine and measuring the neutralizing antibody response. The animal(s) to be used in these tests is not specified.

(2) *Humans.* Data on the antigenicity in man of two bivalent lots and five trivalent lots were submitted and are summarized in Table 37.

Table 37.—*Antigenicity in Man of Bivalent and Trivalent Adenovirus Vaccines* [1], *Parke, Davis & Co.*

Clinical protocol	Vaccine lot	Serological response to vaccine: Number of persons with Preimmunization titer >1:4			Postimmunization titer > 1:4			Percent of persons responding		
		Type 3	Type 4	Type 7	Type 3	Type 4	Type 7	Type 3	Type 4	Type 7
Bivalent vaccines										
371-1	024030	45		72	45		62	100		92
371-3	40184	7		15	7		14	100		93
Trivalent vaccines										
324	081291	17	30	26	16	26	24	94	87	92
	080446	23	30	29	22	26	23	96	87	79
371	B090877	24	30	10	19	18	7	79	60	70
	B090876	22	20	11	16	11	11	73	55	100
381	B090898	10	15	20	10	14	16	100	93	80
Total		148	125	183	135	95	157			
Percent								91	76	86

[1] Bivalent = type 3 and type 7 vaccine. Trivalent = type 3, 4 and 7 vaccine.

Protection data for the Parke, Davis & Co. product were not presented in the original submission, but were extensively reviewed by Parke, Davis & Co. representatives at the meeting of the review panel on April 2–3, 1974. The references cited are numerous. One concerns a hexavalent (Types 1, 2, 3, 4, 5, 7) Parke-Davis vaccine administered to 104 children, which was "moderately" antigenic; there was no change in the number and severity of respiratory illnesses in the year following vaccination as compared to the preceding year (Ref. 2).

In another trial, varying doses of what appears to have been the same vaccine induced greater than two-fold antibody responses in from 7 percent to 76 percent of 63 allergic children, 7 to 12 years of age, depending on dose and serotype. Protective efficacy of the vaccine was not reported (Ref. 3).

Gundelfinger, et al. (Ref. 4) studied a trivalent Parke-Davis vaccine in naval recruits. Twenty percent of the group received vaccine 3 to 5 days after arrival at the basic training installation. Rises in antibody to the vaccine viruses were found in 50 to 70 percent of the vaccines; adenovirus infections were, however, frequent in this population. The rate of reduction of febrile or hospitalized respiratory disease in vaccinees during the third to ninth weeks was calculated by the authors to be 65 percent. In addition, the rate of clinical viral pneumonia in the vaccinated population (0.04/1,000/week) was not significantly different from that in the control population (0.3/1,000/week, $p>0.1$).

Experience similar to this in other military studies has been reported many times with inactivated adenovirus vaccine, with protection rates as high as 90 percent for a Parke-Davis product (Ref. 5). The early studies, summarized by Hilleman suggest that the success of the vaccine depends to a large extent on its potency (Ref. 6).

Studies in the military are, because of the very nature of these groups, short-term, and no efficacy studies in adult civilian populations, or in military recruits, have been conducted over prolonged time periods.

b. *Safety.*

(1) *Animals.* Federal regulations outline the extensive testing required in animals in order to detect possible extraneous agents in adenovirus vaccines. These tests include the following examinations on the inactivated product: inoculation of tissue cultures, with subculturing for detection of SV–40; intracerebral inoculation of mice for lymphocytic choriomeningitis (LCM) land other mouse pathogens; tests (not specified) for *Herpes simiae* virus (B virus) and *M. tuberculosis*; identity tests; tests for live adenovirus; and monkey neurovirulence tests. The marketed vaccine has passed these tests.

The early lots of vaccine undoubtedly contained abundant SV–40 genetic material and, in some instances, low levels of infectious SV–40, since the component vaccine viruses were grown in primary rhesus monkey kidney cells. No comment on this contamination by an adventitious agent was made by the manufacturer in the original submission, but the problem was addressed in a presentation at the meeting of April 2–3, 1974, and changes which would eliminate the SV–40 problem were proposed in the manufacturing precedure.

(2) *Humans.* The vaccine produces few and mild local and systemic reactions. The manufacturer also submitted data on febrile reactions, and the extent of these is acceptable.

The major concern about adenovirus vaccines has been because of the possible oncogenicity for man of both the adenovirus and the SV–40 components. However, the inactivation methods in current use are adequate to eliminate the tumorigenicity of both adenovirus and SV–40 for hamsters, and, in addition, an extensive search failed to implicate adenoviruses in human cancer (Ref. 7). However, there is a lingering sense of uncertainity in the minds of many concerning the potential capacity of an adenovirus vaccine to produce tumors in man, whether or not it contains SV–40, and this uncertainty

must enter the benefit-risk ratio in some form.

The marketing data submitted stated some millions of doses of vaccine were sold between 1957 and 1964, and no major untoward reactions were reported.

c. *Benefit/risk.* The possible benefits of any adenovirus vaccine to the civilian population have never been demonstrated. The Panel found the presentation of the Parke-Davis group in this regard, and in particular there cost-benefit analysis, to be unconvincing. Indeed, there are statements in the literature which clearly express the view that adenovirus vaccines are not of value. Thus, Hilleman et al (Ref. 8) state that:

> * * * adult civilian groups, including families, university students, university employees, and selected cases of acute respiratory illness from hospitals or private practice, have shown very low attack rates for adenovirus-caused respiratory disease. Based on current information therefore general use of the [adenovirus] vaccine among such persons is not warranted and cannot be justified.

A similar conclusion comes from Jordan (Ref. 9):

> While the efficacy and desirability of administering adenovirus vaccine to military recruits has been established, the evidence cited indicates that such immunization of civilian populations, including university students and older adults, is not warranted.

The statement is made in the Parke-Davis submission that:

> Unregimented civilians are not ideal study groups and extended and detailed observations are required if the adenovirus contribution to the general etiology of respiratory illness is to be properly assessed. In spite of these logistic problems, a number of studies have been reported which attest to the ubiquity of adenovirus associated disease. While the figures from each of these reports can be considered valid only for the age group and geographical area studied, the epidemiological outline is clear. Five percent or more of significant civilian respiratory disease (increasing to perhaps 10 percent of children) can be attributed to endemic adenovirus infection with types 3 and 7.

Against this stands Brandt's huge survey among children in the Washington, DC area (Ref. 10) which showed that adenoviruses Types 3 and 7, respectively, were recovered from only 1.3 percent and 0.4 percent of 11,490 children with respiratory disease and 0.4 percent and 0.2 percent of 6,606 matched controls and that, of nearly 1,800 adenovirus isolates, the most numerous were Type 1 (26.3 percent) and Type 2 (34.5 percent), Type 5 (10.6 percent) followed by Type 3 (10 percent) and Type 7 (3.3 percent). Admittedly, virus recovery does not identify all actual infections, but it seems doubtful that the proportion of respiratory illness in children is as high as 10 percent. Indeed, using both virus recovery and antibody response, only 5.5 percent of respiratory illness in hospitalized children could be associated with all adenovirus types.

The recent report of Monto and Ullman (Ref. 11) was quoted extensively by the manufacturer to back his contention that adenoviruses (presumably, according to his argument, of the types included in the vaccine) cause 4.5 percent of respiratory illness in a community. The report, however, states that adenoviruses, all types, constituted 4.5 percent of specific agents isolated from respiratory illnesses. A viral or potentially pathogenic bacterial isolate was recovered from 24.9 percent of specimens. Thus, in the study cited, adenoviruses, including types not in the vaccine, were associated with about 1 percent of acute respiratory illnesses. This qualification makes the manufacturer's argument concerning the medical and economic need for his vaccine less than convincing.

Because of these considerations, it seems apparent that the benefits of a bivalent or trivalent adenovirus vaccine are very small or nonexistent. The risk may also be small, but it should be pointed out that the manufacturer's proposal for producing vaccines free of SV–40 and SV–40 genetic material have not been subjected to actual practical experience in either production or clinical testing. The label and package inserts are factually correct. Nevertheless, the experience quoted is that of early military trials, and hence the benefits implied are greater than those to be expected with the vaccine as used in the general population.

3. *Conclusions.*

a. *Critique.* The points at issue are:

(1) The presence of SV–40 and SV–40 genetic material in the vaccine as originally licensed during the period before SV–40 virus was discovered (the manufacturing process covered by the current license would not eliminate the presence of SV–40 genetic material);

(2) The untested feasibility of producing, by the manufacturer's proposed methods, vaccines free of SV–40 and SV–40 genetic material;

(3) The 10-year period since the last production;

(4) The lack of evidence of efficacy in the populations for which the vaccine is recommended by the manufacturer, namely civilian adults;

(5) The lack of efficacy data for any proposed "pediatric" formulation;

(6) The lack of data on the duration of protective effect;

(7) The doubtful need for a vaccine to prevent a very small (apparently less than 1 percent) proportion of respiratory disease;

(8) Because of (1), (2), and (6) above, the benefit/risk ratio is low or incalculable;

(9) The availability of live, orally administered vaccine for use in military populations.

b. *Recommendation.* Because of the issues raised in the critique above, the Panel believes that, based on considerations of effectiveness and need, the only justifiable use for such products would be for the prevention of respiratory disease in military recruit populations. Questions regarding the safety of these products, and the availability of other means for the control of adenovirus disease in such populations, weigh heavily against licensure even for such limited use.

The Panel recommends that this product be placed in Category II and that appropriate license(s) be revoked because there are compelling reasons to assume a lack of safety or effectiveness and an unsatisfactory benefit-risk ratio for this product.

Adenovirus and Influenza Virus Vaccine, Combined Manufactured by Parke, Davis & Co.

1. *Description.* According to the manufacturer's package insert:

Resprogen is a multivalent vaccine designed to immunize against both epidemic influenza and the more common adenovirus infections.

This vaccine is a sterile combination in 0.85 percent sodium chloride of two products adsorbed on an optimum amount (3.5 mg. per 1 cc. dose) of aluminum phosphate: Influenza Virus Vaccine, Polyvalent and Adenovirus Vaccine, Types 3 and 7. The color may vary from buff to a definite pink due to the residual organic indicator contained in the adenovirus vaccine component which is not entirely removed in the adsorption process.

Each 1.0 cc. contains the following strains of influenza virus propagated in developing chick embryos, concentrated and refined by ultracentrifugation and inactivated by ultraviolet irradiation:

Influenza Virus

Type	Strain	Conc. per ml.
A	PR 8	[1] 100 CCA
A1	Ann Arbor/1/57	100 CCA
A2	Japan/170/62[2]	200 CCA
B	Maryland/1/59	200 CCA
Total		600 CCA

[1] Chicken Cell Agglutinating Units.

[2] Asian Strain.

Each 1.0 cc. also contains adenoviruses types 3 and 7, in approximately equal antigenic proportions, which have been propagated in monkey kidney tissue cultures and inactivated with a combination of treatment with formaldehyde, ultraviolet irradiation and beta-propiolactone, as required. Thimerosal (mercury derivative), 0.01 percent, is used as a preservative. The combined vaccine meets all requirements of the National Institutes of Health as to safety and potency for both Influenza Virus Vaccine and Adenovirus Vaccine.

It is clear that the influenza virus component of the vaccine is made by an early protocol, according to which only modest efforts at purification were made. Details are not supplied.

a. *Recommended use.* As stated in the package insert, the objective of the vaccine is: "To immunize against both epidemic influenza and the more common adenovirus infections."

The package insert states that the recommended dose for adults 16 years of age and over is two intramuscular injections of 1.0 cm^3 each, given at least 2 months apart. "The dosage in children has not been firmly established." In individuals who have completed an immunizing course of injections, an annual booster dose is recommended prior to November 1.

b. *Contraindications* (as stated in the package insert).

When there is a history of allergy to egg proteins, chicken feathers or chicken dander, the use of products prepared from embryonic fluid of chicken eggs is contraindicated.

Resprogen contains small amounts of streptomycin used in culturing the adenovirus. During the adsorption process most of the antibiotic content is removed. However, consideration should be given to the possibility of allergic reactions in individuals sensitive to this antibiotic, and they should be tested for sensitivity where this possibility exists.

2. *Analysis.*

a. *Efficacy.*

(1) *Animals.* See adenovirus vaccine review above.

(2) *Humans.* The data supplied imply that the antibody response to the adenovirus component of the vaccine is the same as for that component alone (see adenovirus vaccine review). However, because the antibody elicited is measured in terms of percent conversion from <1:4 to >1:4, the degree of response cannot be compared. Similarily, the data supplied on response to the influenza virus component are not sufficient to judge the adequacy of the product (percent of vaccine recipients showing seroconversion from <1:5 to >1:5).

A report by Cox et al. (Ref. 12) records antibody responses engendered by several different adenovirus vaccines. The antigenicity of these several vaccines in terms of the seroconversion rate is summarized in Table 38.

Table 38.—*Seroconversion Rates (Neutralizing Antibody) Effected by 3 Different Adenovirus Vaccines Study of Cox et al. (Ref. 12)*

Adenovirus type	Seroconversion rate, percent, at 2 weeks postvaccination—Vaccine[1]			
	No. 1	No. 2	No. 3	Placebo
3	100	82	95	44
4	93	52	52	19
7	78	62	87	24

[1] Vaccine No. 1: Adenovirus types 3, 4, and 7. No. 2: Adenovirus types 3, 4, and 7 plus PR8, PR301, several influenza A viruses, and Great Lakes and Lee influenza B virus. No. 3: Same as vaccine 2, with aluminum phosphate adjuvant added. Vaccines were administered in 1.0 ml doses at 0, 16, and 52 weeks.

No controlled clinical trials for determining the capacity of such vaccines to protect against adenovirus disease have been reported.

Evidence for a protective effect conferred by the combined product is scanty. The literature contains only one study where a Parke-Davis manufactured adenovirus-influenza combination was tested for efficacy (Ref. 13). In this study the reduction in cases of influenza after immunization was similar between the groups receiving influenza vaccine alone, adeno-influenza vaccine or receiving adeno-influenza-para-influenza vaccine. However, statistical significance ($p=0.05$) in the reduction of morbidity was evident only when all three groups were combined (reduction 79 percent).

A mineral oil-arlacel adjuvant combined adenoinfluenza vaccine was found highly protective against both influenza and adenovirus disease in a military population (Ref. 14). Similarly, influenza and adenovirus vaccines administered simultaneously but as separate preparations have been shown to protect against both viruses, although in those studies only the influenza component was made by Parke, Davis and Company (Refs. 15 and 16).

b. *Safety.*

(1) *Animals.* See adenovirus vaccine review.

(2) *Humans.* See adenovirus vaccine review.

The reaction rates to this vaccine are higher than those quoted for adenovirus vaccine alone and are consistent with those seen in earlier years with less highly purified influenza vaccines. Thus, in one study, after a primary injection 28 percent noted local induration and/or erythema, 2 percent systemic reaction only, and 1 percent both. After a booster dose, 33 percent showed a local reaction, 11 percent fever and 7 percent both. In another study almost 50 percent noted a rise in temperature of more than 1° F at 24 hours.

The manufacturer's marketing experience states that several million doses were given in 1959–1965. "Very few complaints of reactivity, local or systemic, were received," but files have been discarded.

c. *Benefit/risk.* See adenovirus vaccine review.

d. *Labeling.* See adenovirus vaccine review. The labeling for the influenza component is not appropriate in the light of current standards.

3. *Conclusions.*

a. *Critique.* The same comments apply here as apply to the adenovirus vaccine. In addition, the influenza virus component has been produced by older methods, and some efficacy and antigenicity studies would be necessary with the combined product if the newer methods were used. It is doubtful, however, that this combined vaccine has any role in civilian medical practice, and its role in the military would be exceedingly limited, for the following reasons:

(1) The combination is not rational.

(i) Adenoviruses do not change in antigenic character.

(ii) Influenza viruses do change and would have to be changed with each substantial antigenic shift in the wild virus.

(2) The composition is inappropriate.

(i) Adenovirus types other than 3, 4, and 7 produce most of the infections and illnesses in civilian populations, particularly in infants and children.

(ii) Influenza antigens are deficient in amount by a factor of 5 to 10.

(3) The recommended usage is contradictory.

(i) Apart from military populations, and perhaps very few civilian groups, the target population for adenovirus vaccine is considered to be young children.

(ii) The target population for influenza vaccine is composed of adults, particularly those at high risk by reason of age or disease.

(4) The vaccine has not been made for some years.

(b) *Recommendation.* The Panel recommends that this product be placed in Category II and that appropriate license(s) be revoked because there are compelling reasons to assume a lack of safety or effectiveness and an

unsatisfactory benefit-risk ratio for this product.

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Review of Rabies Vaccine

Rabies Vaccine (Duck Embryo), Dried Killed Virus Manufactured by Eli Lilly & Co.

1. *Description.* The vaccine is a dried suspension of duck embryo tissue infected with fixed rabies virus, which is inactivated with beta-propiolactone; 1:10,000 merthiolate is used as a preservative. The claim is made that the vaccine contains little or none of the "paralytic factor" (presumably myelin) responsible for posttreatment paralysis associated with vaccine of central nervous system origin. The vaccine is stated to meet potency requirements as measured by the National Institutes of Health mouse potency test, and to induce antibodies detectable by the 10th (often) to the 15th day (nearly always) after initiation of the standard series of 14 daily doses.

a. *Recommended use.*

(1) *Risk.* The risk of fatal disease is a compelling basis for use. The argument against giving rabies vaccine unless actual exposure has occurred relates to posttreatment paralysis, which is said to be minimal with duck embryo vaccine. While the bite of an animal known to be rabid results in approximately a 40 percent risk of rabies, little or no risk follows unless there has been an actual lesion or abrasion made by the animal.

Current ACIP procedures for postexposure prophylaxis are recommended, including the prescribed use of antiserum or human antirabies immunoglobulin.

Since there is a suppressive effect of antibody on active response to vaccine, it is recommended that additional doses of vaccine be given at 10 and 20 days after the last usual dose of the series in order to counteract this effect.

Consultation with local health officials about the prevalence of rabies in a given region is advisable before any decision to use vaccine is made. Preexposure immunization is recommended for specified high risk groups.

(2) *Local treatment.* The recommendations of the WHO should be followed, including, if antibody is to be given, infiltration of antiserum or immune globulin around the site of the bite-wound.

(3) *Prognosis.* It has been suggested that postexposure vaccination is most likely to be effective when the incubation period is expected to be more than 3 or 4 weeks; this interval is usually estimated on the basis of the severity and location of the lesion.

With severe exposure, shorter incubation is expected and vaccine failure is more likely, but by no means certain, and hence prompt initiation of therapy is considered essential.

(4) *Dosage and administration.*

(i) *Postexposure.* the minimum course consists of 14 inoculations over a 14-day period. The vaccine is administered subcutaneously over the abdomen; alternate slides are injected each day and a different site used for each dose. A site previously employed for another vaccine or toxoid should not be used.

Because reactions to the vaccine are minimal, and early development of antibody is important, it is suggested that vaccination be inititated promptly in cases of bites to the head, neck, or arm inflicted by a healthy appearing animal (rather than withholding vaccine for up to 10 days if the animal remains healthy) and discontinue administration after 5 days if the animal is still healthy, pending further observation.

In the cases of bites by wild animals (risk of rabies is higher and incubation period may be short), the suggested regiment involves 2 doses of vaccine each day for 7 days and then 7 single daily doses (total 21 doses). Also, the ACIP recommends that if antibody is used, supplemental doses of vaccine should be given at 10 and 20 days after the last dose of the course.

(ii) *Preexposure immunization.* Two equally effective regimens are described: (1) four doses of 1 ml each, three at weekly intervals and the fourth 5 or 6 months later; (2) three doses of 1 ml each, the second after 1 month and the last 7 months later. Either regimen should elicit demonstrable neutralizing antibody levels in over 80 percent of subjects one month after the final dose. While antibody persistence and the frequency with which booster inoculations are required are not known, it is suggested that persistence of immunity could be assured by periodic (every year or two) 1 ml boosters.

Since an antibody response is not consistently induced, the antibody titer must be determined after a course of

vaccine; (appropriate serum specimens may be sent to the CDC via the local health agency). If no antibody is found, additional doses of vaccine should be given until a response is elicited.

Should mild exposure subsequently occur in persons who do develop antibody, only a single 1 ml booster dose of vaccine is needed. Following severe exposure, five daily doses of vaccine and a booster dose 20 days later should be given.

b. *Contraindications.*

(1) *Precautions.* Use of this vaccine should be avoided in individuals with a history of allergy to chicken or duck eggs or proteins.

The use of steroids postexposure is to be avoided, as these may lower resistance to infection and suppress the antibody response, thereby possibly causing an apprent vaccine failure.

Pregnancy is no contraindication if exposure conditions dictate use of the vaccine.

(2) *Adverse reactions.* Local reactions are common, and later injections in the series may cause flare up in the sites of earlier inoculations; however, these are less frequent and less severe than those associated with nerve tissue vaccine (NTV), a product no longer licensed for manufacture in the United States.

Because the vaccine is a foreign protein, systemic sensitivity to its components may be encountered. Urticaria, respiratory distress (with dyspnea and bronchospasm), abdominal cramps, and nausea have occurred and anaphylactic reactions have been reported. Epinephrine may be helpful in such situations.

Constitutional reactions to the vaccine are difficult to evaluate (patients tend to be apprehensive), but the development of fever, malaise and drowsiness calls for careful observation. Minor neurologic reactions (headache, photophobia, paresthesias, and fatigability) have been reported and major reactions (transverse myelitis, cranial or perepheral palsy, and encephalitis) have been reported rarely. Vaccination should be discontinued if neurologic symptoms develop.

2. *Analysis.*—a. *Efficacy and safety.* The 1972 report of the ACIP states that in the United States, comparative effectiveness can be judged only by reported failures. During 1957 to 1971, there were 6 failures in 125,000 persons treated with NTV for a failure rate of 1:20,800, compared with 12 failures in 310,000 individuals given duck embryo vaccine (DEV) or a failure rate of 1:25,800.

Since these failure rates are not appreciably different, DEV is preferable because of its greater safety.

(1) *Recommendations from the medical literature.* Greenberg and Childress (Ref. 1) reported on 123 persons given DEV and 127 given NTV (Semple type). Duck embryo vaccine induced an earlier antibody response and no CNS reactions as compared with two cases of encephalomyelitis in the NTV group. Both vaccines proved effective boosters in previously immunized individuals. Their findings support the replacement of NTV by DEV.

Powell and Culbertson (Ref. 2) found that DEV protected rabbits against challenge with virus and, in man, induced antibody which neutralized both fixed and street virus.

Rubin et al. (Ref. 3) reviewed retrospectively adverse reactions to DEV used in the United States. Between 1958 and 1971, 424,000 persons had received courses of DEV. A fatal encephalitis developed in two of these, almost certainly rabies in each case, but there was insufficient diagnostic information to be certain. A nonfatal encephalopathy appeared in two others, transverse myelitis in four and cranial and/or peripheral neuropathy, reversible with (steroid) treatment, in five. Thus no fatalities could be attributed with certainty to the DEV, and major neurologic disease was rare and, in general, reversible.

In the same survey, Rubin et al. (Ref. 3) reported 22 instances of anaphylaxis, more than half of which could not be predicted even in retrospect from a history of allergy, etc. However, they noted that prior to their rabies immunization, some of these individuals had received several vaccines containing agents grown in avian tissues.

These authors also reported on a prospective study on the postexposure treatment of 116 individuals and recorded local discomfort in 100 percent of instances, constitutional symptoms during therapy in 33 percent, and anaphylaxis in 0.9 percent. They noted that the figure of 0.5–0.9 percent anaphylaxis is significant, inasmuch as the rate of anaphylaxis associated with administration of penicillin is 0.015–0.4 percent.

Tierkel and Sikes (Ref. 4) reported that giving DEV in a three dose regimen (0, 1, and 8 months) induced antibody in 90 percent of their volunteers.

(2) *Potency testing.* The official United States test for the potency of rabies vaccine is the National Institutes of Health mouse potency test (Ref. 5). Each production lot is compared with the United States reference rabies vaccine and must show a potency ratio of at least 0.3 times this reference standard in order to obtain approval for release by the Bureau. Manufacturing records indicate a rejection rate (failure of potency) of from 3 percent to 10 percent of lots, depending on which reference vaccine was used.

b. *Safety.* See Efficacy above.

c. *Benefit/risk.* The gravity of rabies is such that any vaccine which possesses a fair measure of efficacy, and is virtually nonlethal itself, warrants a favorable ratio.

d. *Labeling.* This should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to updated recommendations of ACIP. The hazard of anaphylaxis should be stressed since this is the most prominent potential reaction to DEV.

3. *Conclusions.*—a. *Critique.* (1) *Efficacy aspects.* Duck embryo vaccine is the only rabies vaccine now available. For obvious reasons, no trails of true efficacy are possible (prevention of rabies by either postexposure therapy or preexposure prophylactic immunization) so that one must rely on ability to induce neutralizing antibody in man as an index of efficacy.

The Advisory Committee on Immunization Practices recommendations urge that rabies antibody be used in postexposure prophylaxis; such administration of immune serum or human rabies immune globulin inhibits an active immune response by the patient. Experience suggests that such inhibition is especially marked with DEV (Refs. 6 and 7).

While there are data indicating that supplementary doses of vaccine 10 and 20 days later (the so called 16-dose course) are adequate to induce an active response after HRIB (Ref. 8), more recent data (Ref. 9) indicate that reliable induction of active response after HRIG requires a 23-dose course of DEV (daily for 21 days and again after 10 and 20 more days). Still more recent data from the CDC, presented to the Panel in June of 1974, indicated that satisfactory response was achieved more reliably in children under age 16 than in adults.

The relative safety of DEV as compared with NTV (see next section) made it possible to consider its use for preexposure immunization in high risk populations. The responses elicited with the regimens recommended are hardly satisfactory and further testify to the inadequate potency of DEV.

(2) *Safety aspects.* Duck embryo vaccine consists of crude embryo extracts containing beta-propriolactone (BPL) inactivated rabies virus. On a comparative basis, it is clearly safer

with respect to allergic CNS sequellae than is NTV. This is supported by data from animal studies and by experience in man.

However, DEV still leaves much to be desired. First, it is not completely devoid of the so-called paralytic factor; second, it contains an abundance of extraneous foreign protein with a demonstrated capability for inducing a variety of allergic reactions; and third, an effort should be made to detect and eliminate (if present) extraneous microorganisms, including avian reticuloendotheliosis viruses that may be present in duck cell substrates. Treatment with BPL plus merthiolate renders any such agents nonviable, but undesirable residual genetic viral material, if present, may persist.

Clearly, there is a need for a new product, one free of extraneous agents and with a greatly reduced proportion of extraneous protein. It is hoped that one of the cell culture vaccines still under study may resolve this situation.

Two such cell-culture vaccines were being studied at the time this report was prepared. Work has stopped on one, a vaccine utilizing virus grown in a baby hamster kidney cell line (BHK), which had excellent antigenic potency and apparent postexposure efficacy in rhesus monkeys (Ref. 10). It has the major theoretical drawback of derivation from a cell line rather than a cell strain or primary cell cultures.

The second tissue culture vaccine, using diploid WI–38 cells for viral propagation, has excellent antigenic potency and exceeds that of DEV by at least a factor of five, in addition to being a much cleaner product. However, recent unpublished data indicate that when it is used for long postchallenge protection of monkeys in an experiment similar to that with the BHK vaccine above, no certain protective effect could be shown (Ref. 13). Very recent preliminary data suggest that it can be used effectively in conjunction with antibody. This vaccine also has been tested on man for preexposure immunization; a three-dose regimen (0, 7, 21 days) induced response in 100 percent of vaccines with antibody levels 10-fold higher than induced by an optimal (0, 1, 6 months) regimen of DEV.

It should be noted that the immunologic phenomena involved in both protection against, and the pathogensis of, rabies are only poorly understood. In particular, recent work with rabies-related rhabdo-viruses and with rabies virus itself has yielded results which are contrary to what might be expected on the basis of classical concepts of immunity and which require further fundamental studies for adequate explanation (Refs. 11 and 12). As examples, immunosuppressed animals (mice) survive longer after challenge inoculation than do normal animals; delayed postchallenge administration of antibody to either immunosuppressed or to normal animals accelerates a lethal outcome; and animals immunized with rabies-related viruses (Lagos bat virus or Mokola virus) develop "neutralizing" antibodies to rabies virsus but are not only not protected against challenge with rabies virus but also die earlier than do controls (Refs. 10 and 11). Along this same line is the early death phenomenon noted by Sikes and other workers and illustrated by data on the postchallenge use of DEV in the mouse foot-pad model; not only did DEV fail to protect mice but the treated animals died earlier (significantly so) than did the untreated controls (Ref. 13).

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product. Every effort should be made to encourage the development of a better vaccine. However, DEV should be reviewed again when (and if) a new product is licensed. Furthermore, this generic product should be reviewed frequently as new information about rabies immunity and pathogenesis is developed in animal model systems. Basic research in these areas is obviously required in view of the uncertain basis for presently recommended procedures for immunoprophylaxis.

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Review of Yellow Fever Vaccine

Yellow Fever Vaccine Manufactured by Merrell-National Laboratories, Division of Richardson-Merrell Inc.

1. *Description.* This is the only yellow fever vaccine licensed in the United States. According to the package insert, it is prepared by growing the 17D strain of yellow fever virus in living chick embryos. The vaccine is frozen, dried, and hermetically sealed under nitrogen in glass ampoules. No preservative is added. The product is a 75-percent suspension of embryos (by weight) in distilled water and is to be reconstituted in five volumes of diluent immediately before use.

The vaccine satisfies the potency and other requirements of the Public Health Service (PHS) and the World Health Organization (WHO).

a. *Recommended use.* (1) *Indications.* The vaccine provides active immunity against yellow fever for travelers visiting countries requiring a certificate of vaccination against this disease. Immunization is required of all individuals over 6 months of age.

(2) *Administration and dosage.* Rehydrate the contents of the ampoule

with the diluent provided, as directed. Shake well, withdraw the contents, and administer 0.5 ml subcutaneously (the dosage is the same for adults and children).

Immunity develops by the seventh day and lasts for many years, but revaccination is required after a lapse of 10 years.

(3) *Special note.* The vaccine retains its potency for at least 12 months if kept in the freezing compartment of a refrigerator. After reconstitution, it should be kept cool and used within 60 minutes. Yellow fever vaccine is available only at officially designated Yellow Fever Vaccination Centers, which are authorized to issue valid certificates of vaccination.

Production and distribution of the vaccine is under the strict control of WHO and PHS.

b. *Contraindications.* Proved or known sensitivity to egg or chick embryo protein is generally a contraindication. Except in high risk areas, pregnant women and infants under 6 months of age should not be vaccinated.

Abnormal immune states (leukemia, lymphoma, generalized malignanacy, and lowered resistance from therapy with steroids, antimetabolites, and radiation) may potentiate vaccine virus infection, and thus consittute a contraindication to vaccination.

(1) *Precautions.* If hypersensitivity to egg proteins is suspected, a skin test should be done with 0.02 ml of vaccine (a tourniquet and epinephrine solution should be immediately available). If uncertainty prevails, intradermal vaccination by the scratch method might be undertaken.

If other live virus vaccines are to be given, they should precede or follow the yellow fever vaccine administration by at least 1 month.

(2) *Adverse reactions.* Fever and/or malaise occurs in 10 percent of the recipients of the vaccine. Encephalitis has occurred, although rarely, in very young infants and usually without sequellae (one death has been reported).

2. *Analysis.* Two types of live virus yellow fever vaccine exist, and both are recognized as acceptable by WHO. The so-called Dakar vaccine, made with mouse passage-adapted "French Neurotropic" strain of virus, is definitely encephalitogenic in man (0.5 percent incidence) and is not recommended by ACIP nor is it licensed in this country.

The other type, produced in chick embryos infected with the 17D strain of virus, is represented by the Merrell-National product, which is the only yellow fever vaccine licensed in the United States (although similar vaccine is produced in other countries). The history of 17D vaccine is interesting and lengthy but only partly relevant to this review.

Wild yellow fever virus is both viscerotropic (in this instance with specific reference to liver disease) and neurotropic. Brief intracerebral passage in mice predictably results in loss of viscerotropism (as shown in rhesus monkeys, which provide an excellent, sensitive model which reflects the disease seen in man). However, neurotropism is retained and, at least for mice, is enhanced as evidenced by a markedly shortened incubation period. The Dakar vaccine is made with virus of this type. Max Theiler and coworkers undertook to develop a strain attenuated for neurotropism as well as viscerotropism by serial propagation of the virus in various types of tissue culture. The 17D line in tissue cultures of chick embryos, from which the CNS tissue had been removed, eventually (passage number 114) satisfied their criteria (negligible disease in intracerebrally inoculated rhesus monkeys) and was shown to produce a safe and effective vaccine for human use. This change proved not to be reproducible, at least at will, although simple passage in intact chick embryos has resulted in a 17D-like virus on one or two occasions.

Since 1937 17D vaccine, produced in chick embryos, has been used on an increasing scale, first in Latin America, and soon on a worldwide basis. In these early years, multiple parallel passages of 17D virus were maintained in tissue culture in different laboratories and often in the same laboratory. Vaccine lots were produced as needed from the then current passage level of these sublines. By 1943, three significant problems had been encountered.

First, failures of the vaccine to immunize were observed. These failures were referable to vaccine lots produced from virus at a very high subculture level (350th passage). Such virus, as was later shown, had become poorly infective for man, although it still poduced lethal encephalitis in cerebrally inoculated mice. This problem was resolved by reverting to earlier passage virus for vaccine production.

Second, a vaccine-associated encephalitis was observed in a few Brazilian children. Review of the testing experience in the yellow fever laboratory in Brazil, where various parallel passage lines of virus were used to make vaccine, revealed that the cumulative occurrence rate of encephalitis in monkeys inoculated with different production lots of vaccine differed appreciably according to the culture passage line used to produce the vaccine (Ref. 1). The significance of this finding was confirmed in large-scale field studies including a carefully controlled trial of vaccines produced from each of five 17D substrains (Ref. 2). This basic problem (and that of diminishing immunogenicity) was resolved by selecting, for production of a master seed lot, the safest substrain at the passage level at which it was employed in the field trial. Secondary seed lots to be used for inoculating producion lots, were prepared from this master seed lot, thereby permitting vaccine production within the confines of a narrow range of passages.

The third problem (chronologically, the second) was the occurrence of serum hepatitis in vaccine recipients. The occurrence of vaccine-associated hepatitis was first recognized in Brazilian populations by Fox et al. (Ref. 3) and later, on a much larger scale, in United States military personnel. The cause was "normal" human serum (heat inactivated at 56° C) incorporated into the vaccine as a source of "innocuous" protein to facilitate lyophilization and subsequent rehydration of the vaccine and to stabilize the vaccine virus once reconstituted. The solution was to omit the serum and to increase the concentration of embryo tissue (fluid) in the final product, thereby providing a protein concentration adequate for lyophilization and virus stability.

A fourth problem did not become apparent until the recognition of avian leukosis virus (ALV) and its almost universal presence in chick embryos. The resolution of this problem is theoretically simple but has proven more difficult in practice. Although a careful follow up study in the United States military did not show any association between human malignancies and yellow fever vaccination, it is clearly desirable to eliminate this extraneous virus (Ref. 4). This has apparently been accomplished in two ways. Draper succeeded by combining neutralization of ALV with passage by the limiting dilution technique whereas Tarauso, et al. achieved separation of the two viruses through graded filtration (Refs. 5 and 6). The resulting 17D virus, free of ALV, was used to produce vaccine seed material which, according to tests reported by them, did not differ from the seed of origin in terms of antigenicity and neurovirulence in monkeys or in immunogenicity and reactogenicity in man (Refs. 7, 8, and 9). On the basis of these findings, this ALV-free seed was judged acceptable by WHO.

In the United States, efforts are in progress to prepare a similar ALV-free seed virus for use in future production of yellow fever vaccine in this country.

The second effort at eliminating ALV from yellow fever was carried out earlier in the Division of Biologics Standards, but it has been found to be unsatisfactory for reasons discussed below.

a. *Efficacy.* The information available in the submission refers only to experience with the original ALV-contaminated vaccine. Extensive worldwide experience with this product, and the similarly derived vaccines produced elsewhere in the world, is highly reassuring with respect to both safety and effectiveness.

The 17D strain is derived from the wild Asibi strain, which is recovered from a Nigerian with a mild attack of yellow fever. In the course of its extended passage in chick embryo tissues, this strain has undergone minor (subtle) change in antigenic character but apparently remains adequately immunogenic against wild yellow fever strains. A review of vaccination experience through 1954 (cited in WHO Monograph No. 30, 1956) indicates that the only significant problem was in infants under 6 months of age, among whom several cases of encephalitis (all with full recovery) occurred.

The only version of the Division of Biologics Standards (Bureau of Biologics) minimum requirements is dated May 18, 1949 and agrees basically with WHO requirements. Production lots are tested for potency (at least 1,000 mouse MLD per dose), safety in guinea pigs, and sterility.

Only the primary and secondary seed lots are tested (all intracerebrally) in monkeys for neurovirulence, circulating virus (index of some retained viscerotropism), and immunogenicity. Merrell-National received the primary seed from PHS in 1952 and has had occasion to produce only three secondary seed lots, which were tested by the Division of Biologics Standards.

Since 1968, several million doses of vaccine have been distributed. A small number of reactions, often of dubious relation to vaccination, have been reported. These included one instance of encephalitis and one death which, after careful autopsy, could not be attributed to the vaccine.

b. *Safety.* See Efficacy above.

c. *Benefit/risk (of ALV-contaminated vaccine).* On the basis of human experience, the 17D vaccine is effective and minimally reactogenic, hence benefit far outweighs demonstrated risk. The known presence of ALV, however, is an undesirable factor of potential, but not yet established, risk.

d. *Labeling.* Since this vaccine is distributed only to officially designated centers, labeling is less important than for commercially available products; however, it is generally adequate. The time of expected acute reactions is not indicated and the possibility that use of the vaccine as a skin test antigen may in fact be immunizing is not considered. In a 1943 report of a vaccine trial in Brazil, data are presented indicating that intradermal inocula containing as little as 10 $TCID_{50}$ of virus induced immunity in all vaccinees (Ref. 9).

3. *Conclusions.*—a. *Critique.* One major problem, not considered previously, requires mention here, viz., no ALV-free vaccine has yet been licensed in this country. This situation exists because (1) the only manufacturer of ALV-free vaccine has not sought a license and (2) the ALV-free seed material produced by the former Division of Biologics Standards has been retested in monkeys by the Bureau of Biologics and found wanting (and also, in effect, by Merrell-National and two or three foreign laboratories). The reasons for this failure to conform the previously reported observations are not clear but may reflect more rigorous and uniform criteria for examining the test animals.

Information obtained during a briefing (March 18, 1974) by Dr. David Barry and others of the Bureau of Biologics indicates that the most important problem is an increased neurovirulence for monkeys, manifested by a clinically severe or fatal encephalitis in 6 of 24 animals (25 percent) and transient weakness in 3 others. Five monkeys died or were killed when moribound. In comparison, only one of 12 animals given the old (ALV-contaminated) seed showed evident weakness and developed severe (but nonfatal) disease. Thus, the new material (two seed lots, one primary and one secondary) failed to pass WHO requirements for neurovirulence. One new seed lot, together with the old seed, also failed to manifest adequate viscerotropism as reflected by viremia detected in mice. However (suggesting that viscerotropism is not a relevant criterion), all lots were highly immunogenic in monkeys. The Brazilian experience, which is not likely to be reproduced suggests that monkey neurovirulence is a valid marker for human risk. While Tauraso et al. (Ref. 10) observed no significant clinical reactions in a limited number of volunteers, the group was probably too small to give conclusive findings and probably too old (all were young adult males) to be sensitive detectors (young children have generally been more prone to give reactions). Thus the problem with the Division of Biologics Standards seed must be accepted as real, and it has both practical and theoretical implications.

On the practical side, the Bureau of Biologics must decide what vaccine should be immediately available in the United States. That now being produced (ALV-contaminated) is "safe" with respect to neurovirulence. Furthermore, Waters et al. (Ref. 4), in their study of cancer mortality among army veterans of World War II in relation to their immunization against yellow fever (ALV-contaminated vaccine), found no evidence that such vaccination had influenced the risk of subsequent malignancy 5 to 22 years later. Thus, it is probable that the presence of ALV is inconsequential. However, it is clearly desirable that vaccines contain no adventitious agents.

The possibility exists that yellow fever virus may have acquired ALV genetic material during the long period of concomitant passage. Hence, even though ALV-free strains of 17D virus are obtained which prove satisfactory with respect to the desired vaccine characteristics, it would seem prudent to explore this possibility.

Efforts by the Bureau of Biologics staff to modernize testing of the vaccine are to be commended. These changes involve: (1) substitution of plaque assay for mouse LD_{50} assay at all levels; (2) revision of criteria of immunogenicity in monkeys (e.g., substitution of parenteral for intracerebral routes of inoculation); (3) efforts to develop shorter and more reliable neurovirulence testing markers in monkeys; and (4) deletion from animal potency and safety testing of criteria involving viremia.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product. The availability of a safe and effective yellow fever vaccine produced in the United States must continue. Steps to exclude ALV contamination should be taken as quickly as possible without jeopardizing the safety of the yellow fever virus strain employed. During the interval required to achieve this, the present vaccine should be maintained in use. By whatever means necessary, the Bureau should move to insure that ALV-free vaccine is made available in the United States. If necessary, this effort should include participation by the Bureau's staff in the research that will

most rapidly lead to development of a new ALV-free seed for acceptable neurovirulence. Modern virologic technology, including virus cloning and genetic studies, will be important in this program.

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Review of Rocky Mountain Spotted Fever (RMSF) Vaccine

Rocky Mountain Spotted Fever Vaccine Manufactured by Lederle Laboratories Division, American Cyanamid Co.

1. *Description.* Rocky mountain spotted fever (RMSF) vaccine is prepared by the method of Cox using yolk sacs and chorioallantoic membranes of embryonated eggs infected with *Rickettsia rickettsii*. This material is purified by ether extraction, inactivated with formaldehyde and ethylene oxide, and contains 0.0037 percent formaldehyde, 0.01 percent thimerosal, and up to 0.04 mg/ml of ethylene oxide. The nitrogen content ranges from 4 to 5 mg/ml. The vaccine is tested for potency and safety by the official methods required by the Bureau of Biologics.

a. *Recommended use.* (Quoted from ACIP, see Ref. 1.)

> Rocky mountain spotted fever vaccine is not recommended for use in the general population because disease is uncommon and the vaccine is of limited effectiveness. However, it is recommended for laboratory personnel working with *R. rickettsii* and might be considered for persons whose occupations result in exposure to ticks in endemic areas. For persons with only recreational exposure to ticks, protective clothing and deticking should be emphasized.

The Lederle label (revised June 1972) follows the recommendations of ACIP except in emphasis, e.g., "Other persons who may be unduly exposed to possible tick bite because of circumstance of environment such as campers, rangers, etc. in endemic areas should be protected by prophylactic vaccination."

b. *Contraindications.* Listed contraindications and precautions follow reasonable and practical guidelines for the inoculation of biological products. A note regarding effect of prior administration of antibiotics affecting immune response is included for unknown reasons.

2. *Analysis.*—a. *Efficacy.* The literature on the efficacy of RMSF vaccine in the protection of man is sparse and provides little basis for any confidence that the vaccine protects against disease although it may perhaps lower the fatality rate. The most recent report, that of DuPont et al. (Ref. 2) describing a comparative study of the active immunity induced in man by inactivated *R. rickettsii* concludes that killed vaccines, which are regarded as efficacious (based on the results of guinea pig protection tests and uncontrolled vaccine studies) are not effective in preventing RMSF in man. Cox in 1959 (Ref. 3) stated:

> Vaccination is an effective method of prophylaxis [and] the vaccines have a definite protective value * * *. The vaccine usually affords complete protection against relatively mild strains, but may be less effective against more virulent ones. Most children are fully protected * * * whereas adults are fully protected only occasionlly.

Although earlier data derived from uncontrolled studies using killed tick-grown vaccine suggested an ameliorating influence, data on the protective capacity of the current egg-grown vaccine are more limited (Ref. 4). It is generally accepted that insofar as guinea pig potency and immunogenicity are concerned, both preparations are comparable (Refs. 2 and 5).

Data to support the induction of a solid immunity in man following vaccination with the Cox-type preparations are lacking. One can state that a number vaccinated adults can still be infected and develop clinical disease even when exposed to low-dose challenge inocula of *R. rickettsii* (Refs. 2 and 6).

The potency test of RMSF vaccine is based on the ability of the vaccine to immunize guinea pigs and to protect them against challenge inoculation, and procedure almost unchanged from 1945. Six or more normal male guinea pigs, weighing approximately 500 grams each, are inoculated subcutaneously with 1 ml of the vaccine under tests.

Ten days after injection, the animals are tested for immunity to a previously determined challenge strain of spotted fever rickettsiae.

The challenge does is injected intraperitoneally and consists of 10 percent infected spleen tissue suspension, or of infected guinea pig blood, or of an appropriate dilution of infected yolk sac suspension. Not less than six normal male guinea pigs are given the same infecting dose of the same material to serve as controls. Both the vaccinated and the conrol animals are observed for 12 days for the effectiveness of the immunization, with body temperatures taken daily during the period.

At least two-thirds of the immunized guinea pigs must not show a temperature elevation above 39.6°C after the third day, nor show overt signs of infection, for the vaccine to be satisfactory. In the control group, at least two-thirds of the animals must show a characteristic temperature curve and other manifestations of infection with the strain of spotted fever rickettsiae used. At least 50 percent should succumb and show the pathological findings characteristics of infection with *R. rickettsii*.

b. *Safety.* The manufacturer's submission noted that for the doses distributed to the general public during 1969 to 1972, there were no complaints. This probably indicated more the failure to report of complaints than inherent safety. The Bureau of Biologics has released nine lots from Lederle in the past 5 years.

c. *Benefit/risk.* The lack of evidence concerning safety plus a similar lack of

evidence for effectiveness suggests an unfavorable benefit/risk ratio.

d. *Labeling.* Labeling should be in accordance with conclusions and recommendations of this review.

3. *Conclusions.*

a. *Critique.* Our assessments are predicated on the above review combined with the following considerations:

Recognition that RMSF is increasing in this country (Fig. 6) and that most cases occur in the Southeastern United States (Fig 7). It is referred to as tick-borne typhus by CDC partly to emphasize this latter point. Most cases in this country occur in children (70 percent), and the overall mortality rate is 5 to 10 percent (Ref. 7).

(2) Recognition that vaccine propylaxis is but one of several measures to control infections and that the vaccine's applicability to the current tick-bone typhus problem in this country is limited to certain occupational and geographical areas (Ref. 8).

(3) The effectivenses of this vaccine in protecting man against RMSF is highly questioned. While a much better vaccine is certainly needed, removal of the present vaccine from the market would make this possibly prophyulactic measure completely unavailable.

b. *Recommendations.*

(1) The Panel recommends that this product be placed in Category IIIA and that the appropriate license be continued on an interim basis pending completion of testing and conformance with recommendations of this report because, while there is no substantial evidence of safety and effectiveness, there is information based on published reports and/or physician surveys which may be deemed to be presumptive evidence of safety and effectiveness for this product. Licensure should be continued for a period of 2 years from the date of issuing of the final order based on this proposal during which time the required substantiating data are to be obtained. Further extension of licensure should depend on the development of convincing evidence for increased potency.

(2) If substantiating data can be obtained, consideration should be given to amending current potency standards (using guidelines similar to those specified in the Armed Forces Epidemiologic Board's recommendations for epidemic typhus vaccine) to provide for a defined whole rickettsial organism content and for the use of a reference preparation in a meaningful assay system.

(3) Mobilization of financial support through the Bureau of Biologics, NIH, and other agencies for research in rickettsial diseases and especially for the development of effective prophylactic measures to replace the current vaccine should be considered.

(4) Safety standards for this vaccine should be updated to provide limits for endotoxin content and for the exclusion of latent viruses, mycoplasma, and other extraneous agents prior to inactivation.

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Review of Typhus Fever Vaccine

Typhus Fever Vaccine, Inactivated Manufactured by Lederle Laboratories Division, American Cyanamid Co., Eli Lilly & Co., and Merck Sharp & Dohme, Division of Merck & Co., Inc.

1. *Description.* The Lederle Laboratories typhus fever vaccine is prepared by the method of Cox from chick embryo yolk sacs infected with *Rickettsia prowazekii.* The yolk sac material is purified and inactivated with formaldehyde. The vaccine is diluted in a phosphate buffered solution containing 0.3 molar glycine. Thimerosal (1:10,000) is added as a preservative.

The Eli Lilly & Co. typhus fever vaccine is a suspension of epidemic typhus rickettsias *(Rickettsia prowazekii)* prepared from refined material derived from an aqueous suspension of infected yolk sac membrane. The organisms are inactivated by formaldehyde and suspended in isotonic sodium chloride solution. The vaccine is preserved with thimerosal solution, 1:10,000.

The Merck Sharp & Dohme typhus fever vaccine is described as containing killed *Rickettsia prowazekii* organisms grown on the yolk sac of developing chick embryos, in amounts sufficient to meet standards of potency as specified in 21 CFR 610.10. The diluent is a physiological solution of sodium chloride. The preservative is thimerosal in a final concentration of 1:10,000.

a. *Recommended use.*

(1) *Dosage.*

(i) *Lederle vaccine.* The package insert dated June 1969 recommends, for adults, two subcutaneous injections of 0.5 ml each with an interval between doses of not less than 4 weeks. If this interval is not practical, the second dose may be given prior to embarkation to an endemic area. A booster dose of 0.5 ml should be given at yearly intervals as long as a threat of exposure continues.

For children under 10 years of age, one-half the adult dose is recommended.

(ii) *Merck Sharp & Dohme vaccine.* The Merck Sharp & Dohme vaccine presumably is prepared primarily for the military establishment since the package insert recommends a dosage of one injection of 0.5 ml to be given during basic training, with a reinforcing dose of 0.5 ml to be given to the unit going overseas. Nonmilitary personnel are to receive two injections of 0.5 ml at intervals of not less than 4 weeks. The reimmunization dose is 0.5 cm^3. The package insert is dated February 1963.

(iii) *Eli Lilly & Co. vaccine.* The package insert, dated June 12, 1972, recommends, for adults, a dosage of two subcutaneous injections of 1 ml each with an interval of 4 or more weeks between injections. Booster injections of 1 ml should be administered at intervals of 6 to 12 months for as long as threat of exposure continues. For children the recommended dosage for primary immunization is 0.5 ml on each of the two occasions and the booster injection may be from 0.5 to 1.0 ml according to the individual's age.

Immunization is recommended for such persons as scientific investigators, medical or laboratory personnel, and those whose work brings them into areas where the disease actually occurs, e.g., anthropologists, archeologists, geologists, oil field construction workers, missionaries, etc.

(2) *General comment.* Local reactions showing varying degrees of redness and tenderness, and systemic reactions as evidenced by chilliness, generalized

aching, headache, and fever, may occur in a variable percentage of individuals receiving typhus fever vaccine.

b. *Contraindications.* Immunization should be postponed in the presence of acute infections. The vaccine should not be administered to persons suffering from debilitating diseases and should not be given to individuals receiving immunosuppressant drugs.

Because it is produced from rickettsii grown in chick embryos, the vaccine is contraindicated in persons sensitive to egg proteins.

2. *Analysis.*

a. *Efficacy.*

(1) *Animals.* Protocols on each commercial lot of vaccine must be submitted to the Food and Drug Administration to show that minimum potency and safety requirements have been met. The safety tests involve mice, guinea pigs, and rabbits, and the procedures are essentially those outlined in the review of rocky mountain spotted fever vaccine prepared by Lederle Laboratories.

(2) *Humans.* Vaccine produced according to the minimum requirements established by NIH was utilized by the Armed Forces during World War II. Most of the evidence as to its efficacy therefore came from the military establishment, primarily the Army, and very few additional data have been added.

In 1947, Sadusk (Ref. 1) reported

> * * * in the period January 1, 1942, to December 31, 1945, there were reported in the entire United States Army 64 cases of epidemic typhus, 603 cases of murine typhus and 6,685 cases of tsutsugamushi fever or scrub typhus. There were no deaths during this period from epidemic typhus fever.
>
> While no conclusions can be drawn concerning a reduction in the incidence of epidemic typhus by prophylactic immunization with Cox type ether-extracted typhus vaccine, it appears definite that such vaccination does serve to greatly modify the disease if it occurs in an adequately vaccinated person and does render the deaths from typhus practically nil.

Comments concerning efficacy will be considered further under Critique.

b. *Safety.*

(1) *Animals.* Animal safety tests must satisfy FDA requirements for safety and efficacy.

(2) *Humans.* There is no evidence that the vaccine, when used under normal conditions and in accordance with the precautions given is associated with an unusual incidence of adverse reactions and no fatalities, so far as the Panel is aware, have been reported.

c. *Benefit/risk.* See b. Safety, (2) Humans, above.

d. *Labeling.* This appears to be adequate.

3. *Conclusions.*

a. *Critique.* The most extensive experience with killed typhus fever vaccines has been that of the Department of the Army and it is to this experience that serious consideration was given in evaluating these vaccines. Much of the critique that follows is taken from reports of the Commission on Rickettsial Diseases, Armed Forces Epidemiological Board, and especially that of Dr. Irene B. Fabrikant, presented before the Commission at its annual meeting November 30–December 1, 1972, at the Walter Reed Army Institute for Research, Washington, DC.

Basically the problems are: (1) Although a series of vaccines may pass the minimum requirements, the individual lots may be quite variable in their antigenic composition and potency, and (2) current potency tests are highly unreliable because they are incapable of distinguishing between vaccines of markedly different potency. Because of these variations in antigenic composition and potencies, the antibody response to these vaccines, aside from being unpredictable, has in general been poor.

Studies by the Commission on Rickettsial Diseases have led to a simple procedure for obtaining a direct count of rickettsial bodies contained in a vaccine and this in turn provides an alternative method to complement fixation and animal tests for assaying a vaccine for potency. The development of a simple batch purification technic permits flotation of yolk sac in high density sucrose and provides a means for removing as much as 90 percent of this material from fresh or formalin killed rickettsial preparations. Recovery of rickettsiae, based upon direct counts, is essentially quantitative, and for live rickettsial preparations, there appears to be no loss in the titer of the toxin. It was noted that subcutaneous inoculation of a single dose of such killed rickettsial vaccine preparations into guinea pigs elicited both complement-fixing and toxin-neutalizing antibodies in relatively high titer. The erratic serologic response previously noted in guinea pigs (intraperitoneal inoculation) was in large part obviated.

In sum, therefore, there is now a method for standardizing antigen content on the basis of total rickettsial count and for evaluating immunogenicity by a single-dose guinea pig potency test based on the fact that the serologic response shows a nearly linear relationship between the log of the number of organisms in the dose and the geometric mean titer of toxin neutralizing antibodies.

Recent reports from the Bureau of Biologics (Refs. 2 and 3) describe the production and evaluation of a reference, inactivated epidemic typhus vaccine. Production closely followed procedures recommended by the Commission on Rickettsial Diseases outlined in a previous section. However, laboratory evaluation of potency did not include electron microscope (EM) counts of rickettsiae or tests for development of antibody (complement-fixing and/or toxin-neutralizing) in guinea pigs given a single subcutaneous dose of vaccine as suggested by the Commission. It included, instead, the now discredited two-dose guinea pig potency test and a careful assay of the complement-fixing antigenicity of the vaccine. The former failed to distinguish between vaccine differing by twofold in potency whereas the latter reliably paralleled such potency for vaccine lots representing a parent lot and 3 lots prepared by successive two-fold dilutions of the parent. It also approximately paralleled the immunogenicity of the same lots in clinical trials in man as measured by titer of toxin-neutralizing antibody developed after a single dose of vaccine. Since these trials identified one vaccine lot as acceptable in terms of reactogenicity and as adequately potent (98 percent seroconversion and GMT of 1:32), it would appear that the Bureau of Biologics now has at hand a satisfactory referency vaccine for use in evaluating the potency of future production lots submitted for release.

The clinical trial raised one potentially important question: the apparent narrow range of rickettsial content which is minimally reactogenic but adequately potent. The one acceptable lot was the second in a series of three lots tested which represented successive two-fold dilutions of a parent lot (not tested in man). The first in the series was too reactogenic (5 of 10 recipients experienced significant constitutional symptoms) whereas the third in the series was appreciably less immunogenic (91 percent seroconversion, GMT of 1:16). If the critical range is indeed so narrow (further clinical trials seem indicated to establish this), than it is critically important to be able to evaluate potency for man by a quantitative and reliable laboratory method. While complement fixation (CF) assay of the set of vaccines tested did prove predictive, it is well recognized that rickettsial antigens can be denatured (as by heat) so as to be of greater diminished immunogenicity but without loss of CF reactivity. Thus, laboratory evaluation must include a

test for immunogenicity such as the one-dose guinea pig test suggested by the Commission.

b. *Recommendations.* The Panel recommends that this product be placed in Category IIIA and that appropriate license(s) be continued on an interim basis pending completion of testing and conformance with recommendations of this report because, while there is no substantial evidence of safety and effectiveness, there is information based on published reports and/or physician surveys which may be deemed to be presumptive evidence of safety and effectiveness for this product.

Consideration should be given to the establishment of new criteria for safety and potency. Examination of the revised specifications for potency advanced by the Commission on Ricketsial Diseases of the Armed Forces Epidemiological Board might provide a starting point.

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Generic Review of Human Immune Serum Globulin and Specific Human and Equine Immune Serum Globulins

Background

The discovery of antibodies by Karl Landsteiner, the association of antimicrobial substances with particular fractions of plasma, and the more recent appreciation of the molecular basis of humoral immunity provide the background for the prophylaxis or modification of infectious disease processes through the use of concentrated antibody preparations. Alcohol fractionation of the globulin proteins by E. J. Cohn's method is an old and well-tested procedure for concentrating antibodies present in human plasma. Application of the method to pools of plasma prepared from the blood of individual donors provides a product that broadly reflects the antibody spectrum of the general population. The use of such human ISG has afforded clearcut benefits in the modification of Type A hepatitis, prophylaxis against measles, and as replacement therapy in dys- or hypogammaglobulinemias.

In recent years, a more potent and effective ISG has been achieved by selection of blood donors with high antibody titers to a specific virus, e.g., varicella, vaccinia, and rabies. Such virus specific globulin products are in limited supply, and hence are restricted to use in specific clinical situations.

1. *Recommendations of the ACIP.* There are no generic recommendations for the use of ISG. However, the section on hepatitis in "Immunization Against Disease," 1972, CDC, contains specific recommendations for ISG use in hepatitis A. Other sections provide comparable recommendations for other virus-specific preparations.

The following are excerpts from "Immunization Against Disease":

a. *Hepatitis A.* Numerous field studies during the past 2 decades have documented the protection against hepatitis-A conferred by ISG administered before exposure or during the incubation period. Its relative effectiveness depends on timing and dose. When administered before, or within 1 to 2 weeks after exposure to hepatitis-A, in the appropriate dose it prevents illness in 80 to 90 percent of those exposed. However, because ISG may not suppress inapparent infection, long-lasting natural immunity may result.

The decision to give ISG is based on assessing the possible hepatitis exposure. If the exposure could have resulted in infection, ISG should be given.

ISG should be given as soon as possible after a known exposure. Its prophylactic value is greatest when given early in the incubation period and decreases with time after exposure. The use of ISG more than 6 weeks after exposure or after onset of clinical illness is not indicated.

Specific recommendations: Household and institutional hepatitis-A case contacts, hepatitis-A needle exposure, common-source hepatitis-A exposure, chimpanzee handlers and travelers to foreign countries.

b. *Measles.* To prevent or modify measles in a susceptible person exposed more than 48 hours before, MIG or standard Immune Serum Globulin (ISG), 0.1 ml/lb, should be given. He should be given live measles vaccine about 3 months later, when the measles antibody will have disappeared, if then at least 12 months old.

c. *Rabies.* Hyperimmune serum has proved effective in preventing rabies. Its use in combination with vaccine is considered the best post-exposure prophylaxis. However, the only preparation of antirabies serum currently available in the United States is of equine origin. Because horse serum has induced serum sickness in at least 20 percent of those who have received it, it should be used only when indicated.

Hyperimmune equine serum is recommended for all bites by animals in which rabies cannot be excluded and for nonbite exposure to animals proven or suspected to be rabid * * *. When indicated, antirabies serum should be used regardless of the interval between exposures and treatment.

However, in 1974 Human Rabies Immune Globulin (HRIG) was licensed, and since 1977 it has been available in adequate supply (Ref. 1). More recent recommendations by ACIP suggest it as a preferred alternate to hyperimmune serum (Ref. 2). The recommended dose of HRIG is 20 IU/kg. Up to 50 percent of the globulin dose should be used for infiltrating the wound and the rest for intramuscular injection.

d. *Vaccinia. Vaccinia Immune Globulin (VIG).* In its recommendations the ACIP considers the use of VIG prophylactically, in such situations as exposure of susceptible persons to smallpox; exposure of eczematous persons to vaccinated household contacts; to minimize complications of vaccination (when absolutely required) in high-risk groups; and therapeutically for any complications of vaccination. These applications are described in detail in the specific product review. Ostensibly the product is no longer being produced in the United States, and hence its future availability is in doubt.

e. *Varicella-Zoster immune globulin (ZIG).* This is a gamma globulin fraction of high antibody titer (1:128 or greater) prepared from plasma obtained from patients convalescing from herpes zoster; it is not a licensed product and may be used only under an Investigational New Drug (IND) (held by CDC). As of 1972, ACIP (Ref. 3) notes that ZIG has been shown effective in preventing varicella when given within 72 hours of exposure and that still under study is its effectiveness: (1) when given later than 72 hours after exposure; (2) for modification of established varicella or zoster; (3) for prevention of dissemination of herpes zoster; and (4) for control and prevention of varicella outbreaks. At the present "ZIG is indicated for the prevention of varicella in susceptible high-risk individuals who have had close V–Z exposure (e.g., household)." Susceptibility can be determined by the Varicella-Zoster (V–Z) fluorescent antibody test. The recommended dose is 5 cc given intramuscularly.

f. *Other products.* There are no current recommendations for passive immunization against mumps, poliomyelitis, or rubella.

2. *Other Indications.* The recommendations cited above cover the specific clinical indications where the use of ISG or specific-immune globulins has been shown to be of benefit. Another and widely accepted indication for ISG is its use as replacement therapy in patients with laboratory documented humoral immune deficiency disease. However, although ISG (and occasionally plasma) therapy is an appropriate therapeutic approach, it is in this area of immunodeficiency that the most common abuses of ISG occur. Diagnoses of recurrent lower respiratory tract "infections"; allergies, including asthma; prematurity; and "failure to thrive" are not adequate indications unless accompanied by specific laboratory evidence of immune globulin deficiency. Similarly, exposure of women to rubella in the first trimester of pregnancy has been cited as an indication; however, use of ISG may modify the maternal illness without protecting the fetus while confusing the serologic status (the use of rebella immune globulin might be considered for exposed individuals where abortion is not permitted).

Probably because of the dilution of antibody which occurs in pools of ISG (derived from at least 1,000 donors), it has not been shown unequivocally to be effective in preventing or modifying hepatitis-B, nor in preventing varicella, although in the latter instance there is some evidence that it may alleviate the disease. With the recognition of hepatitis B surface antigen (HB_sAg), and the ability to assay sera for the corresponding antibody (anti-HB_s), large-scale studies were undertaken to determine the prophylactic effectiveness of both ISG and hepatitis B immune globulin (HBIG). As a result of these studies, HBIG was licensed in 1977.

3. *Comments on PHS Regulations.* Public Health Service regulations deal with processing methods, definitions of lot, final product, and potency, and conclude with some general requirements. On the whole, these rules reflect the technology of the 1960's. More quantitative definitions exist for IgG, the relative content of other immunoglobulins and of contaminating serum proteins. There is no consideration of aggregates, which are the presumed cause of severe reactions and which thus preclude administration of ISG directly into the vascular system. There are no regulations governing specific immune serum globulin other than measles immune globulin, the measles antibody level of which is compared with that of a reference preparation; a two-fold variation in the assay is permissible. It may be noted that, for ISG, a measles antibody level of at least one-half that of the same reference preparation is required.

Analysis

1. *Efficacy*—a. *Hepatitis*—(1) *Hepatitis A.* Although no test for assay of hepatitis A antibody has been available until recently, there is abundant clinical evidence demonstrating the efficacy of ISG in the prevention of Type A hepatitis.

Stokes and Neefe (Ref. 5) and Gellis et al. (Ref. 6) found that ISG could control the severity of viral hepatitis (hepatitis A) epidemics, but had limited value in controlling hepatitis caused by transfusion of whole blood or plasma.

Ashley (Ref. 7) found that the incidence of infectious hepatitis (hepatitis A) in an institution for the mentally retarded was reduced tenfold after use of ISG as a prophylactic measure. The dosage was 0.01 ml/lb of body weight.

Brooks et al. (Ref. 8) and Hsia et al. (Ref. 9) showed the prophylactic effectiveness of ISG in reducing the secondary attack rate in small family groups. Exposed untreated children had a secondary attack rate of 25 percent to 35 percent. Adults in the same category had rates of 0 to 4 percent. Children and adults treated with ISG (0.01 ml/lb) had attack rates of 0 to 2 percent and 0 to 3 percent, respectively.

Stokes (Ref. 10) cites a study in which 40 of 50 persons given 0.06 ml of ISG per pound of body weight were immune 9 months later to experimental infections with hepatitis virus (hepatitis A).

The results of five ISG trials described by Krugman (Ref. 11) further confirmed the efficacy of ISG for the prevention or modification of infectious hepatitis (hepatitis A).

(2) *Hepatitis B.* As noted in an earlier section (Other Indications), both ISG and Hepatitis B Immune Globulin (HBIG) are geing evaluated for prophylactic efficacy against hepatitis B under several exposure circumstances, including "needle-sticks" and work in dialysis units. In the meantime, since the potential benefits from the use of both preparations clearly outweigh known risks, HBIG has been licensed for use in instances of possible exposure to hepatitis B.

b. *Measles.* Well before the development and application of measles vaccines, the efficacy of gamma globulin was recognized both for prevention of the disease (when given in the first 2 days following exposure) and for its modification (when given later, or in lower doses). Dose-dependency of the end result was clear, and with the development and application of the Edmonston live attenuated-virus measles vaccine, it became evident that simultaneous administration of antibody was required to minimize side effects. The original recommendation was that 0.02 ml/kg of measles immune globulin be administered with the vaccine. However, excessive amounts of antibody in the specified volume woud render the vaccine inefficacious. Hence, it became necessary to provide immune globulin with known, predetermined antibody content.

With the development of further attenuated vaccines, the need for concurrent administration of gamma globulin was obviated and with it the need for careful definition of the maximum antibody concentration of measles immune globulins. Thus prevention or modification of measles in exposed susceptible individuals is adequately achieved at present with standard ISG preparations. Their release depends in part on a *minimum* concentration of measles antibodies.

c. *Rabies.* Postexposure immunotherapy (or immunoprophylaxis), until recently had undergone relatively little change since its introduction by Louis Pasteur in the last century. The underlying theoretical basis is that, during the usual relatively long postexposure incubation period, an active immune response of sufficient magnitude to overcome infection and prevent disease can be induced. The efficacy of Pasteurian treatment is frequently questioned, but rigidly controlled field trials in man are not feasible. However, there is little doubt that treatment often prevents fatal rabies; failures occur chiefly in instances of severe exposure with a short incubation period. Observations in India of persons bitten by proved rabid animals have clearly shown the protective effect of immunization when vaccine was available and used (the comparison group consisted of persons for whom treatment was not available).

Antirabies vaccines induce the development of serum neutralizing antibody. This process, however takes time. Antibody rarely appears before 10 days but usually is detectable by 15 days after start of treatment. Assuming that protection is mediated by antibody, it is reasonable to expect that providing pre-formed (passive) antibody as vaccine treatment begins will bridge the gap and increase the level of protection. Working in experimental animals,

Koprowski (Ref. 12) and Habel (Ref. 13) demonstrated that this is indeed true. Koprowski's work emphasized the need to give immune serum (IS) early, i.e., within 72 hours of exposure, and Habel showed the value of local infiltration of IS around the inoculation site to help localize the virus. There is no evidence to suggest that antiserum given later is of benefit, and indeed studies in experimental animals raise the possibility that it may be harmful. A rabid wolf in Iran provided the first opportunity for a semicontrolled study among severely exposed humans. The numbers were small, but use of IS with vaccine appeared highly, although not invariably, protective, even in one patient whose exposure amounted to intracerebral injection of rabies virus (Ref. 14). Examination of sera obtained serially from these patients showed that the use of IS plus NTV resulted in the continuous presence of antibody after treatment had begun (Ref. 15). Subsequent experience, briefly summarized in part by Johnson (Ref. 16), provides further, fairly extensive documentation of the usefulness of IS. An experimental study in guinea pigs related protection to the severity of challenge; vaccine alone conferred good protection against mild challenge, but against severe challenge, IS was needed in addition to the vaccine (Ref. 17).

Few well-controlled animal studies of postexposure immunotherapy have been conducted until recently. In a series of studies using mice and a viral isolate with relatively long incubation period, Baer and Cleary (Ref. 18) found that the virus tended to remain localized (outside the CNS) longer than had been generally appreciated, up to 18 days in some animals. Additionally, they observed that antiserum alone used soon after viral inoculation tended to prolong the incubation period rather than to prevent the disease.

Sikes et al. (Ref. 19), using rhesus monkeys, compared the protective effect of different vaccines given postexposure, and also the protective capacity of antiserum produced in homologous or heterologous animal species. The results were surprisingly unimpressive with respect to the efficacy of serum alone, and a few animals showed the prolonged incubation phenomenon seen in mice.

Recent observations on rabies-related rhabdoviruses in mice are of some interest. In a study of the postexposure effects of immunotherapy in animals infected with Lagos bat virus, Tignor et al. (Ref. 20) found that if administration of passive antibody to immunosuppressed mice was delayed the outcome was rapidly lethal; the same effects were observed with transfer of spleen cells from immunized mice. Such studies, although indirect, may serve to shed light on poorly understood aspects of the pathogenesis of rabies.

In 1960, standards for antirabies serum were established designating an International Standard (equine) antiserum and defining the International Unit (IU) as the activity contained in 1 mg of the International Standard (Ref. 21). The International Standard Antiserum contains 80 IU per ml, and antisera produced for distribution must be shown to be at least as potent as the International Standard (if first comparison shows this, the antiserum passes; if not, two more comparisons are allowed, and if both are satisfactory, the antiserum is approved).

Until recently, the only antisera available in the United States have been preparations of immune globulin of equine origin, which pose the serious problems of serum sickness and anaphylaxis. Various figures for reaction rates are given, but a report of experience in El Paso is illustrative (Ref. 22). Among 526 patients, the overall occurrence of serum sickness was 16.3 percent, ranging with age from 12.3 percent in the 0 to 5 age group to 46.3 percent above age 15. Disturbingly, patients treated from September 1959 to January 1964 had less frequent reaction problems (10 percent of 351) than did those treated between February and September 1964 (29 percent of 175). This may reflect a dosage effect.

An obvious approach to this problem is to employ homologous (human) antiserum. An early study suggested that production of HRIG is feasible, that it is as protective in animals (three species) as that of equine origin, and that, at least in dogs, homologous antiserum is more effective than heterologous antiserum (which would be eliminated more rapidly) (Ref. 23). In clinical trials in man, Cabasso and colleagues (Refs. 24 and 25) reported that the half-life of HRIG is twice that of equine immune globulin and that a dose of 20 IU does not suppress active response to DEV (16 dose course, 14 daily plus an additional dose on days 24 and 34). Rubin et al. (Ref. 26) confirmed the longer persistence of antibody in patients receiving HRIG but emphasized the need to preclude suppression of an active immune response to the vaccine. More recently, Hattwick et al. (Ref. 27) reported that HRIG in doses of 15 or 40 IU interferred with the response to 16 doses of DEV but not to that in a 23 dose course. This last study provides the basis on which recommendations for the use of HRIG were developed. Currently, this product has largely replaced equine rabies immune globulin. A very recent study describes the treatment of 45 persons in Iran, bitten by rabid dogs and wolves, with a new human vaccine produced in diploid cells; the vaccine given in conjunction with HRIG, protected all of the treated, exposed subjects (Ref. 28).

d. *Vaccinia.* See the specific product review.

e. *Varicella-Zoster*—(1) *ISG.* There are no varicella antibody potency standards for ISG. Of the several studies that have been conducted, only that of Ross (Ref. 29) is noteworthy. He studied the course of chickenpox in 773 children in 318 families. ISG in doses of 0.1 ml to 0.6 ml/lb of body weight was administered to 242 children. He concluded that increasing dosage of ISG given within 3 days of exposure produces an increasing diminution of clinical symptoms but no preventive effect was noted.

Rodarte and Williams (Ref. 30) reported that ISG modified and relieved the symptoms in 11 patients suffering from herpes zoster and 5 children with chickenpox.

Trimble (Ref. 31) reported that two interns who received 0.1 ml of ISG per pound of body weight one week before onset of clinical symptoms experienced unusually mild illness. Two other interns with chickenpox did not receive ISG; one died and one had severe symptoms.

Greenberg (Ref. 32) reported that the administration of 5 ml of gamma globulin to 12 of 29 exposed infants did not alter the attack rate.

(2) *Varicella-Zoster Immune Globulin (ZIG).* Evidence for the effectiveness of ZIG is cited in a paper by Judelsohn (Ref. 33).

In 1969 it was shown that ZIG, a gamma globulin fraction of high-titered (1:128 or greater) plasma from convalescing herpes zoster patients, prevented clinical and laboratory evidence of varicella in susceptible children when given within 72 hours of household exposure. Further studies have shown its prophylactic efficacy in high-risk children.

Although ZIG is not a licensed product, the above evidence led Judelsohn (with ACIP assent) to develop the guidelines for the use of ZIG under an IND as stated in section B, ACIP recommendations.

f. *Mumps.* The following is a summary (which includes several papers cited specifically by one manufacturer) of the pertinent literature concerning the efficacy of mumps convalescent serum and mumps immune globulin. The literature falls into two categories: (1)

prevention of mumps in exposed individuals, and (2) treatment of patients with clinical mumps to prevent orchitis.

(1) *Prevention of clinical mumps.* Hess (Ref. 34) administered intramuscularly several ml of whole blood from fresh mumps cases to children exposed to mumps, and reported success in prevention of the disease. This paper, lost for many years and then rediscovered, is not now relevant, however, since the product administered was not gamma globulin and the controls were poorly chosen.

In a trial by Regan, (Ref. 35) convalescent serum obtained from adult patients 10 to 20 days after onset was given, subcutaneously, in 3-ml doses to 81 children in six settings; only 1 child developed mumps. Because susceptibility to infection was based only on history, this study is difficult to evaluate, and its apparently good results are not in accord with subsequent experience.

Zeligs (Ref. 36) used 5 ml intramuscular doses of pooled serum from 6 boys just recovered from mumps; of 44 subjects (susceptibility determined by history) exposed 7 days before treatment none developed clinical mumps.

The report of Lewis and Barenberg (Ref. 37) contains no useful data concerning mumps.

Thalhimer (Ref. 38) gave 20 ml of convalescent serum to children and 40 ml to adults, respectively. The serum was administered by physicians to private patients and their observations were recorded in retrospect. The uncontrolled data do not justify the claim that the treatment prevented mumps nor (in another group) to have reduced the severity of orchitis.

Kutscher (Ref. 39) gave 8 to 10 ml of convalescent serum to 51 "susceptible" and exposed boys. Since only one developed clinical illness, he concluded that the serum was "therefore 98.04 percent protective." Again, the uncertain susceptibility of the subjects coupled with lack of controls does not justify the conclusion.

Reed et al. (Ref. 40) gave mumps immune globulin prophylaxis to 56 exposed seronegative individuals during an epidemic of mumps on St. George Island in the Pribilofs; 46 percent of this group developed clinical mumps within 2 to 25 days, an attack rate similar to that among untreated susceptibles in the same population. Moreover, the incidence of orchitis was the same whether or not gamma globulin was given.

Conclusions. The only test of mumps immune globulin for postexposure prophylaxis, in which laboratory determined preexposure susceptibility was known, gave no evidence of a protective effect.

(2) *Treatment of mumps patients.* DeLavergne and Florentin (Ref. 41) took blood from one case of uncomplicated mumps and one case of mumps orchitis and gave 10, 15, or 20 ml subcutaneously.

Of 107 patients not treated, 25 developed orchitis and 9 meningitis. Of 113 patients treated, 5 developed orchitis and 2 meningitis.

Iversen (Ref. 42) studied military patients to whom pooled serum, obtained from other patients 10 to 20 days post-onset of mumps, was given intramuscularly in 40 ml doses. Of 76 cases treated, 21 (27 percent) developed orchitis. Since about 30 percent of untreated patients also developed orchitis, it was concluded that convalescent serum had no effect.

Bailey and Haerem (Ref. 43) summarized all available data and concluded that the results concerning prevention of orchitis were "uncertain." They observed a group of 734 men, ages 18 to 35 with mumps, and established a rate of 19 to 21 percent orchitis. They treated 183 cases with sera (not pooled) collected from patients 3 weeks after onset of mumps, using 10 or 20 ml doses intramuscularly within the first 3 days of parotitis. They observed orchitis rates of 13 percent with the 10 ml dose, and 22 percent with the 20 ml dose but only 4 percent in patients given serum from donors who had orchitis. They concluded that there was no effect, although the last finding was of interest.

Candel et al. (Ref. 44) did an excellent study of the natural history of mumps and mumps orchitis in young adult males. They studied 105 cases of mumps, of whom 75 were controls and 30 were treated on admission with 100 ml of pooled plasma; no difference was noted in the incidence of orchitis between the two groups.

Gellis et al. (Ref. 45) compared the efficacy of gamma globulin prepared from convalescent donors with that from normal donors (Table 39). These products were given alternately in 20 ml doses intramuscularly to patients admitted within 24 hours onset of parotitis; each treated patient, was matched with an untreated control patient.

They concluded that gamma globulin from patients 1 to 3 months convalescent from mumps was effective but that normal ISG was ineffectual.

Reed et al. (Ref. 40) noted that mumps immune gamma globulin (prepared in the same manner as the present product) had no effect on incidence or severity of orchitis. However, these investigators were referring to cases of mumps which developed despite the preexposure use of mumps immune globulin. It would be surprising if the product, having failed to prevent the primary disease, would prevent complications.

Table 39

Gamma globulin prepared from	Group	Number observed	Incidence of orchitis (percent)
Convalescent serum	Treated	51	7.8
	Controls	51	27.4
Normal serum	Treated	67	20.9
	Controls	67	26.8

Conclusions. With one exception (the best designed study, Ref. 45), these studies suggest that convalescent serum or normal gamma globulin exert no obvious effect on the incidence of orchitis. In view of the availability of live attenuated mumps virus vaccine, the need for mumps immune globulin should be small, since the populations that would ordinarily be most at risk (military and institutional) can readily be immunized. With respect to parotitis, however, the Gellis study (Ref. 45) suggests that in postpubertal males early use (within 24 hours) of mumps immune globulin may be of some benefit. If the results of this study can be confirmed using a product, prepared by current techniques, this limited but significant need might justify licensure.

g. *Rubella.* ISG not recommended.

h. *Poliomyelitis.* ISG not recommended.

i. *Immunoglobulin deficiency syndromes.* One investigator concludes from a study of 200 agammaglobulinemic and hypogammaglobulinemic children that a monthly maintenance dose (2 ml to 10 ml depending on weight and age and severity of illness) is indicated. He reports that over a period of 1,057 patient-months prior to ISG therapy, 31 patients were hospitalized; with initiation of ISG therapy, one hospitalization occurred from among these same patients in 723 patient-months.

A British study of 176 patients with hypogammaglobulinemia showed that although the death rate was not reduced in the group in general, the incidence of infections was reduced in children under the age of 10 years (Refs. 46 and 47).

Premature infants with gamma globulin deficiency who were treated with immune serum globulin had a lower incidence of staphylococcal infections than did a similar group of untreated infants (Ref. 48).

In an investigation of hypogammaglobulinemia and its relationship to the allergic diathesis,

Goldfarb and Fudenberg (Ref. 49) studied 26 agammaglobulinemic to hypogammaglobulinemic patients. Six of these were congenitally agammaglobulinemic with serum gamma globulin levels of 6 to 100 mg/100 ml. The remainder was classified as hypogammaglobulinemic with gamma globulin levels of 100 to 400 mg/100 ml. The normal range was listed at 800 to 1,200 mg/100 ml. Most of the patients were treated with an empirically determined dose of 10 ml intramuscularly of pooled gamma globulin (provided by the American Red Cross) once a month. Very young children received the same dose. While gamma globulin treatment did not appear to relieve allergic symptoms, 15 of 16 patients treated for 6 months or more showed a decrease in the number of clinically overt infections.

Gordon and Spencer (Ref. 50) also studied hypogammaglobulinemic children who were allergic and suffered from repeated infections. Sixteen of the 17 patients were from families with histories of allergy. These patients responded well to therapy of 2.0 to 4.0 ml of 16.5 percent gamma globulin solution every 4 weeks. All had an acquired hypogammaglobulinemia (five were females), possessed normal isohemagglutinins, and were able to respond to antigenic stimulation.

Conclusions. The foregoing studies, some of which were not well controlled, are consistent in this indication that use of ISG in gamma globulin deficient patients helps to prevent many clinical infections. In all instances, the subjects studied had been shown by laboratory tests to be deficient in serum gamma globulin.

J. *Allergic conditions—"Infectious Asthma."* Brown et al. (Ref. 51) reported that 23 of 29 asthmatic children treated with ISG responded favorably.

Hilman et al. (Ref. 52) concluded from a controlled study of 50 allergic children that there was no significant difference in the effects of ISG over those of placebo in the management of children with allergy.

Redner and Markow (Ref. 53) found in a study of 40 allergic children that minute doses of ISG of placental origin were effective in the control and prevention of various types of allergic manifestations. Harner and Knerr (Ref. 54) reported inconclusive results from a study of 42 asthamatic children at an Army base. Injection of placental ISG reduced asthmatic episodes by 72 percent from the preceding year. However, saline solution and ISG both were equally effective in diminishing wheezing during or after colds.

Conclusion. The above evidence seems inadequate to support the use of ISG for the treatment of patients with allergies and/or asthma.

2. *Safety.* The administration of ISG is not without some risk. Intravenous administration of the only products currently available in the United States is contraindicated, since it can result in serious systemic reactions. One product (pepsin treated ISG) is licensed for intravenous use, but in some 7 years has never been put on the market, possibly because the half-life of the ISG conferred antibodies in the recipients is very short (mean of 4.5 days, range of 10 hours to 8.5 days), although the titers of specific antibody are claimed not to be affected by the pepsin treatment.

Intramuscular administration of the ISG products available is frequently associated with pain and tenderness at the site of injection, and systemic reactions such as fever, diarrhea, and rashes have been reported. Repeated administration can result in sensitization to heterologous IgG genetic determinants and to thimerosal, a preservative present in all ISG preparations. A variety of allergic manifestations has been reported, the most serious being anaphylactic shock. Although the rate of serious complication is stated in one study (Ref. 4) to be as high as 0.66 percent, most investigators have found that ISG is remarkably nontoxic. Over a 25-year period, some 20 to 25 million doses have been distributed. There are few contraindications.

3. *Benefit/risk.* There is no question that ISG and specific immune serum globulins, although probably over-utilized can be of significant benefit in the prophylaxis and/or attenuation of viral diseases. Generally, it seems most practical to utilize ISG to modify only those diseases not amenable to other methods of specific treatment, e.g., hepatitis A. For passive protection, the use of specific immune serum globulin is to be encouraged, albeit for rather limited distribution. In the following outline, benefit/risk ratios have been considered for specific uses of ISG and certain specific immune serum globulin products.

a. *Hepatitis.* (1) *Hepatitis A.* The benefit of ISG has been clearly established for prophylaxis against hepatitis A, and the risk is negligible; hence, the benefit-risk ratio is highly favorable.

(2) *Hepatitis B.* Recent studies, referred to above, point to a proable prophylatic efficacy of HBIG, and possibly also of ISG. In view of the small risk, the benefit-risk ratio for both products must be viewed as favorable (more so for HBIG).

b. *Measles.* For postexposure prophylaxis against measles, the benefit of both ISG and measles specific immune serum globulins has been well established, and the benefit-risk ratio for these products is highly favorable.

While measles specific immune serum globulin was a safe and desirable adjunct to active immunization with Edmonston B virus vaccines, replacement of these vaccines by more attenuated strains of measles virus makes and the combined administration of specific immune serum globulin and vaccine undesirable for two reasons: (a) an extra inoculation is required, and (b) an active unusual response to the vaccine may be suppressed.

c. *Rabies.* (1) *Equine rabies immune globulin.* For rabies antiserum (equine rabies immune globulin), the benefit-risk ratio, as with rabies vaccine, varies with the likelihood of development of actual rabies. The risk of major reactions to equine immune globulin is so high that its use is warranted only when there only when there is a strong likelihood of rabies supervening after exposure. However, there is considerable reason (both theoretical and experimental) to regard its use in conjunction with vaccine as a more effective regimen than vaccination alone, at least when the golbulin is administered within 24 hours of infection. Thus, if HRIG is not available and the probability of rabies exposure great, the benefit-risk ratio must be considered as favorable.

(2) *Human rabies immune globulin.* The risk attending use of HRIG is, as it is for ISG, negligible. Its use in recommended dosage, coupled with an appropriately prolonged course of vaccine to insure active antibody response, should afford the same benefit as does equine rabies immune globulin. Hence, the benefit/risk ratio is highly favorable.

d. *Vaccinia.* See specific product review for VIG.

e. *Varicella.* Zoster immune globulin is not a licensed product. There is no good evidence that ISG will prevent varicella in exposed susceptible individuals, and it is only suggestive that it may exert a favorable modifying effect on the disease. This possible benefit provides at best a weakly favorable benefit-risk ratio; however, any importance it has is diminished by the fact that modification of disease is important chiefly in the case of high risk persons (for whom the much more effective ZIG is available under an IND).

f. *Mumps.* With no evidence for beneficial effect in either prevention of mumps or of mumps orchitis, the

benefit/risk ratio for use of ISG for these purposes is essentially nil. For mumps immune globulin, see the specific product review.

g. *Rubella.* Although in some cases ISG used prophylactically has been shown to prevent clinical rubella, it cannot be relied upon to prevent infection. Since the most important potential use of ISG in relation to rubella is to prevent rubella infection in exposed pregnant women, the uncertainty of such a result is a major factor in judging the benfit-risk ratio for ISG so used to be unfavorable.

h. *Poliomyelitis.* Prophylactic use of ISG to prevent poliomyelitis has been fully discredited. Hence, for such use, the benefit-risk ratio unfavorable.

i. *Immune globulin deficiencies.* The evidence that continued treatment of patients deficient in gamma globulin with ISG affords relative protection against common infections appears to outweigh the discomfort of the repeated injections and the risk of the rare reactions associated with such use. Hence, for this purpose the benefit-risk ratio is judged to be favorable.

j. *Allergic conditions and "infectious asthma."* With no convincing evidence of efficacy, use of ISG to treat patients with allergies, or who are subject to attacks of "infectious asthma," entails only risk and no benefit and the ratio obviously is adverse.

Critique

The major problem unique to immune serum globulin of nonhuman origin (for example, equine rabies immune globulin) is the frequent induction of serum sickness. To the extent that HRIG is available for the same use, this problem is overcome. Information at this time (September 1976) is that HRIG is fully available. Additional problems are shared by all preparations of fractionated gamma globulin available in the United States. When given intramuscularly (as they should be), they cause pain and persisting local tenderness, the degree increasing with the dose. Also, when given repeatedly, as in the treatment of patients deficient in gamma globulin, sensitization to the common preservative, thimerosal, and even to heterologous IgC genetic determinants may occur. Finally, serious systemic reactions can result if the product, by accident or intent, is administered intravenously. This precludes use of a potentially useful route of administration. As noted previously, the one ISG product licensed for intravenous use has never been marketed in this country.

The beneficial effects of these products depends on the antibodies present (chiefly IgG). Human ISG products are derived from pools of plasma obtained from donors selected for high specific serum antibody titers, either naturally acquired or stimulated (e.g., rabies and mumps) by specific hyperimmunization. Except for measles immune globulin, minimum specfic antibody titers have not been established. ISG is usually produced from large plasma pools (each lot from some 1,000 donors) on the presumption that antibodies to commonly prevalent agents will be present. However, the only assays required are for measles, poliovirus, and diptheria antibodies. To the extent that ISG is used to combat specific viral infections, e.g., hepatitis A and B, rubella, or varicella, knowledge of specific antibody titers for individual lots of ISG would be desirable and could prove valuable in future efforts to evaluate ISG efficacy for such applications as prophylaxis of rubella, varicella, and even hepatitis A.

Recommendations

1. *Product improvement.* The main efforts here should be to determine the necessity for thimerosal as a preservative and, more importantly, to explore further ways to render the gamma globulin product (a) safe for intravenous administration and (b) more stable.

2. *PHS regulations.* These should be expanded to include standards for acceptable composition of each lot in terms of quantity of IgG and relative content of other immune globulins and of adventitious serum proteins. Also, within the limits of applicable technology, lots of ISG should be characterized with respect to important specific antibody titers. At the present time, in view of ACIP recommendations, information concerning antibody levels to measles and hepatitis A is most pertinent. Labeling should include these titers and, with respect to indications for use, should conform to ACIP recommendations. The regulations also should cover ISG, in particular by establishing potency standards which should be reviewed periodically.

3. *Licensure.* The Panel recommends that immune serum globulins licensed for intramuscular use be placed in Category I, and that for ISG, licenses should be continued for specified uses, which currently should include prophylaxis of measles and hepatitis A and the continuing treatment of patients with gamma globulin deficiencies. Usage should be reviewed periodically in conjunction with ACIP which, thus far, has not addressed the full range of possible uses of ISG.

The question of licensure of ISG products for specific viruses is dealt with in the specific product reviews.

Review of Specific Immune Serum Globulin and Specific Human and Equine Immune Serum Globulin Products

Manufacturers who submitted data for currently licensed ISG products are listed below. With one exception, all of these are licensed only for intramuscular use. For these, the preceding generic statements are believed to constitute and adequate review. These ISG products for intramuscular use should all be placed in Category I as safe and effective for approximately indicated purposes.

Abbott Laboratories
Armour Pharmaceutical Co.
Division of Biologic Products, Bureau of Laboratories, Michigan Department of Public Health
Cutter Laboratories, Inc.
Dow Chemical Co.
E. R. Squibb & Sons, Inc.
Lederle Laboratories Division, American Cyanamid Co.
Massachusetts Public Health Biologic Laboratories
Merck Sharp & Dohme, Division of Merck & Co., Inc.
Osterreichisches Institut fur Haemoderivate G.m.b.H.
Parke, Davis & Co.
Travenol Laboratories, Inc., Hyland Division
Wyeth Laboratories, Inc.

Immune Globulin (Human) pepsin-modified "Gammagee-V" produced by Merck Sharp & Dohme, Division of Merck & Co., Inc., and licensed for intravenous use, should be placed in Category IIIA in view of the inadequacy of information concerning its efficacy. The Panel considers that availability of a product of this type is highly desirable and would encourage the manufacturers to develop more extensive data on efficacy.

Immune Serum Globulin (Human) Manufactured by North American Biologicals, Inc.

No data have been provided by the manufacturer for Immune Serum Globulin (Human) for which they were licensed at the time of this review. In the absence of any information from the manufacturer, the Panel can make no determination regarding the relative benefits and risks of this product.

Recommendations. The Panel recommends that this product be placed in Category IIIB and that the appropriate license be revoked pending submission of evidence regarding the safety and effectiveness of this product.

Antirabies Serum Manufactured by Instituto Sieroterapico Vaccinogeno Toscano SCLAVO

1. *Description.* Antirabies serum 'Sclavo' is a sterile aqueous solution of refined and concentrated globulin obtained from the blood of horses immunized against rabies virus.

Preserved with 0.3 percent m-Cresol. Each ml contains 500 units.

The submission described in adequate detail the various phases of production and testing including: production of rabies vaccine to immunize horses (CNS tissue from rabbits infected with CV 12 rabies virus); the regimens for immunizing horses (repeated subcutaneous doses of vaccine until desired neutralizing antibody titer achieved); collection and processing of plasma (ammonium sulfate precipitation of globulin fraction with standard methods of filtration and dialysis); and basic tests for safety and potency in animals.

a. *Recommended use.* For the prevention of hydrophobia in humans the use of antirabies serum in combination with vaccine is considered the best post-exposure prophylaxis. However, because serum of animal may induce serum sickness or acute anaphylactic reactions, it should be used only when indicated.

Antirabies serum is recommended for most exposures classified as severe and for all bites by rabid animals and unprovoked bites by wild carnivores and bats (see chart).

When indicated, antirabies serum should be used regardless of the interval between exposure and treatment.

Of the recommended dose (1,000 units per 40 lb of body weight), "a portion * * * should be used to infiltrate the wound, and the rest administered intramuscularly."

b. *Contraindications.* No contraindication is given as such. Under the heading of "Side Effects/ Precautions" the statement is made that Patients giving a history of allergic symptoms and/or of previous injections of horse serum may be dangerously sensitive and should receive antirabies serum with the utmost caution. Skin and eye tests for sensitivity (both procedures described in detail) are recommended regardless of patient history.

Labeling. In addition to the above material, the labeling and package insert contain a well-presented discussion of sources and types of exposure, the management of biting animals, and the then current ACIP recommendation.

2. *Analysis.* a. *Efficacy.* See generic discussion. Comments made in the generic review concerning the efficacy of equine antirabies sera apply to this product.

b. *Safety.*

(1) *Animal.* This product meets Federal requirements.

(2) *Human.* See generic discussion. Comments made in the generic review concerning the safety of equine antirabies sera apply to this product.

c. *Benefit/risk ratio.* See generic discussion. Comments made in the generic review concerning the benefit/ risk of equine antirabies sera apply to this product.

d. *Labeling.* The label and package insert are reasonable in general, but specific changes should be made. Under "Manufacturer's indications" the statement that serum therapy should be instituted "regardless of the interval between exposure and treatment" is unsubstantiated by any existing data. In view of the lack of data and the inherent serum sickness hazard of this product, the statement is unwarranted and should not appear.

A further fault with the package insert is the failure to cite any contraindications. The statement concerning persons with an allergic history is weak, particularly in view of the present availability of HRIG.

3. *Conclusions.* a. *Critique.* This product has all the limitations of horse serum for use in humans, and as noted in the generic review carries a high risk of serum sickness and other reactions. Its use also complicates the efficacy of rabies vaccine, a point less well discussed in the package insert than might be. Its use is likely to diminish as human rabies immune globulin becomes available; but limited supply of the latter makes it likely that there will be continued need for a supply of equine antiserum for some time to come. Where human rabies immune globulin is not available, the potential benefits of this product, i.e., decreased risk of rabies, clearly outweigh the product's disadvantages.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that licensure be continued at least until adequate availability of preferred human rabies immune globulin is assured. Even when such assurance has been realized for this country (as is now reported to be the case), there presumably will be a need for antirabies serum elsewhere in the world. The package insert should be revised in accordance with the Panel's recommendations.

Antirabies Serum (Equine Origin) Manufactured by Lederle Laboratories Division, American Cyanamid Co.

1. *Description.* Antirabies serum (ARS), a "refined and concentrated" antiserum obtained from hyperimmunized (with fixed rabies virus) horses, contains phenol (0.4 percent) and phenylmercuric borate (1:20,000) as preservatives. Under this heading, the mode of action is described as "delays virus propagation, thus allowing more time for rabies vaccine to induce antibodies."

a. *Recommended use.* ARS is used as an adjunct in postexposure treatment; it should be given as promptly as possible after exposure. Use is indicated in all persons suspected of exposure, *irrespective of interval elapsed since exposure.* Types of possible exposure are described, as is range of incubation periods; emphasis is given to the import of ARS in cases of severe exposure associated usually with short incubation.

b. *Contraindications.* Positive intradermal or conjunctival test for sensitivity is a contraindication unless required as a life-saving measure.

c. *Diagnosis.* A detailed, very good account of diagnosis of rabies in biting animals is provided followed by, *in italics,* the admonition that initiation of treatment should never await results of laboratory diagnostic tests (but when negative, treatment may be terminated).

d. *Treatment.* Detailed instructions following ACIP and WHO recommendations, for management of suspected exposure, including use of ARS are provided. The equine origin of ARS is emphasized as is the necessity for careful history of allergies and a skin test. A procedure for desensitization is outlined for cases when ARS must be given to sensitive individuals. *Precautions* are carefully stated but also, under this heading, the possible occurrence of immediate anaphylactic reactions and of serum sickness is noted.

e. *Processing.* The basic manufacturing process is summarized. Horse blood is drawn into anticoagulant solution, treated, and globulins precipitated by ammonium sulfate. Subsequent steps include neutralization, addition of preservatives, dialysis, reprecipitation, separation in Sharples centrifuge, further clearing, and final concentration. The resulting clear fluid is sterile filtered and ready for quality control.

2. *Analysis.*

a. *Efficacy.* The submission includes abstracts of revelant literature and a

review (discussed in detail in the generic review).

b. *Safety.*

(1) *Animal.* This product meets Federal requirements.

(2) *Human.* For the finished biological product, the manufacturer stated that *no reactions were reported* (in terms of documented case reports) for the years 1969 to 1974 based on distribution of millions of units in that period.

c. *Benefit/risk ratio.* See generic discussion. The hazard of serum sickness necessarily weighs against ARS as the newly licensed HRIG (Human) becomes available.

d. *Labeling.* The label and package insert are reasonable in general but one specific change should be made. Under "Indications" the statement that serum should be administered to all persons suspected of exposure to rabies "irrespective of the interval between exposure and treatment" is unsubstantiated by any existing data. In view of the lack of data and the inherent serum-sickness hazard of this product, the statement is unwarranted and should not appear.

3. *Conclusions.*

a. *Critique.* The submission documents adequate procedures required to insure potency and freedom from undesired contaminants. It also includes abundant reproductions of published papers, many of which deal more with general management of suspected exposure than with ARS in particular.

b. *Recommendation.* The Panel recommends that this product be placed in Cateory I and that licensure be continued at least until adequate availability of preferred HRIG is assured. Even when such assurance has been realized for this country (as is now reported to be the case), there presumably will be a need for ARS elsewhere in the world. The package insert should be revised in accordance with the Panel's recommendations.

Measles Immune Globulin (Human) Manufactured by Lederle Laboratories Division, American Cyanamid Co.

No data have been provided by the manufacturer for Measles Immune Globulin (Human) for which they are presently licensed. In the absence of any information from the manufacturer, the Panel can make no determination regarding the relative benefits and risks of this product.

Recommendations. The Panel recommends that this product be placed in Category IIIB and that the appropriate license be revoked pending submission of evidence regarding the safety and effectiveness of this product.

Measles Immune Globulin (Human) Manufactured by Parke, Davis & Co.

No data have been provided by the manufacturer for Measles Immune Globulin (Human) for which they are presently licensed. In the absence of any information from the manufacturer, the Panel can make no determination regarding the relative benefits and risks of this product.

Recommendations. The Panel recommends that this product be placed in Category IIIB and that the appropriate license be revoked pending submission of evidence regarding the safety and effectiveness of this product.

Mumps Immune Globulin (Human)-Hyparotin (R) Manufactured by Cutter Laboratories, Inc.

1. *Description.* A solution of gamma globulin prepared from venous blood of humans hyperimmunized with mumps virus vaccine. [Note: package label says "live" but in fact killed mumps virus vaccine is used.] It contains 16.5 percent ± 1.5 percent gamma globulin dissolved in 0.3M glycine and preserved with 1:10,000 thimerosal. * * * Its mumps antibody content is approximately twenty times that of human mumps immune serum * * * [from sera nonreactive for hepatitis associated antigen] * * *. Hyparotin (R) supplies antibodies for the prevention of mumps.

a. *Recommended use.* Hyparotin (R) is indicated in the prophylaxis of mumps * * * should always be given by the intramuscular route and never intravenously * * *. The physician should make sure that his (sic) patient understands that no specific protective or therapeutic end result can be assured in any given case.

There are insufficient data on the relationship between antibody concentration and protective action in mumps to develop a dosage schedule on a firm scientific basis. Although the dosage schedule suggested below has been arrived at empirically, it appears to be effective in some instances in preventing serious sequelae of mumps in older children and adults * * *.

For prophylaxis in children under age 12, 1.5 ml is recommended; for individuals age 12 and older, the dose is 3 to 4.5 ml. For treatment: "Such treatment can be expected to have little or no therapeutic effect * * * it may, if used as heroic doses, prevent complications such as orchitis * * * [at] not less than five times the minimum prophylactic dose and preferably more.

Precautions. Skin tests should not be done. In most human beings the intradermal injection of concentrated gamma globulin cause (sic) a localized area of inflammation which can be misinterpreted as a positive allergic reaction. In actuality, this does not represent an allergy; rather, it is localized tissue irritation of a chemical nature. Misinterpretation of the results of such tests can lead the physician to withhold badly needed human antitoxin from a patient who is not actually allergic to this material. True allergic responses to human gamma globulin given in the prescribed intramuscular manner are extremely rare.

b. *Contraindications.* Individuals known to have an allergic response to gamma globulin.

2. *Analysis.* See generic statement.

a. *Benefit/risk ratio.* The risk associated with the use of gamma globulin intramuscularly is very small. However, since there is no evidence for benefit when used to prevent mumps, the ratio for this purpose must be considered as unfavorable. When used to treat mumps to prevent orchitis, however, some beneficial effect of an analogous product has been reported. If this can be confirmed for this specific product, a favorable ratio would result.

b. *Labeling.* The Advisory Committee on Immunization Practices recommendations do not include the use of mumps immune globulin in any circumstance and therefore cannot be cited. The label is erroneous regarding live vaccine for immunization. The package insert is quoted above.

3. *Conclusions.* a. *Critique.* As discussed in the generic review, the need for mumps immune globulin is limited but significant. The available data, including the excellent study on St. George Island, provide no evidence for its efficacy in prevention of mumps. Most studies directed at treatment of mumps to prevent orchitis employed convalescent serum and yielded negative results. The well-designed study, conducted in 1945, did show a significantly reduced incidence of orchitis, but this required a very large dose (20 ml) of an experimental preparation derived from mumps convalescent serum.

b. *Recommendation.* The Panel recommends that this product be placed in Category II and that the appropriate license be revoked because there are compelling reasons to assume a lack of effectiveness and an unsatisfactory benefit/risk ratio for this product.

Mumps Immune Globulin (Human) Manufactured by Travenol Laboratories, Inc., Hyland Division

1. *Description.* No labels for distribution in final dosage form have been used since 1971. The sole product

is for bulk distribution and is described as follows:

Cohn Fraction II. Derived from plasma found nonreactive for hepatitis associated (Australia) antigen by counterelectrophoresis. For manufacturing use only. For export only. Not sterile. Not tested for potency, sterility, pyrogen or stability. Must be sterilized by filtration within 24 hours after dissovling. Suitability of final preparation for human use is responsibility of final processor.

Contains no stabilizer or preservative.

Protein is at least 95 percent gamma globulin by electrophoresis.

The manufacturer no longer markets the product directly, and thus cites no specific indications or contraindications.

2. *Analysis.* See generic statement.

3. *Conclusions.*

a. *Critique.* The comments pertinent in the generic review remain pertinent here. There is perhaps an issue about export, but in view of the total lack of evidence of efficacy in controlled circumstances it is not compelling. No labeling was provided.

b. *Recommendation.* The Panel recommends that this product be placed in Category II and that appropriate license(s) be revoked because there are compelling reasons (namely, complete lack of information concerning this product) to assume a lack of safety or effectiveness and an unsatisfactory benefit-risk ratio for this product.

Vaccinia Immune Globulin (Human) Manufactured by Travenol Laboratories, Inc., Hyland Division

1. *Description.* The following is the description given on the package insert:

Hyland Vaccinia Immune Globulin (Human) is a 16.5 (±1.5) percent solution of the gamma globulin fraction of the serum of healthy adults who have been recently immunized with vaccinia virus. The solution has been made isotonic and stabilized with 0.3 molar glycine. It contains 0.1 percent sodium chloride and 0.01 percent thimerosal as a preservative. The antibody content, as determined by tissue culture virus neutralization tests, complies with the United States potency requirements for the product and is approximately equal to that of the World Health Organization's International Standard for Anti-Smallpox Serum. Hyland Vaccinia Immune Globulin (Human) is similar to investigational-use preparations which have been available through the American National Red Cross.

A somewhat more detailed list of the ingredients is as follows:

Cohn Fraction II (gamma globulin) from vaccinia immune Source Plasma (Human)	16.5 ±1.5g
Glycine (stabilizer) (0.3 molar)	2.25g.
Sodium chloride (viscosity-reducing agent)	0.1g.
Thimerosal (preservative)	0.01g.
Water for injection	q.s to 100 ml.

Bulk powder, nonsterile, for export is also described in the manufacturer's submission. Instructions include proper directions for sterilization and a waiver of responsiblity for the final product by Hyland.

Potency of the final product is tested as follows:

Suitable dilutions of the reference and the lot under test are mixed with a constant amount of vaccinia virus, added to a human cell tissue culture system, and observed for their ability to reduce plaque formation caused by the virus alone. From the dilutions of reference and lot under test which produce a 50 percent reduction of plaques, the ratio of the respective potencies is calculated.

The test procedure is an adaption of tests described in the published literature. The detailed protocol for the test is on file with the Bureau of Biologics. Review of the protocol indicates that this is an adequate potency test.

a. *Recommended use:* (1) Prevention or modification of smallpox. It should be used in conjunction with smallpox vaccination or revaccination.

(2) Prevention or modification of the complications of smallpox vaccinations. VIG may be used prophylactically in vaccination, when necessary, of eczematous children or adults, individuals with virus, individuals with other extensive skin lesions, pregnant women, and those at particular risk of encephalitis.

(3) Prophylaxis in vaccination contacts with eczema or other extensive skin disease, immune deficiency diseases, etc.

(4) Treatment of complications of smallpox vaccination, eczema vaccination, vaccinia necrosum generalized vaccinia, accidental infections of the eye, mouth, etc., and vaccinia infection of burns, impetigo, etc.

Recommended dosage is 0.3 ml/kg for prophylaxis and 0.6 ml/kg or more for treatment. Route is intramuscularly, with warnings against intravenous use.

The recommendations of ACIP are not sufficiently detailed for a package insert, and are as follows:

Prophylactic use. Dose. 0.3 ml/kg by the intramuscular route.

Therapeutic use. Dose and indications. 0.6 ml/kg by the intramuscular route. For eczema vaccinatum, progressive vaccinia, or autoinoculation vaccinia of the eye, VIG may be effective. For severe cases of generalized vaccinia, VIG may be helpful in treatment; but such cases almost invariably have a favorable outcome anyway, provided the primary vaccination site heals. For mild cases of generalized vaccinia or autoinoculation not involving the eye, VIG is generally considered unnecessary. For post vaccinial encephalitis, VIG is of no proved therapeutic value.

b. *Contraindications.* Administration of VIG in the presence of active keratitis has resulted in increased scarring in rabbits. Since it is presumed that a similar response might occur in humans, VIG should not be used in the treatment of keratitis caused by vaccinia virus.

2. *Analysis.*

a. *Efficacy.* (1) *Animal.* None available.

(2) *Human.* Most of the published studies of the value of VIG have used products produced by manufacturers other than Hyland. Nevertheless, it is important to review these since they probably would apply equally well to the material under consideration.

(i) *Prophylaxis of smallpox.* The evidence that VIG is effective, in conjunction with vaccination, in preventing smallpox is good but stems from only a few studies. In one study (Ref. 55) of 75 control (vaccination alone) contacts of smallpox cases, 8 developed smallpox and 3 died. Of 56 VIG (vaccination plus vaccinia immune globulin) contacts, 2 developed smallpox and 1 died. In a larger study (Ref. 56) the figures were as follows: of 379 control contacts (vaccination alone) 21 developed smallpox within 14 days; of 326 VIG treated contacts (VIG plus vaccination), 5 developed smallpox within 14 days. The two groups in this study were well matched in every important respect. The calculated combined reduction of smallpox cases achieved by the addition of VIG to prophylaxis was 70 percent.

One other published study (Ref. 57) provided anecdotal data on the mild illness in two individuals given VIG and vaccine several days after exposure.

(ii) *Prophylaxis of the complications of smallpox vaccination.* Evidence for a prophylactic effect in the prevention of eczema vaccinatum is less clear-cut but is provisionally accepted. This complication occurs infrequently after deliberate vaccination of eczematous individuals, even when prophylaxis is not administered. Kempe estimates that only 1 out of 200 vaccinated eczematous children gets eczema vaccinatum. In the report of Sharp and Fletcher (Ref. 58), one case of mild eczema vaccinatum developed among 290 eczematous persons given VIG prophylactically. Another failure of prophylactic VIG is reported by Sussman and Grossman (Ref. 59). Nevertheless, there is a general impression that such prophylaxis is effective (Ref. 60).

There is no evidence that VIG prevents the complications of smallpox vaccination in immune deficiency states, immunosuppression, pregnancy, or skin diseases other than eczema. It is nevertheless recommended in situations where vaccination is imperative.

Prophylaxis in the prevention of encephalitis is illustrated best in the report of Nanning (Ref. 61). Antivaccinia gamma globulin (AGG) was administered in a dose of 2 ml to 53,630 Dutch recruits, aged 19 to 22, and a placebo was given to 53,044. Dutch recruits are thought to have an incidence of encephalitis of 1 in 4,000 primary vaccinations and 1 in 50,000 revaccinations. There were 13 cases of postvaccinial encephalitis in the controls and 3 in the prophylactically treated group. This difference was highly significant ($p < 0.001$).

(iii) *Treatment of the complications of vaccination.* The value of VIG in treatment of eczema vaccinatum must be inferred from uncontrolled reports by Kempe (Ref. 62), Sussman and Grossman (Ref. 59), and Sharp and Fletcher (Ref. 58). The mortality of eczema vaccinatum in children under 2 cared for with supportive therapy alone is quoted by Kempe as 30 to 40 percent. In his group given therapeutic VIG, the mortality was 7 percent (9 of 132). In Sussman and Grossman's group, mortality was 1 of 37, and in Sharp and Fletcher's cases, 2 of 47 died. In the last two reports, methisazone was occasionally used in conjuction with VIG in very ill cases. The overall mortality in these reports, then, is 11 of 216, or 5 percent. All three reports are quite emphatic about the temporal relationship between VIG treatment and clinical improvement in almost all cases.

Treatment of vaccinia necrosum is likewise uncontrolled. Some patients appear to respond and others clearly do not (Ref. 62). Again, its use is recommended.

Treatment of less severe complications of vaccination may also be effective. In the instance of generalized vaccinia, the evidence for efficacy is slim indeed, particularly since this diagnosis is often wrong because the rash is confused with various forms of allergic rash in response to vaccination. Patients with accidental inoculation in crucial areas such as the eye, finger, mouth, etc., appear to respond to VIG, but there are no well-controlled data.

b. *Safety.* (1) *Animal.* The product meets the standards of the "General Safety" tests specified in § 610.11 (21 CFR 610.11). Likewise it has passed sterility tests and tests for pyrogenicity in animals.

(2) *Human.* The data for this particular product are not available. However, there is no reason to believe that the human safety differs from that of other immune serum globulins produced by the same manufacturer.

c. *Labeling.* All labeling should conform to FDA's proposed regulations for labeling for prescription drugs used in man as reported in the **Federal Register** of April 7, 1975 (40 FR 15392) and to the updated recommendations of ACIP.

3. *Conclusions.* a. *Critique.* Vaccinia immune globulin as prepared by Hyland appears to be a useful product as long as smallpox continues to be present somewhere in the world. The evidence for efficacy is at times spotty, but the benefit/risk ratio remains high.

b. *Recommendations.* The Panel recommends that this product be placed in Category I and that the appropriate license(s) be continued because there is substantial evidence of safety and effectiveness for this product. The Panel has been informed that this product is no longer being produced and expresses the hope that this decision be reconsidered since there is a clear, albeit infrequent need.

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FDA Response to the Panel's Recommendations

The FDA is responding to the Panel's recommendations as follows:

1. The Panel recommended that Viral and Rickettsial Vaccines be grouped into regulatory categories as follows:

a. *Category I. Biological products determined to be safe and effective and not misbranded: [and may continue in interstate commerce]* Poliomyelitis Vaccine (Purified), Connaught Laboratories, Ltd., License No. 73; Poliovirus Vaccine, Live, Oral, Trivalent (Orimune), Poliovirus Vaccines, Live, Oral, Type 1, Type 2, and Type 3, (Monovalent) (Orimune), Lederle Laboratories Division, American Cyanamid Co., License No. 17, Poliovirus Vaccine, Live, Oral, Trivalent (Diplovax), Pfizer Ltd., License No. 338; Smallpox Vaccine (in three formulations: Glycerinated Vaccine; Dried Vaccine; Dried Vaccine for Jet Injection), Connaught Laboratories, Ltd., License No. 73; Smallpox Vaccine, Avianized, Lederle Laboratories Division, American Cyanamid Co., License No. 17; Smallpox Vaccine and Smallpox Vaccine Freeze-Dried, Merrell-National Laboratories, Division of Richardson-Merrell Inc., License No. 101; Smallpox Vaccine, Bureau of Laboratories, Michigan Department of Public Health, License No. 99; Smallpox Vaccine (Dryvax), Wyeth Laboratories, Inc., License No. 3; Measles Virus Vaccine, Live, Attenuated (Schwarz Strain), (Lirugen), Dow Chemical Company, License No. 110; Measles Virus Vaccine, Live, Attenuated (M-Vac), Lederle Laboratories Division, American Cyanamid Co., License No. 17; Measles Virus Vaccine, Live, Attentuated, (Attenuvax); Mumps Virus Vaccine, Live (Mumpsvax); Rubella Virus Vaccine, Live (Meruvax); Measles, Mumps, and Rubella Virus Vaccine, Live, M–M–R); Measles and Rubella Virus Vaccine, Live (M–R–Vax); Measles-Smallpox Vaccine, Live (Attenuvax-Smallpox); Rubella and Mumps Virus Vaccine, Live (Biavax), Merck Sharp & Dohme, Division of Merck & Co., Inc., License No. 2; Rubella Virus Vaccine, Live (Cendehill Strain) (Cendevax), Recherche et Industrie Therapeutiques, S.A., License No. 430; Influenza Virus Vaccine, Bivalent (Flu-Immune), Lederle Laboratories Division, American Cyanimid Co., License No. 17; Influenza Virus Vaccine, Bivalent (Zonomune), Eli Lilly and Company, License No. 56; Influenza Virus Vaccine, Bivalent (Fluax), Merck Sharp & Dohme, Division of Merck & Co., Inc., License No. 2; Influenza Virus Vaccine, Bivalent (Fluzone), Merrell-National Laboratories, Division of Richardson-Merrell Inc., License No. 101; Influenza Virus Vaccine, Bivalent (Fluegen), Parke, Davis and Co., License No. 1; Influenza Virus Vaccine, Bivalent (Chromatograph and Filter Purified Subvirion Antigen), Wyeth Laboratories, Inc., License No. 3; Rabies Vaccine, (Duck Embryo) Dried Killed Virus, Eli Lilly and Company, License No. 56; Yellow Fever Vaccine, Merrell-National

Laboratories, Division of Richardson-Merrell Inc., License No. 101; Immune Serum Globulin, Abbott Laboratories, License No. 43; Armour Pharmaceutical Company, License No. 149; Bureau of Laboratories, Michigan Department of Public Health, License No. 99; Cutter Laboratories, Inc., License No. 8; Dow Chemical Company, License No. 110; E. R. Squibb & Sons, Inc., License No. 52; Lederle Laboratories Division, American Cyanamid Co., License No. 17; Massachusetts Public Health Biologic Laboratories, License No. 64; Merck Sharp & Dohme, Division of Merck & Co., Inc., License No. 2; Osterreichisches Institut for Haemoderivate G.m.b.H., License No. 258; Parke, Davis and Co., License No. 1; Travenol Laboratories, Inc., Hyland Division, License No. 140; Wyeth Laboratories, Inc., License No. 3; Vaccinia Immune Globulin (Human), Travenol Laboratories, Inc., Hyland Division, License No. 140; Antirabies Serum, Instituto Sieroterapico Vaccinogeno Toscano Sclavo, License No. 238; Antirabies Serum (Equine Origin), Lederle Laboratories Division, American Cyanamid Co., License No. 17.

The FDA agrees with the Panel's findings and recommendations and hereby proposes to adopt its conclusions, including proposed labeling revisions concerning product use. Comments and/or additional data on this classification are invited. The following licenses for products in Category I were revoked at each manufacturer's request:

Product	License No.	Manufacturer	Date of revocation
Poliovirus Vaccine, Live, Oral, Trivalent.	338	Pfizer Ltd.	6/12/79
Smallpox Vaccine	101	Merrell-National Laboratories, Division of Richardson-Merrell Inc..	1/3/78
Smallpox Vaccine (Avianized).	17	Lederle Laboratories Division, American Cyanamid Co..	5/24/78
Measles Virus Vaccine, Live, Attenuated (Schwarz Strain), (Lirugen).	110	Dow Chemical Co..	6/21/78
Influenza Virus Vaccine, Bivalent (Zonomune).	56	Eli Lilly and Company.	7/11/77
Influenza Virus Vaccine.	101	Merrell-National Laboratories, Division of Richardson-Merrell Inc..	1/3/78
Yellow Fever Vaccine.	101	Merrell-National Laboratories, Division of Richardson-Merrell Inc..	1/3/78
Immune Serum Globulin.	110	Dow Chemical Company.	6/7/77
Immune Serum Globulin.	258	Osterreichisches Institut fur Haemoderivate G.m.b.H..	7/22/76
Immune Serum Globulin.	43	Abbott Laboratories.	8/15/78

Merrell-National Laboratories, Division of Richardson-Merrell Inc., transferred its manufacturing processes and facilities for manufacturing Smallpox Vaccine, Influenza Virus Vaccine, and Yellow Fever Vaccine, License No. 101, to Connaught Laboratories, Inc. Connaught was issued License No. 711 of January 3, 1978.

Abbott Laboratories transferred its manufacturing processes and facilities for manufacturing Immune Serum Globulin, License No. 43, to Alpha Therapeutic Corp. Alpha Therapeutic Corp. was issued License No. 744 on August 15, 1978.

b. *Category II. Biological products determined to be unsafe or ineffective or to be misbranded and which should not continue in interstate commerce:* Mumps Immune Globulin (Human)—(Hyparotin), Cutter Laboratories, Inc., License No. 8; Mumps Immune Globulin (Human), Travenol Laboratories, Inc., Hyland Division, License No. 140; Mumps Virus Vaccine (Inactivated), Eli Lilly and Company, License No. 56; Mumps Vaccine (Killed), Lederle Laboratories Division, American Cyanamid Co., License No. 17; Adenovirus Vaccine, Parke, Davis and Co., License No. 1; Adenovirus and Influenza Virus Vaccine, Combined, Parke, Davis and Co., License No. 1.

The FDA agrees with the Panel's findings and recommendations concerning these drugs and, in accordance with §§ 601.5 and 601.25(f)(2), FDA intends to publish a notice of an opportunity for a hearing (NOH) to revoke the licenses for these products. Interested persons may comment and/or submit additional data in response to the notice. These revocation proceedings will not be necessary for (1) Mumps Virus Vaccine (Inactivated), the license for which was revoked on April 7, 1977, at the request of Eli Lilly and Company and (2) Mumps Vaccine (Killed), the license for which was revoked on May 24, 1978, at the request of Lederle Laboratories Division, American Cyanamid Company.

Following the publication of standards for inactivated Adenovirus Vaccine in 1957 (see **Federal Register** of September 24, 1957 (22 FR 7560)) several manufacturers were issued product licenses. In addition, two manufacturers received product licenses for Adenovirus and Influenza Virus Vaccine, Combined, Aluminum Phosphate Adsorbed, which is a combination of the Adenovirus Vaccine with another licensed biological product.

During the years subsequent to the issuance of these licenses, it became evident that there were certain persistent problems concerning the contamination of adenovirus with a newly discovered simian virus known as SV40. As a result, licensed manufacturers of these products were advised in October 1964 that no further lots of the inactivated Adenovirus Vaccine could be released until these problems were resolved.

Since 1964, there has been no evidence that these problems have been resolved. In the **Federal Register** of January 3, 1973 (38 FR 48), FDA announced its conclusion that (1) the vaccine cannot be manufactured in a manner that assures its safety, purity, and potency, (2) the additional standards for Adenovirus Vaccine (21 CFR 273.1040 through 273.1045, redesignated as 21 CFR 630.20 through 630.25) should be deleted from the biologics regulations, and (3) the licenses governing any adenovirus vaccines, either singly or in combination, should be revoked. That **Federal Register** announcement also provided a notice of opportunity for a hearing (NOH) to manufacturers of adenovirus vaccines on the Commissioner's intent to revoke all licenses remaining in effect. All manufacturers, except Parke, Davis and Co., requested that their product licenses be revoked. Parke Davis did not respond to the notice. Although no adenovirus vaccine has been released for sale since August of 1964, the Parke Davis product license for these vaccines has not been officially revoked.

The Panel reviewed (as part of their review of pre-1972 licensed products) information on file with the Bureau of Biologics and other information submitted directly to the Panel, including presentations by representatives of Parke, Davis and Co. in April 1974, in support of adenovirus vaccines. The Panel found this information to be inadequate to support the continued licensing and placed

adenovirus vaccines in Category II. Consistent with the procedures established for such products, a NOH covering the Parke Davis vaccines will be published as part of the implementation of the Panel's report. In addition to the lack of proven safety and effectiveness, the agency intends to base revocation, as authorized by § 601.5(b)(2), upon the fact that manufacture has discontinued to such an extent that a meaningful inspection cannot be made. Should the Parke Davis product license for adenovirus vaccines be revoked, a final order also will be published revoking the additional standards for Adenovirus Vaccine.

c. *Category IIIA. Biological products for which available data are insufficient to classify their safety and effectiveness but which may remain in interstate commerce pending completion of testing:* Rocky Mountain Spotted Fever Vaccine (RMSF), Lederle Laboratories Division, American Cyanamid Co., License No. 17; Typhus Vaccine, Lederle Laboratories Division, American Cyanamid Co., License No. 17; Eli Lilly and Company, License No. 56; Merck Sharp & Dohme, Division of Merck & CO., Inc., License No. 2; Immune Globulin (Human), Pepsin Modified, (Gammagee-V), Merck Sharp & Dohme, Division of Merck & CO., Inc., License No. 2.

The FDA agrees with the Panel's findings and recommendations concerning these drugs and, in accordance with § 601.25(f)(3), hereby proposes that products listed in Category IIIA remain on the market and their licenses remain in effect, on an interim basis, pending completion of testing and the submission of acceptable data based on scientifically sound studies (as recommended in the Panel report) to demonstrate efficacy in humans. Such studies shall be in accordance with the Panel's recommendations and § 601.25(h), and shall be completed within 2 years of publication of the final order. Failure to submit adequate data, in the form of a license amendment, within the specified time will result in the publication of a notice of intent to revoke the product license. Comments and/or additional data on this classification are invited.

The additional studies will not be necessary for Rocky Mountain Spotted Fever Vaccine, manufactured by Lederle Laboratories Division, American Cyanamid Co. and Typhus Vaccine, Manufactured by Eli Lilly and Co. At the request of the manufacturers, the licenses for these products were revoked on June 11, 1979 and June 7, 1979, respectively.

The Panel concluded that additional data are needed for the Category IIIA drugs. The absence of such data is a material fact within the meaning of section 201(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(n)) and applicable regulations, § 1.21 (21 CFR 1.21). The failure to disclose a material fact would cause these drugs to be misbranded. Therefore FDA proposes to extend to viral and rickettsial vaccines the requirements in § 601.25(h)(4) that the circular and promotional material for Category IIIA drugs contain a prominent boxed statement referencing the need for further data to establish effectiveness. The boxed statement should appear in the *Indications* section of the labeling. The FDA also proposes to extend to viral and rickettsial vaccines the requirement of § 601.25(h)(5) that a written informed consent be obtained from participants in the requisite additional studies, and that participants receive an explanation of the product and the purpose of the study and a clear opportunity to refuse to participate.

d. *Category IIIB. Biological products for which available data are insufficient to classify their safety and effectiveness and should not continue in interstate commerce:* Poliovirus Vaccine, Live, Oral, Type 1, Type 2, and Type 3, Pfizer, Ltd., License No. 338; Poliomyelitis Vaccine, Cutter Laboratories, Inc., License No. 8; Poliomyelitis Vaccine (Purivax), Merck Sharp & Dohme, Division of Merck & Co., Inc., License No. 2; Poliomyelitis Vaccine; Poliomyelitis Vaccine, Adsorbed, Parke, Davis and Co., License No. 1; Poliovirus Vaccine, Live, Oral, Trivalent, Poliovirus Vaccines, Live, Oral, Type 1, Type 2, and Type 3, (Sabin), Wyeth Laboratories, Inc., License No. 3; Smallpox Vaccine, Massachusetts Public Health Biologic Laboratories, License No. 64; Smallpox Vaccine, Merck Sharp & Dohme, Division of Merck & Co., Inc., License No. 2; Immune Serum Globulin (Human), North American Biologicals, Inc., License No. 413; Measles Immune Globulin (Human), Lederle Laboratories Division, American Cyanamid Co., License No. 17; Measles Immune Globulin (Human), Parke, Davis and Co., License No. 1.

The Panel found that many of these products have not been manufactured for a number of years and that the only way to assure that competence currently exists for their production, and to guarantee their safety and efficacy, is to require a new submission when or if the licensee desires to resume marketing. The Panel did not receive sufficient information from Pfizer Ltd., for the monovalent poliovirus vaccines or from the producers for the human immune serum globulins, and could make no determinations regarding the relative benefits and risks of these products. The Panel recommended that the licenses be suspended or revoked pending the satisfactory completion of additional testing because there is no evidence presumptive of safety or effectiveness for the products.

The FDA agrees with the Panel's findings and recommendations concerning these drugs and, in accordance with §§ 601.5 and 601.25(f)(3), intends to publish a NOH to revoke the licenses for these products. In addition to the lack of proven safety and effectiveness with respect to Poliomyelitis Vaccine (Purivax), manufactured by Merck Sharp & Dohme, Poliomyelitis Vaccine, and Poliomyelitis Vaccine, Absorbed, manufactured by Parke, Davis and Co., and Measles Immune Globulin (Human), manufactured by Lederle Laboratories Division, American Cyanamid Co., FDA also intends to base revocation, authorized by § 601.5(b)(2), upon the fact that manufacture has discontinued to such an extent that a meaningful inspection cannot be made.

The following licenses for products in Category IIIB were revoked at each manufacturer's request and revocation proceedings are unnecessary:

Product	License No.	Manufacturer	Date of revocation
Poliovirus Live, Oral, Type 1, Type 2, and Type 3.	338	Pfizer Ltd	6/12/79
Poliomyelitis Vaccine	8	Cutter Lab., Inc.	12/28/78
Poliovirus Vaccine, Live, Oral, Trivalent (Sabin) Poliovirus Vaccine Live, Oral, Type 1, Type 2, and Type 3 (Sabin).	3	Wyeth Lab., Inc.	9/06/74
Smallpox Vaccine	64	Massachusetts Public Health Biologic Laboratories.	12/22/76
Immune Serum Globulin (Human).	413	North American Biologicals Inc.	5/21/75
Measles Immune Globulin (Human).	1	parke, Davis and co.	11/4/77

North American Biologicals, Inc., transferred its manufacturing processes and facilities to Merieux Institute, Inc., Miami, FL. Merieux Institute, Inc., was issued License No. 623, on May 21, 1975, for the manufacture of Immune Serum Globulin (Human).

2. The Panel recommended that a public compensation system be established under which the government accepts; responsibility to recompense

those who suffer damages from the recognized hazards of immunication when licensed vaccines are used.

A similar recommendation concerning a public compensation system was made at the National Immunization Conference held in April 1977. The agency advises that such a public compensation system is a policy issue which is under study by the office of the Secretary, Department of Health, Education, and Welfare (DHEW). If endorsed by the Secretary, implementation of a public compensation system would require Congressional action.

3. The Panel recommended that FDA, acting through the Bureau of Biologics, rather than the Center for Disease Control (CDC) and the Advisory Committee on Immunization Practices (ACIP), should be responsible for promulgating vaccine usage recommendations.

The FDA notes, first, that ACIP now is advisory to the Assistant Secretary for Health and renamed the Immunization Practices Advisory Committee (IPAC). In addition, FDA is cognizant of the Panel's acknowledgement that "in view of the present commendable collaboration between CDC (and its IPAC appendage) and the Bureau of Biologies, the question might appear to be academic * * *." Therefore, because this interaction between the two organizations can be expected to continue, this matter is not an urgent problem at this time. Any further consideration of this issue will be referred to the Office of the Assistant Secretary for Health.

4. The Panel directed several comments to the IPAC concerning its recommendations for the use of various products. The Panel's comments will be discussed with IPAC and the preamble to final rule will advise manufacturers of their conclusions and any additional labeling revisions that may be necessary to accurately reflect PHS policy (see item 5 below).

5. The Panel recommended a number of specific labeling changes concerning manufacturers' labeling. The agency agrees with the Panel's recommendations for labeling changes. The public is invited to comment on the Panel recommendations affecting product labeling. All labeling changes concerning product use will be discussed with the IPAC and other appropriate groups (e.g., the American Academy of Pediatrics Committee on Infectious Diseases). Upon publication of the final rule, FDA will advise manufacturers when to submit appropriately revised labeling to the Bureau of Biologics for review and approval. Such proposed labeling should conform to the Panel's recommendations, as they may be modified by the final rule, and to regulations governing the content and format of labeling for human prescription drugs, as well as the procedures for requesting a waiver from certain labeling requirements, when those regulations become effective for viral and rickettsial products under review (21 CFR 201.56, 201.57, and 201.58, see the **Federal Register** of June 26, 1979 (44 FR 37434)).

6. The Panel recommended that the government study vaccines for possible subtle and/or long delayed adverse effects.

The FDA agrees that studies designed to evaluate such effects are desirable. The agency has already engaged in selected postmarket surveillance studies with other interested government agencies—the CDC, the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), and the Department of the Army. These efforts will be continued as opportunities for meaningful studies present themselves. The FDA has endorsed postmarketing surveillance in its legislative proposals, particularly the drug reform bill presented to the 95th Congress.

7. The Panel recommended that FDA consider ways of improving laboratory techniques for evaluating and updating standards for safety, potency, and effectiveness for some of the reviewed products.

Standards for determining the safety, potency, and effectiveness of viral and rickettsial vaccines are related to the current state of biomedical knowledge and technology. The existing policy of FDA encourages improvement of standards whenever sound and substantiated laboratory and clinical data demonstrate that changes in methods of production and quality control testing will result in a better product. Within this context, and noting that most of the products reviewed by this panel were found to be safe and effective, the FDA agrees with these recommendations. The agency will continue to be cognizant of new procedures which will improve standards for vaccines.

8. The Panel found that licensed viral vaccines which are safe and effective as single viral products are also safe and effective when combined with other licensed viral vaccines. Accordingly, the Panel recommended that the Bureau of Biologic's interpretation of § 610.17 (21 CFR 610.17) concerning permissible combinations of licensed products be modified to allow a licensed manufacturer to purchase and combine another licensed viral vaccine without being licensed for the purchased component vaccine(s).

The regulation on permissible combinations, § 610.17, requires that manufacturers of combination biological products be licensed for the combination product. In addition, to assure that the individual therapeutic, prophylactic, or diagnostic products of the combination product are compatible, safe, potent, and effective, it has been the agency's policy to require the manufacturer of the combination product to obtain a license for each product in the combination as well.

FDA adopts the Panel recommendation and will now permit manufacturers of combination viral vaccine(s) to purchase licensed viral vaccine(s) from another manufacturer(s) and combine them without obtaining a license for the purchased vaccine(s), provided that the manufacturer of the combination product—(1) performs laboratory and clinical studies to demonstrate compatibility, safety, potency, and effectiveness of the combination product (§ 601.2), (2) obtains a license for the combination product, and (3) identifies, in the package insert, the manufacturer of each purchased vaccine component used in the manufacture of the combination product.

9. The Panel recommended the following for both the live and the inactivated poliovirus vaccines:

(i) Research into the seed strains and the substrates used for cultivation of the virus.

(ii) Surveillance of large comparison groups of recipients of vaccines produced in diploid and in simian cell substrates.

(iii) Identification and development of better in vitro marker correlates of the neurovirulence of poliovirus strains used for the live vaccine, and application of appropriate statistical definitions for interpretation of the monkey test for neurovirulence.

(iv) Comparison testing of inactivated poliomyelitis vaccines licensed in the United States and of those used in Europe to determine their relative potency, and reevaluation of the U.S. potency standards in light of these results.

(v) Use of new methodologies, as they evolve, for the detection and elimination of adventitious agents as well as other foreign nucleic acids or proteins from the substrates used for viral vaccine production.

The Panel found, as have other expert groups, that both the live and the inactivated poliomyelitis vaccines are

safe and effective. The FDA agrees that it is important to continue to apply scientific advances to vaccine technology.

The FDA has supported and will continue to support research on cell substrates, in vitro and in vivo measures of attenuation, assays for extraneous agents and substances, and alternate strains of virus for vaccine production. As in other areas of biologics research, these efforts involve a productive interchange between FDA and other biomedical research groups in government, academia, and industry.

In cooperation with other national control authorities and the World Health Organization (WHO), FDA has for several years been involved in an analysis of data relating to neurovirulence testing of live poliovirus vaccine in primates. The testing is complex and difficult and is meaningful only insofar as results are shown to be related to predictable vaccine performance in humans. Nevertheless, it is anticipated that data analysis will ultimately serve as a basis for revising and updating the existing standards for neurovirulence interpretation both here and abroad.

A related problem not specifically addressed in the Panel report but discussed by FDA with the Panel in public sessions concerns the international shortage of primates essential for this type of testing and for the required neurovirulence testing of vaccines. In anticipation of this current shortage, FDA established domestic colonies of Rhesus monkeys. Through the funding of such activities by FDA and other HEW components, the supply of polio vacine for the United States and the availability of monkeys for vaccine testing is secure.

The FDA has already been in contact with other national control authorities, the WHO, and other interested parties regarding the need for new data relating to the comparative immunogenicity of inactivated poliomyelitis vaccines produced by differing methodologies. FDA is supporting studies that should provide information on the immunogenicity of these vaccines in humans as well as in animals. With the completion of these international comparative studies, it is possible that the resulting data will serve as a basis for modifying the labeling as well as changing potency standards for inactivated poliomyelities vaccines licensed in the United States.

FDA advises that research by the Bureau of Biologics on new methods for the detection and elimination of adventitious agents and extraneous material in substrates used for vaccine production is in progress. For example, biophysical and biochemical methods have been employed in testing for the presence of type C retroviruses; the interaction between bacteriophage and cell substrates used for vaccine production has been studied; and new systems for tumorigenicity testing of cell substrates have been developed. In addition, the Bureau is supporting extramural studies designed to detect and eliminate adventitious agents and has discussed with manufacturers research on new manufacturing methods that may improve the purity of viral vaccines.

10. Although the Panel found that all licensed smallpox vaccines currently produced are safe and effective, they recommended that the standards in 21 CFR Part 630, Subpart H, be amended, for the improvement of the quality of the product, to require—

(i) Use of the same strain of seed virus by all manufacturers;

(ii) Use of a seed lot system;

(iii) A test for potency by the pock counting method;

(iv) Sterility standards for percutaneous vaccines consistent with those currently required for jet-gun vaccines; and

(v) The elimination of viable bacterial organisms in jet-gun vaccines.

The Panel also suggested that an effort be made to detect other extraneous organisms, in addition to bacteria, in calif lymph vaccines.

The FDA agrees that these suggestions would improve the vaccine's quality. However, the greatly reduced need for smallpox vaccine resulting from the international eradication of smallpox makes it probable that manufacturers may terminate their production of vaccine rather than commit new funds to upgrade existing production methods. Therefore, the agency particularly invites comments on these recommendations, noting that the possible termination of the production of smallpox vaccine may be potentially of more concern than achieving a marginal increase in the benefit/risk ratio by moderately upgrading existing production methods.

As the Panel notes, differing degrees of documentation exist on the effectiveness of the strains of vaccine virus being used in production. Although the Panel found those smallpox vaccines currently produced to be effective, they recommended that the strain with greatest documentation of safety and effectiveness be used by all manufacturers. The FDA will explore the feasibility of such a change with those manufacturers who intend to continue to produce the vaccines.

The FDA agrees that a seed lot system should be used in the production of smallpox vaccine and invites comments on its intention to require those manufacturers continuing production to amend their product license to adopt a seed lot system.

With respect to the use of the pock counting method for potency testing, § 630.73 (21 CFR 630.73) has already been amended to require such testing (see the **Federal Register** of November 19, 1976 (41 FR 51009)).

The FDA will investigate the feasibility of requiring that vaccines meet more stringent sterility standards. The development of new tests for extraneous organisms in calf lymph vaccines and the determination of the tests' usefulness in the manufacture of smallpox vaccine will likely require a collaborative research effort between FDA and the manufacturers.

11. The Panel commented that the required testing of cell substrates for extraneous agents or indigenous viruses should be updated, especially in the duck embryo system, noting the absence of required testing for duck infectious anemia virus (DIAV).

The regulations for live rubella virus vaccine, propagated in duck embryo cell cultures, in § 630.62(b) prescribe that the embryonated eggs used as a source of the tissue for the propagation of rubella virus shall be derived from flocks certified to be free of agents pathogenic for ducks. There are similar regulations for the manufacture of measles virus vaccine, live, attenuated (§ 630.32(b)) and mumps virus vaccine, live (§ 630.52(a)). A report in the *Journal of the National Cancer Institute* (H. G. Purchase, C. Ludford, K. Nazerian and H.W. Cox, 51:489–499, 1973) identifies DIAV as a member of the reticuloendotheliosis virus (REV) group which includes REV isolated from turkeys, spleen necrosis virus isolated from ducks, and chick syncytial virus isolated from chickens. The report states that the members of the REV group are serologically indistinguishable in the fluorescent antibody test. The author noted that antibody indicative of contact with these agents occurred in white Pekin ducks only when they were in contact with wild ducks and not when reared in closed flocks under commercial conditions.

As a result of the Panel's discussions, a manufacturer of measles, mumps and rubella vaccines that are produced in avian cell cultures submitted data demonstrating that closed duck and chicken flocks, from which the embryos used for vaccine production are derived, are free of REV as evidenced by the lack of antibodies specific for those agents.

In addition, representative lots of measles, mumps, and rubella virus vaccines were tested for REV by the indirect fluorescent antibody method and were found to be free of the agents.

Nevertheless, assurances should be provided that commercial ducks have not contracted DIAV from accidental contact with wild ducks. For this reason, FDA agrees with the Panel's comments that embryonated eggs for propagating viral vaccines should be derived from flocks certified to be free of DIAV as well as any other REV organism. Since the hazard of biocontamination with agents of the REV group applies to measles and mumps virus vaccines as well, manufacturers of live virus vaccines produced in avian tissue should test birds for REV viruses before introduction into the breeding colony and periodically thereafter.

Accordingly, FDA is proposing that §§ 630.32(b), 630.52(a), and 630.62(b) be amended to require that embryonated eggs intended for manufacture of measles virus vaccine, live, attenuated, mumps virus vaccine, live, and rubella virus vaccine, live, be derived from flocks certified to be free of REV. There is no need to change the wording of § 630.52(a) because § 630.52(a) currently states that embryonated eggs for propagating mumps virus shall be derived from flocks certified or tested as prescribed in § 630.32(b).

12. The Panel recommended that the regulations concerning safety tests for rubella vaccines (§ 630.65) should specify the incubation period for the embryonated eggs before and after inoculation with virus, and the subpassage requirement of tests to be employed.

The FDA agrees with the Panel's recommendation. The tests for safety performed on live virus vaccines prior to clarification are designed to detect the presence of possible adventitious agents which may originate from the cell substrate or from personnel processing the vaccine. The tests include a variety of host systems, i.e., adult mice, suckling mice, and at least four different cell cultures as well as media for the detection of bacteria and mycoplasma. The embryonated egg is a classic host for the detection of a variety of adventitious agents and is used in addition to these host systems.

Measles virus vaccine, live, attenuated, mumps virus vaccine, live, and rubella virus vaccine, live, are produced in avian cell cultures, and similar safety tests are applied to all three vaccines. The embryonated egg safety test prescribed for rubella virus vaccine in § 630.65(a)(5) and (6) and (c)(5) and for mumps virus vaccine in § 630.55(a)(5) requires that the test shall be performed as prescribed in § 630.35(a)(5) for measles virus vaccine. Therefore, it is appropriate to specify, in § 630.35(a)(5), the incubation period and subpassage requirements that are appropriate for all three live virus vaccines, and the agency proposes to amend § 630.35(a)(5) accordingly.

The proposed requirements for the inoculation of embryonated eggs (§ 630.35(a)(5)) are based upon generally accepted methods. A description of the methods of inoculation, incubation, harvesting, and subpassaging and their application is found in "Diagnostic Procedures for Viral and Rickettsial Infections," Fourth Edition, American Public Health Association, New York, E. H. Lennette and N. J. Schmidt, Editors, 1969.

13. For influenza vaccines, the Panel recommended that (i) additional controlled trials of safety, antigenicity, and efficacy be required when a major change is introduced into the process of vaccine production, (ii) other possible tests of potency be explored, particularly animal test models and in vitro measurement for antigenic mass, (iii) standards be established for the maximal acceptable level of contaminants such as diffusable chick proteins and other foreign nonviral protein, and (iv) additional special studies be performed.

The FDA agrees with the Panel's findings that additional testing be required for influenza vaccine if major manufacturing changes are made. The establishment licensing regulations, § 601.12 (21 CFR 601.12), require manufacturers to advise FDA of major proposed changes before the changes are made. When major changes in the production of vaccine have been proposed, FDA has required manufacturers to provide experimental in vitro and in vivo data demonstrating the safety and effectiveness of the vaccine produced by the new method.

As the Panel notes, experience over the years has shown that the presence of circulating antibodies directed against the surface antigens of influenza virus generally correlates with protection against the disease. The conclusion by the Panel that the currently licensed inactivated influenza vaccines are effective is in good part based upon this established relationship between antibody levels and vaccine efficacy. The FDA agrees that when major changes in manufacturing are proposed, it is important to evaluate the safety and antigenicity of the modified product by appropriate clinical trials. Experience has shown that such studies can be completed and their results analyzed within a matter of months, making the acquisition of such data entirely practical. Compared to the evaluation of human antibody response (an indirect measure of vaccine effectiveness), the direct determination of effectiveness is far more difficult. The direct measure requires detailed virologic and epidemiologic study of both vaccinated and unvaccinated populations over an extended period of time. Since influenza may not occur or may occur only sporadically in the populations during the period of study, even a large, complex, and costly trial may fail to provide useful results. For these reasons, data of this nature have more often been provided retrospectively, and by studies supported by public funds, than prospectively by vaccine manufacturers.

The FDA believes that direct protection data should continue to be collected whenever epidemiologic circumstances suggest that a reasonable opportunity exists. As in the past, several government agencies (e.g., NIH, CDC, FDA, DOD) as well as industry will be encouraged to participate in such studies, which are best characterized as a continuing documentation rather than an absolute prelicense requirement. The collection of direct protective efficacy data by animal studies is generally feasible within a reasonable time frame. Consequently, laboratory studies in animals and clinical data relating to antigenicity are normally required of manufacturers proposing new or substantially changed inactivated influenza virus vaccines.

The FDA policy is to continually upgrade those laboratory and research techniques, including potency tests, which form the basis of FDA decisions. Several experimental parameters of influenza vaccine potency have been evaluated in vitro and in vivo in laboratory animals. Indeed, the Bureau of Biologics, working with CDC and NIAID, have performed research correlating in vitro potency determinations with antigenicity in clinical investigations and, as a result, in 1978 instituted a new in vitro procedure for assaying potency of influenza vaccines based on content of hemagglutinin.

FDA agrees with the Panel's recommendations concerning the establishment of standards for maximal acceptable levels of nonviral components in influenza vaccine. As soon as sufficient data to develop additional standards for nonviral contaminants are available and evaluated, FDA will propose standards

regarding acceptable levels of nonviral contaminants in influenza vaccines.

Additional special studies were recommended by the Panel, including (i) evaluation of safety, antigenicity and efficacy of influenza vaccines in high risk adults and children under 6 years of age; (ii) evaluation of the protective efficacy of the Type B components; (iii) review of the status of adsorbents and adjuvants in experimental influenza vaccines; and (iv) surveillance of rare but severe vaccination sequellae.

Since 1973, the Bureau of Biologics has supported clinical trials which have demonstrated that the antigenicity and reactivity of influenza vaccines are similar in high risk and normal individuals. Extensive studies evaluating the safety and antigenicity of influenza vaccines in children under 6 years of age were conducted in 1976 as part of the National Influenza Immunization Program and in 1978 with A/USSR/77 vaccines. As previously noted, due to the sporadic nature of influenza epidemics, it is difficult to evaluate field efficacy. However, one study sponsored by the Bureau of Biologics has demonstrated that both a whole and split-product influenza vaccine were protective in a high risk group of children with cystic fibrosis when they were exposed to an epidemic of A/Victoria (Gross, et al., *Journal of Infectious Diseases*, 136:623–632, 1977).

In addition, studies to monitor the benefits and risks of influenza vaccines are in progress in NIAID-sponsored clinical trails in vaccine evaluation centers throughout the United States. Other special studies will be considered as opportunities permit, and will be explored with agencies such as CDC and NIH, which also have interests and responsibilities in these matters.

Concerning the evaluation of the reactivity of the Type B component in relation to the Type A antigens, the immediate issue of the local and systemic reactivity of influenza vaccines in young children has been largely circumvented by using reduced amounts of antigen and divided vaccine dosages. Studies conducted in 1976 and 1977 demonstrated that vaccines containing two Type A antigens (A/Texas and A/USSR) and the Type B component had reactivity low enough to make them acceptable for use in young children. Additionally, field studies sponsored by NIAID to evaluate the protective effectiveness of Type B vaccines are currently in progress.

The FDA agrees that the status of adsorbents and adjuvants used in experimental influenza vaccines should be reviewed periodically. This policy is currently followed by FDA in the review of clinical studies performed under an IND and in support of license applications or amendments.

The FDA agrees that increased surveillance of rare but severe vaccination sequellae is desirable. To aid in this effort, the FDA announced in the **Federal Register** of April 24, 1979 (44 FR 24233) the availability of a proposed regulation requiring records and reports of adverse reactions and product experiences involving licensed biological products. According to the draft proposal, manufacturers of licensed biological products would be required to immediately report any severe (life threatening or fatal) reactions to the Bureau of Biologics. Copies of this draft proposal are available from the Hearing Clerk under docket number 79N–0089. The comment period on the draft proposal ended June 25, 1979.

CDC, in cooperation with the American Academy of Neurology is currently monitoring the nation-wide incidence of Guillain-Barre Syndrom (GDS). This monitoring system will help determine the relative risk of GBS from vaccinations. In addition, the CDC, by Congressional authority, maintains a general vaccine surveillance program for all Federally-supplied vaccines.

14. The Panel recommended that efforts be made to detect and, if present, eliminate extraneous microorganisms, including avian REV, which may be present in duck embryo used for the production of rabies vaccine.

A license application for rabies vaccine produced in human diploid cells is currently under review by the Bureau of Biologics. It is anticipated that the manufacture of duck embryo rabies vaccine will terminate as soon as the product is no longer needed. However, should production continue, the development of procedures for the detection and elimination of extraneous organisms will be discussed with the manufacturer.

15. The Panel expressed concerned that no avian leukosis virus (ALV)-free yellow fever vaccine is available in this country and requested that every effort be made to insure that ALV-free vaccine is made available in the United States.

The FDA is also concerned about this problem and has conducted extensive research in an effort to aid in the development and assessment of a safe and effective ALV-free yellow fever virus strain for vaccine production. These efforts have a high priority and will continue until an ALV-free vaccine is made available in this country.

16. The Panel recommended improving Rocky Mountain Spotted Fever (RMSF) vaccine and typhus fever vaccine by changing current potency standards to require a defined whole rickettsial organism content and by requiring the use of a reference preparation in the assay test to better correlate the potency for humans. In addition, the Panel recommended that the safety standards be amended to establish limits for endotoxin content and to exclude mycoplasma and other extraneous agents prior to inactiviation.

The FDA agrees with the Panel's recommendation to improve RMSF vaccine and typhus fever vaccine. However, with the revocation of Lederle's product license on June 11, 1979, there are no RMSF vaccines licensed for manufacture in the U.S. The U.S. Army Medical Research Institute on Infectious Diseases and the NIAID Rocky Mountain Laboratory are, however, conducting RMSF vaccine studies. These studies are designed to answer questions concerning potency standards, define a whole rickettsial organism content, establish limits for endotoxin content, and provide methods to exclude extraneous agents from RMSF. There has been no active effort to establish a reference RMSF vaccine. However, a reference preparation or one that closely parallels the vaccine the Army is studying will likely result when the clinical trials with the vaccine developed at the U.S. Army Medical Research Institute on Infectious Diseases are finished. The NIAID has also expressed an interest in the question of an improved RMSF vaccine. The FDA has been and will continue to be in close contact with these agencies concerning this matter. Appropriate changes in the regulations will be proposed as soon as requisite laboratory and clinical data have been obtained and reviewed.

The FDA agrees that efforts should be made to improve the potency test method for typhus vaccine, including the use of an appropriate reference, if this Category IIIA product is to continue in interstate commerce. FDA proposes to require that the manufacturers who intend to continue production of this product initiate appropriate studies in accordance with the Panel's recommendations and § 601.25(h) (21 CFR 601.25(h)).

17. The Panel recommended that efforts be made to improve immune serum globulin (ISG) by exploring the possibility of (i) replacing thimerosal as a preservative because of the possibility of sensitization, (ii) developing ISG's that can be safely and effectively administered intravenously and (iii) improving the product's stability.

The desirability of replacing thimerosal as a preservative in

biologicals is of major concern primarily with intradermally inoculated skin test products and where thimerosal-induced skin reactions may interfere with an accurate diagnostic reading. However, there is no evidence that thimerosal affects either the safety or the effectiveness of ISG, and reactions to thimerosal have presented little if any problem. There are only a few preservatives that have been found to be safe and effective for use in injectable biological products. Other substances, frequently employed as preservatives in nonbiological products, are unacceptable because of interactions with the proteinaceous components of biologicals and because they may also be sensitizing. Extensive research is therefore required to demonstrate the acceptability of any new preservative in each product. Therefore, before considering regulations proposing the replacement of thimerosal in ISG, data must be developed showing that other preservatives are safe and effective. Interested persons are invited to submit data on the safety and effectiveness of other preservatives or single dose forms of globulin products containing no preservative.

The FDA concurs with the Panel that it would be useful to have ISG which can also be safely and effectively administered intravenously (IV–ISG). There has been considerable interest and progress in this area by both the manufacturers and university-based scientists. On October 30 and 31, 1979, FDA, in conjunction with NIH, held an Immunoglobulin Workshop to discuss the characteristics and current or potential uses of immunoglobulins for intramuscular and intravenous administration, including a review of the European experiences regarding the use of IV–ISG. The information provided by this Workshop will aid interested manufacturers and FDA in developing and assessing immunoglobulin preparations suitable for intravenous administration.

The agency concurs that efforts to improve the stability of Immune Serum Globulin and other immune globulins should be pursued. The Bureau of Biologics' Division of Blood and Blood Products has performed studies to assess the stability of Immune Serum Globulin and to develop methods not only for quantitating any physicochemical deterioration of the product that occurs during the dating period, but also for predicting stability (A. M. Young, D. L. Aronson and J. S. Finlayson, " Urokinase-incubation Method for Predicting the Stability of Immune Globulin," *Journal of Biological Standardization*, 6:27–43, 1978). Studies designed to identify factors responsible for instability are continuing.

18. The Panel recommended that the indications for use of ISG included on the labeling conform to IPAC recommendations

The Bureau of Biologics has developed guidelines for the package insert for Immune Serum Globulin. On April 14, 1978, the availability of these guidelines was announced in the Federal Register (43 FR 15779). The recommendations of the IPAC, as well as those of other bodies such as the Committee on Infectious Diseases, American Academy of Pediatrics, were used in the development of these guidelines. All manufacturers of the product have now adopted or are in the process of adopting the guidelines. The guidelines, as well as the manufacturers' labeling, will be reviewed periodically for conformity with the best current medical practice, scientific information, and IPAC recommendations.

19. The Panel recommended that the regulations for ISG be modified to include standards for the composition of each lot in terms of quantity and characteristics of immunoglobulin-G (IgG), relative content of other immunoglobulins and of other contaminating serum proteins. Also, within the limits of applicable technology, the Panel recommended that lots of ISG should be characterized with respect to antibody titers against measles, and hepatitis-A viruses.

The agency agrees that revised regulations for ISG should include standards for the quantity and molecular characteristics of IgG, which is the major protein constituent of ISG. At present, the purity of ISG is defined on the basis of electrophoretic mobility (21 CFR 640.103(b)). When more direct methods for defining this purity in terms of IgG have been established and when appropriate limits for the purity and the molecular characteristics of the IgG can be determined, the agency will propose revised regulations that embody these changes. The issue of molecular characteristics is closely related to that of ISG stability, which is addressed in item 17 of this preamble. In general, the amount of contaminating proteins other than immunoglobulins is determined by measuring the percent of immunoglobulins and treating the remainder as contaminating proteins in a manner analogous to that used for albumin (see 21 CFR 640.82(b)). Studies by the Bureau of Biologics' Division of Blood and Blood Products have also dealt with contaminating proteins that may be present in ISG at levels too low to permit detection by protein analyses and hence can only be measured by enzymic assays. If further study supports limits for the content of these proteins in ISG, regulations including such limits will also be proposed.

As regards the establishment of standards for the relative content of immunoglobulins other than IgG, the Division of Blood and Blood Products has completed a survey of the levels of IgG, immunoglobulin A (IgA), and immunoglobulin M (IgM) in products submitted for release by the Bureau of Biologics. The results of this survey show that these levels were relatively constant among different lots prepared by various manufacturers and were virtually the same as those reported in 1967 (Heiner, D. C. and L. Evans, "Immunoglobulins and Other Proteins in Commercial Preparations of Gamma Globulin", *Journal of Pediatrics*, 70:820–827, 1967). Because of this consistency and the expense that would be incurred if these analyses were performed on all lots, the agency does not intend to propose regulations for the relative contents of IgA and IgM. The agency, however, invites the submission of data concerning the effect of IgA and IgM content on the safety and effectiveness of ISG.

As regards antibody testing of ISG, the agency has taken note of a variety of situations in which specific antibody testing is useful. The required testing of globulins for measles antibodies is illustrative of these. The test has utility in (1) providing the user with a product that contains an amount of antibody known to be effective for the prevention or modification of natural measles; (2) providing a general indication that individual ISG lots contain the expected level of antibodies widely distributed in the population; and (3) providing a means of monitoring an antibody level that conceivably might change as a result of alterations in the epidemiology of the disease and the extensive use of vaccines. In addition to tests for measles antibodies, the regulations currently require that each lot of final product be tested for levels of diphtheria and poliomyelitis antibodies (21 CFR 640.104(a)).

For many years ISG has been widely used for the prevention of hepatitis A. In addition to specific studies cited in the Panel Report, general experience has indicated that ISG preparations prepared from large plasma pools are effective for this purpose. The requirement that ISG lots be prepared from plasma pooled from a large number of donors is based in part on the premise that such preparations will include

plasma from an adequate number of persons with antibodies to hepatitis A virus (HAV) to assure that the final product consistently contains comparable levels of such antibodies. A test has recently been developed and shown to be useful for measuring antibodies to HAV in ISG. As expected, the antibody levels observed in ISG preparations tested thus far confirm that all contain antibody and the titers fall within a relatively narrow range. These observations are consistent with the considerations mentioned above (the size of donor pools used and the experience suggesting that the ISG appears to be generally effective for immunoprophylaxis of hepatitis A). However, a minimum effective level of antibody for prevention of hepatitis A has not been established. The Bureau of Biologics is currently involved in activities which are expected to be useful in making decisions about the need for HAV antibody standards. These include: (1) measurement of levels of antibody to HAV in representative lots of ISG currently being produced and from past years; (2) preparation of a reference hepatitis A immune globulin to be used as a standard; and (3) work in experimental animal models to determine the effectiveness of ISG preparations of varying antibody content. The agency invites comments on both the appropriate tests and the minimum antibody levels to be met. The FDA intends to publish a proposal covering the specific antibody tests to be applied to ISG.

At this time the agency does not plan to require the inclusion of the antimeasles antibody level on ISG labeling. Manufacturers are currently required to determine the level of antimeasles antibody in each lot of ISG, which may be no less than the minimum effective level set by FDA (21 CFR 640.140 (a) and (b)(2)). Therefore, requiring the inclusion of the assay results on the labeling would provide little meaningful information. It seems likely that the same considerations would apply if measurement of anti-HAV antibody levels becomes a requirement.

20. The Panel found vaccinia immune globulin (VIG) to be a safe and effective product but noted that this product is no longer being produced. This is of concern to the Panel because there is a well-defined, albeit infrequent, need for VIG. The Panel therefore requested that the manufacturers reconsider their decision to discontinue the production of VIG.

The FDA notes the Panel's concern regarding the availability of VIG. Accordingly, the Bureau of Biologics will review this matter with CDC, NIH, DOD and, as appropriate, the licensed manufacturers to assess the degree of need for VIG and to determine what steps might be taken to continue the availability of VIG.

Additional background data, information, and references on which the agency relies in this proposal may be seen in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The FDA has carefully considered the environmental effects of the proposed regulation and, because the proposed action will not significantly affect 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 (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)), the Public Health Service Act (sec. 351, 58 Stat. 702 as amended (42 U.S.C. 262)), and the Administrative Procedure Act (secs. 4, 10, 60 Stat. 238 and 243 as amended (5 U.S.C. 553, 701–706)), and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), it is proposed that Parts 601 and 630 of Chapter I of Title 21 of the Code of Federal Regulations be amended as follows:

a. In Part 601, by revising § 601.25(h) (4) and (5) to read as follows:

§ 601.25 Review procedures to determine that licensed biological products are safe, effective, and not misbranded under prescribed, recommended, or suggested conditions of use.

* * * * *

(h) *Additional studies and labeling.* * * *

(4) Labeling and promotional material for Bacterial Vaccines and Bacterial Antigens with "No U.S. Standard of Potency," Skin Test Antigens, and Viral and Rickettsial Vaccines requiring additional studies shall bear a box statement in the following format:

Based on a review by the Panel on Review of (insert name of appropriate panel) and other information, the Food and Drug Administration has directed that further investigation be conducted before this product is determined to be fully effective for the labeled indication(s).

(5) A written informed consent shall be obtained from participants in the requisite additional studies for Bacterial Vaccines and Bacterial Antigens with "No U.S. Standard of Potency," Skin Test Antigens, and Viral and Rickettsial Vaccines explaining the nature of the product and the investigation. The explanation shall consist of such disclosure and be so made that intelligent and informed consent be given, and that a clear opportunity to refuse is presented.

* * * * *

b. In Part 630:

1. By revising § 630.32(b) to read as follows:

§ 630.32 Manufacture of live attenuated Measles Virus Vaccine.

* * * * *

(b) *Virus propagated in chick embryo tissue culture.* Embryonated chicken eggs used as the source of chick embryo tissue for the propagation of measles virus shall be derived from flocks certified to be free of Salmonella pullorum, avian tuberculosis, fowl pox, Rous sarcoma, avian leucosis, reticuloendotheliosis virus, and other adventitious agents pathogenic for chickens. If eggs are procured from flocks that are not so certified, tests shall be performed to demonstrate freedom of the vaccine from such agents. (See § 630.35(a)(8) for test of avian leucosis.)

* * * * *

2. By revising § 630.35(a)(5) to read as follows:

§ 630.35 Test for safety.

(a) * * *

(5) *Inoculation of embryonated chicken eggs.* A volume of virus suspension of each undiluted virus pool, equivalent to at least 100 doses or 10 milliliters, whichever represents a greater volume, after neutralization of the measles virus by a high titer antiserum of nonhuman, nonsimian, nonavian origin shall be tested as follows:

(i) Embryonated eggs, 10 to 11 days old, shall be inoculated by the allantoic route using 0.5 milliliter per egg. Following incubation at 35° C for 72 hours, the allantoic fluids shall be harvested, pooled and subpassed by the same route into fresh embryonated eggs, 10 to 11 days old, using 0.5 milliliter per egg and incubated at 35° C for 72 hours. Both the initial pool and the subpassage harvest shall be tested for the presence of hemagglutinin. The virus pool is satisfactory if the embryos appear normal and there is no evidence of hemagglutinating agents.

(ii) Embryonated eggs, 6 to 7 days old, shall be inoculated by the yolk sac route using 0.5 milliliter per egg. Following

incubation at 35° C for at least 9 days, the yolk sacs shall be harvested and pooled. A 10-percent suspension of yolk sacs shall be subpassed by the same route into fresh embryonated eggs, 6 to 7 days old, using 0.5 milliliter of inoculum per egg and incubated at 35° C for at least 9 days. The virus pool is satisfactory if the embryos in both the initial test and the subpassage appear normal.

* * * * *

3. By revising § 630.62(b) to read as follows:

§ 630.62 Production.

* * * * *

(b) *Virus propagated in duck embryo tissue cell cultures.* Embryonated duck eggs used as a source of duck embryo tissue for the propagation of rubella virus shall be derived from flocks certified to be free of avian tuberculosis, the avian leucosis-sarcoma group of viruses, reticuloendotheliosis virus, and other agents pathogenic for ducks. Only ducks so certified and in overt good health and which are maintained in quarantine shall be used as a source of duck embryo tissue used in the propagation of rubella virus. Ducks in the quarantined flock that die shall be necropsied and examined for evidence of significant pathologic lesions. If any such signs or pathologic lesions are observed, eggs from that flock shall not be used for the manufacture of Rubella Virus Vaccine, Live. Control vessels shall be prepared, observed and tested as prescribed in § 630.32(f).

* * * * *

Interested persons may, on or before July 14, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall 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 the hours of 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: March 30, 1980.

Jere E. Goyan,

Commissioner of Food and Drugs.

[FR Doc. 80–10670 Filed 4–14–80; 11:24 am]

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April 15, 1980

Part III

Department of Health, Education, and Welfare

Food and Drug Administration

Requirements for Designating Manufacturer's Name on a Drug Product's Label

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Parts 201, 207 and 314

[Docket No. 78N-0320]

Requirements for Designating Manufacturer's Name on a Drug Product's Label

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule specifies the conditions under which a person may be identified on the label of a drug product as its manufacturer. This rule revokes the "man-in-the-plant" policy under which a firm has been permitted to claim to be manufacturer of a drug product on the basis of having placed quality control staff in the plant of a subcontractor. The agency believes that the continued application of the "man-in-the-plant" policy would mislead consumers about who actually manufactured certain drug products.

EFFECTIVE DATES: Effective April 10, 1981, for drugs and drug products initially introduced or initially delivered for introduction into interstate commerce. This document also extends the effective date of § 201.100(e) (21 CFR 201.100(e)), which requires that prescription drug labeling bear the name and place of business of the manufacturer, packer or distributor, to April 10, 1981.

FOR FURTHER INFORMATION CONTACT: Steven H. Unger, Bureau of Drugs (HFD-30), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5220.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 3, 1978 (43 FR 45614), the Food and Drug Administration (FDA) proposed to amend § 201.1 (21 CFR 201.1) of the agency's general drug labeling regulations to specify the conditions under which a person may be identified on the label of a drug or drug product as its manufacturer. The rulemaking was intended to end the "man-in-the-plant" policy under which a drug firm marketing a product has been permitted to claim to be manufacturer of the product on the basis of having placed quality control staff in the plant of the subcontractor that actually produced the product. The proposal identified 10 manufacturing operations that are important in formulating a drug product. Under the proposal, in order to claim to be the manufacturer of a drug product, a firm must perform all the listed operations that apply to production of the labeled product. If a firm performs none of the applicable operations, it cannot claim to be manufacturer of the drug product under any circumstances. However, if a firm performs some but not all the applicable operations, and still chooses to identify itself as the manufacturer, it must identify itself as the joint manufacturer along with each other firm that performs one or more of the remaining applicable operations. The proposed regulation also specified the conditions under which a person may claim to have performed the listed manufacturing operations.

The agency also proposed to amend the drug registration and listing regulations (1) to prohibit an owner or operator of a drug establishment from registering the establishment, if any part of the establishment is registered by any other owner or operator, and (2) to require that any change made in a registered establishment firm name made within 6 months of the registration of the establishment be supported by a signed statement of the establishment's owner or operator that the change is not made for the purpose of changing the name of the manufacturer under § 201.1.

By the close of the original comment period the agency had received 53 written comments on the proposal. Several complained that the proposal, if adopted, would have an anticompetitive effect on the drug industry by discouraging the use of contract manufacturing. This would happen, the comments asserted, to the extent that the proposal would prevent a drug company from claiming to be sole manufacturer of a product whose manufacture had been contracted out in whole or in part. To assist the agency in responding to these comments the agency asked the Antitrust Division of the Department of Justice for its analysis of the matter. On April 26, 1979, the Department of Justice responded. The response suggested that before attempting an analysis of the effects the proposal might have on drug industry competition, "additional development of the record is needed to assess the probable effects both beneficial and adverse." In the **Federal Register** of June 26, 1979 (44 FR 37234), the agency published a notice which announced the availability of the Department of Justice letter and solicited the submission of data and analyses on the claim that the proposal would have an anticompetitive effect. The notice reopened the comment period for an additional 60 days. During this time the agency received about 20 additional comments. These comments are summarized and discussed in paragraphs 49 through 51 below.

In all, FDA received 73 comments on the proposed rule. These comments have come from trade associations, professional groups, individual manufacturing firms (both brand name and generic firms), pharmacists, teachers, and other interested persons. A summary of the substantive comments and the agency's responses follows:

Need for Rulemaking

1. Many comments questioned the need for making a rule to define who can properly claim on a drug product label to be the manufacturer of the drug product. Several comments contended that the preamble to the proposed rule had failed to identify any specific instance of misinformation about or misidentification of the manufacturer that resulted from labeling practices under previously sanctioned policies. Other comments asserted that, if under the proposed revision, a manufacturer or joint manufacturers were identified on a drug product label, the information disclosed thereby—information about the person or persons who had performed the manufacturing operations needed to produce the product—was neither desired by most consumers nor helpful to them. Several comments argued further that even if consumers did desire this sort of information, it could be obtained or made obtainable elsewhere, for example, by a FDA-prepared pamphlet presumably listing the manufacturing source of all drug products.

While the preamble to the proposed rule did not cite any specific cases of misinformation conveyed to consumers under previously sanctioned labeling policy, it did describe in general terms several labeling practices sanctioned under previous policy that could mislead consumers about who manufactured a drug product. Further the preamble described in detail the "man-in-the-plant" policy and concluded that the "policy is no longer appropriate as a basis for identifying a firm as a manufacturer of a drug or drug product for purposes of section 502(a) and (b)(1) of the act." Also in support of the proposed action the preamble cited hearings on the problems associated with the "man-in-the-plant" practice that were held before the Senate Subcommittee on Monopoly and Anticompetitive Activities and the House Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce. Therefore, FDA believes that the proposal adequately demonstrated the

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existence of policies that permit the use of potentially misleading label information and the consequent need to revise these policies.

The agency strongly believes that all consumers of drug products not only desire, but need, truthful and accurate information about drug products. While FDA has not conducted a survey to establish a consumer preference for nondeceptive labeling, it should be noted that many commentors did state their emphatic support for the proposed rule and stressed that it would ensure that information on drug product labels would be of value to physicians, pharmacists, and lay consumers in making rational drug product selections. Of course, even if consumers did not find the information disclosed under this final rule helpful or informative, the agency would still have a statutory responsibility to ensure that the identification on the drug product label of the name and place of business of the manufacturer, packer, or distributor (as required by section 502(b)(1) of the act) was not false or misleading. This rule carries out that agency responsibility.

The agency does not believe that publishing a pamphlet containing information about the manufacturing source of all drug products, assuming that such a list could be drawn up and distributed, would solve the problem of misleading label information. The problem of misleading drug label information can only be addressed through policies that regulate the kinds of information that can appear on drug product labels.

Definition of Manufacturer

Revisions To Proposed Definition of Manufacturer

2. Many comments criticized the proposed definition of manufacturer as it would affect the label of a product whose manufacture involved the participation of two or more drug firms. Several comments conceded that a definition of manufacturer might be useful but contended that the particular definition proposed prevented "actual manufacturers" from truthfully claiming to be sole manufacturer of a product. In particular, these comments objected to the provision that would require, if no single person performed all the § 201.1(b) manufacturing operations that were needed to produce the product (and the label purported to identify the manufacturer), that all persons who had performed any of the necessary operations be identified on the label as "joint manufacturers." These comments contended that the "joint-manufacturer" concept is deficient in a number of respects, including the following:

a. The naming on a product label of several persons as "joint manufacturers" would make it more difficult for consumers to determine what person was responsible for marketing the product and to identify the person to be contacted for further information about the drug product. As an example, one comment suggested that, if companies x, y, and z are identified on the label as "joint manufacturers", consumers attempting to learn about the product would be as likely to contact x or y as z, even though z might be the only company able to respond to consumer inquiries.

b. If several persons are identified on the label as joint manufacturers, the label would tend to be crowded and perhaps illegible.

c. Requiring a marketing drug firm to identify subcontractors as joint manufacturers would discourage the contracting out of § 201.1(b) operations and would tend, as a consequence, to increase drug prices as well as the concentration of the drug industry.

d. If a company marketing a drug product is unwilling to acknowledge on the label the contribution of other parties, the "joint manufacturer" provision might discourage the identifying of anyone as manufacturer because the marketing company could instead identify itself as distributor of the drug product.

e. The concept is inconsistent with a consumer's understanding of what is meant by "manufacture" or "manufacturer".

f. The joint manufacturing identification would not inform the consumer which steps each of the joint manufacturers had performed in making the product.

g. The concept would threaten an "esteemed and proper prerogative" of business organizations marketing a product to be identified as sole manufacturer of the product.

h. Identifying all persons who performed the operations needed to produce the product would increase the number of defendants named in products liability suits brought by plaintiffs who had been injured by the product.

In addition, several comments contended that the contracting out of certain highly specialized operations such as aerosol filling, lyophilizing, and sterilization by irradiation is common practice and a reasonable response to the economics of drug manufacturing. Several comments suggested that if the manufacture of a product involves the contracting out of one or two operations that are commonly contracted out, the marketing firm that has performed the remaining operations needed to produce the product should have the right to name itself sole manufacturer.

Several comments offered alternative definitions of manufacturer. One suggested that a manufacturer that performs more than one half of the § 201.1(b) operations needed to produce the product should be permitted to designate itself as sole manufacturer. Another suggested that, if a drug firm contracts out certain operations, it should still be permitted to claim to be sole manufacturer if it identifies the subcontractors involved by name and operation performed.

The agency has carefully considered these comments and has decided that certain modifications can be made to the proposed definition that will not sacrifice the consumer's interest in nondeceptive drug product label information but will make it more likely, when two or more firms participate in the manufacture of a product, that a single drug firm will be able to make an appropriately qualified claim to be manufacturer of the product.

As finalized, § 201.1 permits a person who has performed some but not all operations needed to produce the product to represent itself on a drug product label as the product's manufacturer as follows:

a. If the person performs all the manufacturing steps needed to produce the product except for those that are listed in the rule as steps that the agency has found to be commonly contracted out.

b. If the person performs at least one half of the § 201.1(b) operations needed to produce the product and acknowledges the contribution of the other drug firms by stating on the drug product label that "certain manufacturing operations have been performed by other drug firms."

c. If the person performs at least one § 201.1(b) operation and the label appropriately identifies by name and by step performed the persons who have performed the remaining applicable operations. Under this alternative, a label might read, for example, "Made by A, Sterilized by B, Filled by C."

d. The person could still be identified as a joint manufacturer along with all other persons who had performed the remaining manufacturing operations.

The alternatives that are provided carry out the essential purpose of the regulation: under each alternative a person may not truthfully represent itself as manufacturer of a product unless the person has been significantly and personally involved in performing

the manufacturing steps (listed in § 201.1(b)) needed to produce the product. Thus, under none of the alternatives would a drug firm be able to represent itself as manufacturer on the basis of having placed quality control staff in the plant of a subcontractor that actually manufactured the labeled product.

These revisions provide alternative nondeceptive ways for a person to be represented on a drug product label as the product's manufacturer. The alternatives are intended to provide a means of avoiding some of the difficulties the comments attributed to the proposed provisions that would have required the identification of two or more persons on the product label as joint manufacturers. In particular the alternatives are intended to make it more likely that a single person may be identified as manufacturer and thus to reduce whatever tendency existed under the proposed scheme to "crowd" labels, to threaten the "prerogative" of a firm to identify itself as sole manufacturer, to discourage the identification of any person as manufacturer (as the label could identify the distributor instead), and to curtail subcontract arrangements. (For a full discussion of the claim that the proposal would discourage the use of subcontractors and thus have an anticompetitive effect on the drug industry, see paragraphs 49 to 51 of this preamble.)

Drug Firm To Be Contacted for Further Information

3. The agency agrees that the identification on a product label of several persons as joint manufacturers might confuse and mislead consumers as to the proper source of information about the drug product. The alternatives to the joint manufacturing concept should increase the likelihood that a label will unambiguously identify a single person as the proper source of further information about the product. Furthermore, the agency would have no objection to the label explicitly identifying a single person as the proper source of further information about the product. The regulation has been revised by adding a new provision in § 201.1(h)(3) to state that the label may identify a person as the source of further information about the product.

Man-in-the-Plant Policy

4. Several comments argued in support of the "man-in-the-plant" policy and urged that the policy be retained. One comment, which was representative of several others, stated that this policy correctly recognized that the person who contracted for the manufacture of the drug product and who controlled and supervised its production was the person most responsible for its manufacture. The comment asserted that the "mechanical functions of mixing, granulating, milling * * *" could be performed by any person to another's specifications and that what was important was to which person's specifications the product was being manufactured. The comment claimed that consumers were unconcerned about whether a person actually manufactured the product or contracted out its manufacture under the person's supervision and control. The comment concluded that a person who contracts for the manufacture of the product is most responsible for the product, that it is in every sense that person's product, and that consumers would be misled if that person's name did not appear as manufacturer on the drug product label.

FDA does not agree that a person who arranges for a product to be manufactured but who does not perform any of the manufacturing operations needed to produce the product can truthfully represent itself as the product's manufacturer. Section 502(b)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 352(b)(1)) requires that the label of a drug or drug product bear the name and place of business of the manufacturer, packer, or distributor. Because the term manufacturer is not defined in that section of the act or in the pertinent legislative history, in defining manufacturer the agency has appropriately considered the word's common or ordinary meaning. As commonly or ordinarily understood, the manfacturer of a product cannot reasonably be taken to identify a person who took no part in the actual production of the product even if that person exercises some degree of supervision and control of the actual manufacturing process.

Further, the agency does not agree that in looking for the manufacturer of a product one should look for the person "responsible" for having the drug made. If drug firm "A" contracts with a subcontractor, drug firm "B," to have a drug product made by "B" to "A's" specification, "A" does in a sense become "responsible" for the drug product's manufacture because without the contract the product would not have been made. However, the contract in itself does not make drug firm "A" the manufacturer because "A" has not actually taken part in the production of the product.

Even if it were true that "any person" could mix, mill, granulate, and perform the other manufacturing processes needed to make drug products, while only a few presumably could write specifications for the product, that would not be relevant to identifying the manufacturer of the product. What is relevant, as indicated above, is the identity of the person or persons who have actually performed the operations needed to produce the product. Finally, the agency along with a number of consumer commentors disputes the contention that consumers are unconcerned about whether the person identified as manufacturer on a product label was in fact the product's manufacturer. And, as discussed in paragraph 1 above, even if there were consumer indifference to the truthfulness of the manufacturer designated on a product, the agency has a statutory responsibility to ensure the label's truthfulness.

Legislative History

5. Several comments contended that the legislative history of section 502(b)(1) of the act (21 U.S.C. 352) does not support the proposed action. The comments suggested that the legislative history indicates that the primary purpose of section 502(b)(1) of the act is to require that one company take responsibility for the drug and to ensure that the name on the label is not merely fictitious. One comment argued that the proposed regulation would not achieve the Congressional intent of clarifying the sponsor of the drug product because it would eliminate the consumer's ability, when two or more firms were identified as joint manufacturers, to identify the responsible company, and therefore to know which company to contact. Another comment argued that the legislative history as cited in the preamble to the proposal did not support that part of the proposed rule that would prohibit a separately incorporated subsidiary from claiming to be manufacturer, if the plant or equipment used in the manufacturing process were owned or leased by the subsidiary's parent corporation.

FDA believes that the provisions of this final rule are consistent with the legislative history of section 502(b)(1) of the act. That history, which is not extensive, suggests that section 502(b)(1) was intended to "prevent the sale of commodities under labels which remain silent with respect to the sponsorship of the products or which utilize merely fictitious names." As finalized, § 201.1 provides a mechanism that both permits the identification of a person responsible for the product and ensures

that the identification of the person and the role the person has played in making and/or marketing the product is truthful and nondeceptive.

It should be noted that the purpose of looking at the legislative history of a statute is to illuminate the meaning of the statute and not to replace the statutory language with other language. Section 502(b)(1) of the act specifies that the drug product label must bear the name and place of business of the manufacturer, packer, or distributor, and section 502(a) of the act demands that the information that does appear on the label not be false or misleading. It is thus clearly insufficient for a drug product label to bear the name of a "responsible" person who is neither the manufacturer, packer, or distributor, or to bear the name of a person identified as manufacturer who did not, in fact, manufacture the labeled product.

Dictionary Definition

6. A comment argued that the dictionary definition of manufacturer that was cited in the proposal in support of the proposed action ("to make into a product suitable for use" from Webster's New Collegiate Dictionary) does not support the proposal. The comment asserted that a person makes a drug into a product suitable for use whether the person owns, leases, or simply uses the plant or equipment that is needed in the manufacturing process. Similarly, the comment argued that the conditions set forth in § 201.1(e) (§ 201.1(c) as proposed) under which a person who performs the § 201.1(b) operations can claim to be manufacturer are not consistent with either the dictionary definition or the common and usual understanding of the word "manufacturer." Also, the comment asserted that the dictionary definition is not helpful in determining what manufacturing steps are important in making a product suitable for use and that the definition does not support a regulatory provision requiring that every step in the manufacturing process must be done by a single person.

The comment misunderstands the use to which the dictionary definition was put by FDA. The agency does not regard the cited definition as the definitive statement of the common or ordinary meaning of the word "manufacturer" but rather as a helpful starting point in developing a definition. The dictionary definition is consistent with a regulatory approach that insists that a person who claims to have manufactured a product actually take part in performing the steps needed to produce the product.

Federal Trade Commission Precedents

7. Several comments contended that the Federal Trade Commission (FTC) advisory opinions that were cited in the preamble to the proposal did not support the proposed definition of manufacturer. One comment said the FTC citations demonstrated that it was possible to have more than one manufacturer of a product, and that it was not necessary to identify each manufacturer to satisfy section 502(b)(1) of the act. Another comment said there was no indication that the FTC would require that the firm claiming to be manufacturer perform all manufacturing operations or that the FTC would require the firm to own or lease the manufacturing plant and equipment. Finally, a comment suggested that the FTC statements were not relevant to FDA regulatory concerns because the lay consumers served by FTC regulatory action are less sophisticated than the physicians and pharmacists who are the "consumers" of FDA-regulated drug products.

FDA agrees that the proposed definition of manufacturer was a good deal less flexible than the definitions stated or implied in the FTC opinions. However, FDA believes that the FTC advisory opinions on who may truthfully be represented as "manufacturer" are consistent with the approach of this final rule. A common thread running through the FTC opinions and this regulation is that to justify a manufacturing claim a person must take part in the actual production of the product in a "substantial and significant" way. The two agencies' approaches are also similar in finding that a person or firm who supplies a formula or specifications to a contract packager or a subcontractor, but who does not take part in the actual production of the product, is not the product's manufacturer.

FDA acknowledges that, unlike its own proposal, the FTC opinions cited do not define the conditions for determining whether the person claiming to have performed the manufacturing operations needed to make a product has, in fact, performed them. The absence of these definitional provisions (including the provisions requiring the ownership or leasing of plant and equipment) may well be due to the fact that the cited opinions were not called upon to address the kinds of labeling practices sanctioned by the "man-in-the-plant" policy.

FDA disagrees with the observations that FTC opinions are irrelevant to FDA concerns because the consumers of FTC-regulated products are less sophisticated than the consumers of drug products. First, most consumers of drug products, including prescription drug products, are neither physicians nor pharmacists. Secondly, FDA has no reason to believe that physicians and pharmacists are any less interested than "lay persons" in truthful, nondeceptive information about drug products. Several pharmacist professional groups as well as a number of individual pharmacists urged the adoption of the proposal. Finally, the agency does not agree that the definition of manufacturer should be any different for "sophisticated" professionals than for other persons.

Authority

8. One comment contended that the "man-in-the-plant" policy was primarily an economic issue and argued that economic issues are not related to FDA's statutory mandate and, therefore, are not proper subjects for FDA regulatory action.

FDA rejects this comment. FDA has the responsibility under section 502 of the act to ensure that the information that appears on drug product labels and labeling is not false or misleading. This regulation, which is intended to end a consumer deception, proceeds under paragraphs (a) and (b)(1) of that section. FDA has no doubt that in defining the meaning of manufacturer for purposes of sections 502(a) and (b)(1) of the act, this regulation serves consumers interest in truthful and nonmisleading information about drug products. If consumers' economic interests are also served by less deceptive label information, that does not make the subject matter of the rule an improper subject for FDA regulatory action.

Meaning of "Joint Manufacturer"

9. One comment criticized the concept of "joint manufacturer" contending that the concept is unknown at retail level in American commerce. The comment suggested that in ordinary usage joint "indicates fractional equality as in 50/50 ownership of a home by a married couple." The comment concluded that the joint manufacturer designation would mislead consumers by suggesting equal participation by all persons identified on the label.

While it may be true that the "joint manufacturer" designation suggests to some consumers that each joint manufacturer named on the label participated equally in the manufacturing process, the agency believes that, in general, the term will be correctly understood to mean that the designated persons shared in the production of the product and that no single person performed all steps

necessary to produce the product. If a person believes, nevertheless, that the joint manufacturing designation might mislead consumers as to the roles of the "manufacturers" named, the person may elect to use the alternative designations outlined in paragraph 2 above.

Temporary Shortages in Capacity

10. Several comments urged that the requirements of the proposal be relaxed to permit a person to claim to be sole manufacturer of a drug product when a temporary shortage in capacity compels the person to subcontract the production of a drug product ordinarily manufactured exclusively by the person.

The agency believes that the public has the right to be assured when a person claims on a drug product label to be the product's manufacturer, that the person has, in fact participated in the manufacture of the product. For this reason the agency does not believe that it can "relax" the regulation to permit a drug company to state or imply that it has manufactured a product when it has not performed any of the manufacturing operations that are needed to produce the product. Of course, if during a time of temporary shortage in capacity, a firm contracts out some but not all of the operations needed to produce the product, it may still be able to claim to be manufacturer under one of the alternatives described in paragraph 2 above.

Unconventional Dosage Forms

11. A comment asserted that the proposal failed to address the problems associated with the labeling for products that, although regulated as drug products, differ significantly from the more conventional dosage forms. A comment pointed to the intrauterine contraceptive (IUD) as an example of a drug product having an other-than-conventional dosage form for which the proposal, it claimed, would be inappropriate. The comment noted that of the 10 listed manufacturing steps in § 201.1(b), the first 8 do not apply to the manufacture of the drug IUD. The comment said the manufacture of the drug IUD involved the assembly of several structural elements supplied from different specialized sources outside of the drug firm. The comment complained that although the drug firm marketing the product performed the essential culminating assembly operations and assumed responsibility for the product, under a literal application of the proposed regulation, if a manufacturer designation were made on the product label, "some six or seven" separate contractors would have to be listed as joint manufacturers.

FDA does not agree that the rule fails to address the problems associated with the manufacture of unconventional dosage forms. The prerequisite for "finding" the manufacture of a product is determining who performed the § 201.1(b) operations that are needed to make the product. The agency is not aware of any drug product whose manufacture does not involve at least one of the steps listed in § 201.1(b). Therefore, the agency doubts there is any drug product that cannot be labeled in compliance with § 201.1.

As indicated in paragraph 41 below, this regulation is not intended to regulate the label of drug components. The operations listed in § 201.1(b) refer to steps performed in the preparation of the finished dosage form, not to steps performed in making the components of the drug. Therefore the fact that the structural "elements" referred to in the comment came from different specialized sources would not compel the drug firm marketing the IUD to acknowledge the suppliers of the structural elements as joint manufacturers. Rather, the determination of who could claim to be manufacturer would be based on the identity of the person or persons who performed the § 201.1(b) steps that did apply to the manufacture of the finished dosage form. If, in the case raised by the comment, the marketing drug firm performed all the listed steps that applied to the manufacture of the IUD (steps 9 and 10 according to the comment) that firm could claim to be sole manufacturer of the drug product.

Space Limitations on Label

12. Several comments suggested that in some circumstances the label may be too small to accommodate the names of several joint manufacturers. One comment suggested that the proposal be revised to indicate which of several joint manufacturers should be included on the label if the label is too small to permit inclusion of all.

Section 502(b)(1) of the act requires that drug labels bear the name and place of business of the manufacturer, packer, or distributor. While the agency does have authority to exempt products packaged in small containers from certain other section 502 labeling requirements, the agency has no such authority with respect to section 502(b)(1) of the act: all drug product labels must bear the name of the manufacturer, packer, or distributor. Therefore, if a firm chooses to meet the section 502(b)(1) requirements by identifying the manufacturer on the label (rather than the packer or distributor), and if it then chooses or is obliged by the terms of this regulation to adopt the joint manufacturer designation, the agency has no authority to permit the deletion from the label of one or more of the names of the joint manufacturers.

Drug Product Labeling

13. A comment stated its support for the aims of proposed § 201.1, but urged that the regulation require that drug product labeling (as defined in section 201(m) of the act) as well as the product label bear the name and place of business of the manufacturer, packer, or distributor. The comment contended that consumers generally do not receive drug products in the original container of a manufacturer and, therefore, generally do not see or have access to its label. The comment suggested that because drug product information is more likely to reach consumers through advertising or package inserts, these should also contain a declaration of the name and place of business of the manufacturer, packer, or distributor.

The agency has undertaken several regulatory initiatives to ensure that prescription drug labeling include the same information about the name and place of business of the manufacturer, packer, or distributor that is required under section 502(b)(1) of the act and § 201.1 of the regulations to appear on drug product labels. Thus, in the regulation revising the requirements for the content and format of prescription labeling (published in the **Federal Register** of June 26, 1979 (44 FR 37434)), the agency required in § 201.100(e) that prescription drug labeling bear conspicuously the name and place of business of the manufacturer, packer, or distributor, as required for the label of the drug under § 201.1. (The effective date of § 201.100(e) has been made the same as this regulation. See paragraph 54 below.) Similarly, the proposed rule to require patient labeling for most prescription drugs (published in the **Federal Register** of July 6, 1979 (44 FR 40016)) would require that patient labeling contain the name and place of business of the manufacturer, packer, distributor, or dispenser in a manner consistent with the requirements of § 201.1 of the regulations.

The agency is also considering the need to propose that over-the-counter (OTC) drug labeling as well as advertising of prescription drug products bear the same information that is required under section 502(b)(1) of the act and § 201.1 of the regulations to appear on drug labels. The agency notes that with few exceptions OTC labeling and prescription drug advertising

already contain information as to the manufacturer, packer, or distributor.

As discussed, this regulation does not require that all labeling contain the same information that is required by section 502(b)(1) of the act and § 201.1 of the regulations to appear on drug labels. However, as proposed and as finalized herein the regulation does require, if a drug firm voluntarily includes information in the labeling as to the manufacturer, packer, or distributor, that that information comply with the provisions of § 201.1(b) et seq. The intent of the regulation to subject labeling to the provisions that govern drug labels is made plain in proposed § 201.1(b), which defines manufacturer not only for purposes of section 502(b)(1) of the act (applying solely to labels) but also for purposes of section 502(a) of the act, which applies to all labeling. Further to clarify this intent a new paragraph (1) has been added stating that a drug product is misbranded if its labeling includes information as to the manufacturer, packer, or distributor, and that information does not comply with the provisions of § 201.1. Labeling as defined in the act (section 201(m)) and the regulations (21 CFR 202.1(l)) includes such things as package inserts, brochures, booklets, reference works like the "Physicians Desk Reference" (PDR) and other written, printed or graphic matter for use by medical practitioners, pharmacists or nurses, containing drug information supplied by the manufacturer, packer, or distributor of the drug and which are disseminated by or on behalf of its manufacturer, packer, or distributor.

Type Size

14. One comment suggested that the requirement that the listing of joint manufacturers be printed together in the same type size and style be revised to permit the name of the person who would customarily respond to inquiries about the labeled product to appear in a larger type size and to be more prominently placed on the label than the names of the other joint manufacturers. The comment contended that, if the names of all joint manufacturers were printed together in the same type size and style, consumers would more likely be confused as to the proper person to contact for further information about the product.

Under section 502(c) of the act and the regulations issued pursuant to that section (21 CFR 201.15), the agency is required to ensure that words, statements, and other information that are required by the act to appear on the label or labeling of drugs and drug products be given sufficient prominence and conspicuousness as to render it likely that the information will be read and understood by the ordinary person under customary conditions of purchase and use. By permitting the names of joint manufacturers to be printed separately and/or in different type styles and sizes, the agency believes that it becomes more likely that the less prominently displayed name will not be read. Therefore, the agency does not believe that it can permit the names of joint manufacturers to appear separately or in different type styles or sizes.

While the regulation does not permit the names of joint manufacturers to appear separately or in different type sizes or styles, as indicated in paragraph 3 above, the agency would not object to a statement on the label that identifies which of the persons named on the label should be contacted for further information.

Pharmacists Responsibility

15. One comment expressed overall support for the proposal, but urged that the proposal be revised to clarify the responsibilities of pharmacists in labeling prescription drugs at the dispensing level. The comment noted that, as proposed, § 201.1(a) would state that a drug or drug product is misbranded under sections 502(a) and 502(b)(1) of the act "if its label does not bear conspicuously the name and place of business of the manufacturer, packer, or distributor." The comment argued that this provision, as applied to the labeling responsibilities of pharmacists, would be inconsistent with section 503(b)(2) of the act which, among other provisions, exempts prescription drugs at the dispensing level from section 502(b)(1) of the act. The comment asserted that, if these provisions of the proposal were read literally, the failure of a pharmacist to include information on the label of a dispensed prescription drug as to the manufacturer, packer, or distributor would result in misbranding the drug product under section 502(a) of the act. To prevent that, the comment requested that the proposal be revised to state that § 201.1 does not apply to any drug or drug product dispensed in compliance with section 503(b)(1) of the act.

The proposal was not intended to require that pharmacists identify the manufacturer, packer, or distributor on prescription drug product labels dispensed under section 503(b)(1) of the act. To clarify FDA's intent, paragraph (a) of § 201.1 has been revised to state that it does not apply to any drug or drug product dispensed in accordance with section 503(b)(1) of the act. Thus, there is no affirmative obligation on pharmacists to identify the manufacturer, packer, or distributor on the labels of dispensing containers. However, this does not mean that if a pharmacist voluntarily makes a representation on a drug or drug product label as to the manufacturer, packer, or distributor that the other sections of the regulation would not apply. To the contrary, if the label of a prescription drug product dispensed by a pharmacist does contain a representation as to the manufacturer, packer, or distributor, it must comply with all the provisions of § 201.1 of the regulations regarding the designation of the manufacturer, packer, or distributor.

Preliminary Processes

16. One comment suggested that the listing in § 201.1(b) of drug manufacturing operations be revised to delete references to the operations of mixing, granulating, milling, and sterilizing of the bulk drug substance. The comment claimed that these operations should be deleted because they are "preliminary and intermediate" steps and argued that designation of the person who performs these operations on the label would be meaningless and would produce confusing and misleading labels. The comment gave the following reasons for this judgment:

a. Virtually all raw materials undergo one or several mixing or milling operations between the time they are prepared as a chemical entity and their eventual use as an ingredient in a drug product.

b. While the preliminary or intermediate operations may affect the quality of some dosage forms, subsequent events in production have an overriding effect on the quality of the final dosage form. It is then not relevant whether these operations are performed on the raw material. This is especially true because in most cases, the ultimate manufacturer verifies that the raw materials meet the required characteristics.

c. Similarly, while the sterilization of the bulk drug affects the quality of the dosage form, the subsequent placing of ingredients in the final dosage form is the critical operation which will determine the quality of the product reaching the consumer.

The comment contended that the critical operations are the formulation and placement of ingredients in the final dosage form and stated that it was not in the public interest to identify the person or persons performing the preliminary or intermediate operations.

As explained in paragraph 41 below, the agency did not intend for bulk drug substances or components to be labeled

in conformity with the provisions determining who could properly claim to be manufacturer of a drug product. The steps that are listed in § 201.1(b) pertain to the production of finished dosage forms and not to the manufacture of drug components. Therefore, the person or persons who perform mixing, milling, granulating, or sterilizing operations in preparing drug components need not be identified on the label of products that incorporate the components as ingredients. Of course, once drug components have been fabricated and are being used as ingredients in the preparation of a finished dosage form, the agency believes that the consumer should be told who is mixing, milling, granulating, or sterilizing the ingredients in manufacturing the finished dosage form. The performance of these operations at that stage of production of the finished dosage form is crucial to the overall quality of the finished dosage form. For purposes of § 201.1, the definition of drug components is the same as that given in the regulations describing current good manufacturing practices for drug products: "* * * [A]ny ingredients intended for use in the manufacture of a drug product, including those that may not appear in such drug product." (21 CFR 210.3(b)(3)).

Drug Products Manufactured at More Than One Site

17. One comment claimed that the proposal does not recognize the problems posed for the "supervisory manufacturer" when a particular drug, although manufactured completely at two or more sites, is subject to the quality assurance, technological design, and process development of the "supervisory manufacturer." The comment contended that under the proposal, if a drug product is manufactured for the "supervisory manufacturer" at different sites, a different label would be required for the product at each site. The comment concluded that this result would be unnecessarily costly and confusing and there would be a greater probability of mislabeling through manufacturer mistake. Another comment suggested that when a marketing firm has a product made for it by two subcontractors (Firms A and B for example) it should be permitted to label the product "Manufactured by *Firm A* or *Firm B.*"

One purpose of this regulation is to end the deception involved in designating on a drug product label a person as a manufacturer of the product who is not, as the word is commonly and usually understood, the manufacturer of the product. Manufacturer is defined in terms of the performance of certain significant manufacturing operations. If the "supervisory manufacturer" described in the comment fails to perform any of the significant operations applicable, it cannot claim to be manufacturer under this regulation in any circumstance.

The agency appreciates that there may be additional problems associated with compliance with the revised policy for a firm distributing a product manufactured at two or more sites. However, as discussed in paragraph 4 above, the agency does not believe a firm involved in the design and quality assurance of a product that it does not manufacture can truthfully claim to be the manufacturer of the product. If the problems that the comment identified cannot be eliminated through skillful administrative responses, the agency believes they must be viewed as the unavoidable costs of a policy that demands that drug products be truthfully and nondeceptively labeled.

FDA does not believe that it can permit the identification on product labels of the manufacturer through the use of a phrase like "Manufactured by Firm A or Firm B." The agency believes that such a phrase would leave consumers uncertain as to who manufactured the product and that this uncertainty would render the label misleading under section 502(a) of the act.

Finally, the agency does not agree that compliance with the regulation will be confusing to the consumers of the affected drug products. Rather, the agency is convinced that more truthful and less deceptive labels on drug products should reduce and not increase consumer confusion.

Conditions Under Which a Person Can Claim To Be Manufacturer

Full-Time Employment

18. One comment objected to the provision in § 201.1(e)(1) (§ 201.1(c)(1) as proposed) that would condition a person's claim to have performed the manufacturing steps listed in § 201.1(b) on a showing that the majority of the individuals performing the § 201.1(b) manufacturing operations were permanent full-time employees of the person. The comment claimed that this requirement wrongly prevented a person who employed a majority of manufacturing personnel on a permanent part-time basis or on a nonpermanent full- or part-time basis from claiming to be manufacturer. The comment noted that permanent part-time and nonpermanent full-time hiring is used when seasonal products such as special bath oils and hand creams are manufactured for a limited time before a holiday or season. The comments stated that such hiring practices might also be used in the production of small volume products with a long shelf-life for which production may be run only once a year.

The conditions set forth in § 201.1(e) are intended to ensure that a person who is represented on the label of a drug product as its manufacturer performs the required manufacturing operations under conditions that consumers would consider to qualify the person as its manufacturer. The agency agrees that employment by a person claiming to be manufacturer of more than half of the work force on a permanent full-time basis is not commonly understood to be a crucial condition determining that person's status as a manufacturer. Section 201.1(e)(1) is revised accordingly.

19. A comment suggested that § 201.1(e) was too specific and should be deleted. The comment argued that the intent of the manufacturer in regard to its personnel operations and the owning and leasing of equipment used in the manufacturing process should be the controlling criteria in determining who had performed the applicable § 201.1(b) operations. The comment stated that under the proposed requirements it would be possible for a person to perform all manufacturing operations and still be unable to claim to be the drug product's manufacturer. The comment suggested that if, for example, an incorporated subsidiary performed all the manufacturing operations on a drug product in a plant owned or leased by a separately incorporated parent company, neither the subsidiary nor the parent could claim to be the product's manufacturer. The comment claimed that this result would be inconsistent with the agency's intent to end consumer deception.

The agency does not believe that the provisions of § 201.1(e) (§ 201.1(c) as proposed) are too specific or that the intent of the person claiming to be manufacturer should determine the validity of the claim. The conditions set forth in § 201.1(e) are based on the observation that a manufacturer is commonly understood to be a person who has a significant involvement with and control over the employees, plant, and equipment that are needed in the manufacturing process. To the extent that the conditions set forth in that section are specific, that specificity is necessary in the agency's opinion to ensure that the person claiming to be manufacturer has performed the

applicable manufacturing operations under conditions that consumers would consider to qualify the person as manufacturer.

As the comment claims, if an incorporated subsidiary performed all the applicable operations in the manufacture of a product in a plant owned or leased by a separately incorporated parent company, neither subsidiary nor parent could represent itself on the label of the product as the product's manufacturer. While this result may seem somewhat anomalous, the result may be more a theoretical possibility than an actual consequence of the final regulation. However, if a situation arises in which it is impossible for either a parent company or separately incorporated subsidiary to claim to be manufacturer, the agency will carefully consider a request for waiver from the relevant provisions of § 201.1(e).

20. A comment recommended that § 201.1(e) (§ 201.1(c) as proposed) be revised to allow a lessee who enters into a flat fee lease agreement with a subcontractor to claim to be manufacturer of products produced during the term of the lease. The comment noted that § 201.1(e) would prevent a person from claiming to be manufacturer on occasions when the facility and employees are leased on a flat fee basis, in which employees are under the direct control of the lessee but are not considered full-time employees of the lessee. The comment urged that the proposal be revised to state that lessees in such situations would be considered manufacturers.

FDA rejects the comment. The agency believes that the conditions set forth in § 201.1(e) for determining whether a person performs an operation listed in § 201.1(b) must include a requirement that the employees performing the applicable manufacturing operations are employees of the person identified on the label as the manufacturer of the drug product. Central to the common and usual meaning of manufacturer is the notion that the employees responsible for producing the product are employees in fact of the manufacturer. A lessee who enters into a flat fee lease agreement in a situation like the one described in the comment cannot reasonably be considered employer of the individuals working in the plant.

21. A comment asked for clarification of § 201.1(e) (2) and (3) (§ 201.1(c) (2) and (3) as proposed). The comment asked whether under these provisions it would be sufficient for a distributor who wished to be considered manufacturer to lease that portion of the plant and equipment needed to manufacture the labeled product during the time that the product is being produced, or if the distributor would be required to lease the entire facilities for a full 12 months.

The agency advises that to justify the claim to have performed a § 201.1(b) operation, the conditions set forth in § 201.1(e) must apply for the entire period required to perform the applicable operations. The specific terms of § 201.1(e) do not demand that the person who is identified as manufacturer own or lease the manufacturing premises for 12 months or for any other specific period. However, it should be noted that two aspects of this regulation that relate to the drug listing and registration regulations have the effect of requiring in most circumstances that the person whose name is represented on the label as manufacturer continuously own or lease the premises used in the manufacturing process for at least 6 months. Section 201.1(f) (§ 201.1(d) as proposed) provides that the name of the manufacturer under § 201.1 must be the same as the firm name of the establishment (as defined in § 207.3(b)) at which the operations listed in § 201.1(b) were performed when the product was produced. Additionally, as amended in this final rule, § 207.26 requires that a change in a registered establishment's firm name within 6 months of the registration of the establishment be supported by a statement signed by the establishment's owner or operator that the change was not made for the purpose of changing the name of the manufacturer of a drug product under § 201.1 of the regulations. The effect of these provisions together with § 201.1(e)(2) is to ensure that no person can claim to have performed a § 201.1(b) manufacturing operation unless the plant at which the manufacturing operations were performed was registered in the person's name and to require that the person continuously own or lease the plant for at least 6 months.

Separately Incorporated Subsidiary

22. A number of comments objected to the provision in § 201.1(g) (§ 201.1(e) as proposed) which stated that the requirement for declaration of the manufacturer, packer, or distributor can only be satisfied by the actual corporate name (qualified at the option of the labeler by the name of the particular division of the identified corporation) and which prohibits a separately incorporated subsidiary from using the name of its parent company. A comment suggested that no regulatory problem could be attributed to the use of the parent's rather than the subsidiary's name and argued furthermore that in many cases it would be of more informational value to consumers to use the more familiar name of the parent company rather than the name of the subsidiary. Several comments observed that there are many sound business reasons for a company to incorporate a plant as a separate subsidiary rather than operate it as a division. Finally, one comment asked for a "grandfather" exemption from § 201.1(g) for those products that have become associated in the public's mind with the names of particular subsidiaries, divisions, or parent companies.

As stated in the preamble to the proposed rule (43 FR 45617), the agency regards the separately incorporated company as a separate "person" within the meaning of section 201(e) of the act. Therefore, the agency believes that representing the parent company as the manufacturer, packer, or distributor rather than the separately incorporated subsidiary, when the subsidiary is the actual manufacturer, packer, or distributor, would not satisfy section 502(b)(1) of the act or § 201.1 of the regulations.

That the decision to separately incorporate a plant rather than to operate it as a division of the parent company may be taken for the soundest economic reasons is not relevant to a determination of the legal status of the plant or parent company for purposes of section 502(b)(1) of the act and § 201.1 of the regulations. Once a plant is separately incorporated it becomes a separate person for purposes of section 502(b)(1) of the act regardless of the factors that led to the decision to separately incorporate.

FDA does not believe that a grandfather provision exempting certain products from § 201.1(g) is warranted. The agency understands that the practice of some drug companies to identify the parent company as the manufacturer, packer, or distributor instead of a separately incorporated subsidiary may have led consumers to associate particular drug products with the name of a parent company rather than with the name of the actual manufacturer. The consumer confusion that may result from this practice is not a persuasive argument in favor of the agency continuing to sanction the practice.

23. One comment objected to the provision in § 201.1(g) (§ 201.1(e) as proposed) which would only permit the declaration of the actual corporate name contending that a manufacturer should be allowed the option to use individually or in combination the names of the parent company, subsidiary, affiliate, and division.

Another comment urged that § 201.1(g) be revised to permit a subsidiary to identify not only its name on the drug product label but also the name of its parent company. The comment suggested that the presence of both names when appropriately qualified would not mislead or confuse the consumer. As mentioned in the previous response, the requirement that the label of a drug or drug product bear the name of the manufacturer, packer, or distributor can only be satisfied by the actual corporate name which in the case of a separately incorporated subsidiary would be the subsidiary's name. However, the agency agrees that the identification of the parent company on drug product labels in conjunction with the name of a separately incorporated subsidiary should be permitted at the option of the firm. Section 201.1(g) (§ 201.1(e) as proposed) has been revised accordingly.

Identification of Distributor

Section 201.1(h) (201.1(f) As Proposed)

24. As proposed, this section would prohibit the identification on drug labels of anyone other than the manufacturer, packer, or distributor. This section also states that the appearance on a label of a person's name without qualification is deemed to be a representation that the person is the sole manufacturer of the product. The proposed section also prescribes phrases to be used in identifying a packer or distributor. Under the proposal if a packer were identified, its name would be qualified by the phrase "Packed by ———." Similarly, if a distributor were identified, its name would be qualified by the phrase "Distributed by ———."

25. A number of comments complained that as proposed the regulation would prevent truthful disclosure of information relating to the source and distribution of drug products. The comments disagreed with the contention in the preamble to the proposal that the use of a phrase such as "Manufactured for ———" to identify a distributer would mislead because the consumer who did not closely examine the label might easily misread it and assume the person named was the manufacturer of the product. A comment suggested that there was no evidence of consumer deception to support the prohibition against use of this phrase. Another comment noted that if consumers misread "Manufactured for ———" as "Manufactured by ———" it would be unlikely that "Distributed by ———" would signify to consumers that the product was not manufactured by the company distributing the drug product. Another comment urged that truthful and nondeceptive alternatives to "Packed by ———" and "Distributed by ———" should be allowed. The comment suggested that acceptable phrasing should not be defined in advance as companies would still be subject to misbranding provisions if the language were misleading.

The agency agrees that a distributor should have the option to identify itself using the phrase "Manufactured for ———". Section 201.1(h) has been revised accordingly.

The agency does not agree that acceptable phrasing to identify the distributor should not be defined in advance but rather should be regulated after the fact on a case-by-case basis. The agency believes that for the efficient enforcement of the act it is necessary that the regulated industry be apprised of the criteria under which drug product labeling will be in compliance with sections 502(a) and 502(b)(1) of the act. By specifically identifying what qualifying phrases are permissible, § 201.1(h) provides a precise statement of those criteria. The provision should be useful to both FDA and industry in determining compliance with the act.

"Manufactured for (Firm A) by (Firm B)"

26. One comment noted that the statutes of several States require the identification of both the manufacturer and distributor on the label of prescription drug products. The comment suggested that the phrase adopted by some drug firms marketing products made by others to identify both the manufacturer and distributor—"Manufactured for ——— by ———"—is a nondeceptive way to comply with the State law requirements and at the same time identify the distributor.

The agency agrees that distributors should at their option be permitted to adopt the phrase "Manufactured for ——— by ———". Section 201.1(h) has been revised accordingly.

Distributor

27. One comment urged that § 201.1(h) be revised to permit a distributor to identify itself by stating and fully spelling out the word "distributor". Another comment recommended that a distributor be allowed to identify itself using the phrase "Marketed by ———." The comments suggested that the use of these words to identify a person unambiguously tells consumers that the person identified sells but does not manufacture the product.

The agency agrees and has revised § 201.1(h) to make "Distributor" and "Marketed by" permissible options in identifying the distributor of the product.

Definition of Packer and Distributor

28. One comment asked that "packer" and "distributor" be defined to give guidance to companies that both pack and distribute drug products.

The agency does not believe that the distinction between "packer" and "distributor" for purposes of section 502(b)(1) of the act has presented a regulatory problem. Because these terms, like the term "manufacturer," are not defined in section 502(b)(1) of the act, the agency believes that they should be given their common and usual meaning. The dictionary definition of these two terms is helpful in establishing an adequate basis to distinguish the two terms. Namely, a distributor is one "that markets a commodity," and a packer is one that "packages goods for shipment." Of course, when a company both packs and distributes a drug product, it may at its option identify itself as a packer or distributor or as both packer and distributor.

29. A comment asked that the proposal be revised to permit a packer to be identified by the phrase "Packaged by ———."

The agency agrees with the comment and has revised the regulation accordingly.

"Manufactured by (Firm A) to the Specifications of (Firm B)"

30. Several comments noted that the proposal would prohibit the use of the phrase "Manufactured by ——— to the Specifications of ———". One comment conceded that a prohibition would be appropriate if the distributing firm's specifications were no more stringent than other firms also distributing the product. However, the comment insisted that the phrase should be allowed when (1) the written specifications are in fact more demanding than those generally applied to equivalent drug products when manufactured for other distributors, and (2) when the manufacturer and distributor are both clearly identifed on the label of the drug product. A comment argued that to prohibit the use of labels that specifically name the manufacturer and additionally convey truthful and honest information about the distributor's specifications would raise serious constitutional problems.

FDA rejects these comments. While the agency is no longer prepared to argue (as it did in the preamble to the proposal) that phrases such as "Manufactured for ——— to the Specifications of ———" and

"Manufactured to the Specifications of ———" are any more likely to mislead a consumer as to the identity of the manufacturer than the phrases permitted by the final regulation, the agency believes that these phrases can be misleading in suggesting that a product made to one distributor's specifications is superior in quality to equivalent products marketed by other firms. As noted in the proposed rule on therapeutically equivalent drug products, "Except for identified problems of bioinequivalence, FDA is not aware that any therapeutically significant differences currently exist among pharmaceutically equivalent drug products which result from differences between public compendial (or antibiotic) standards and higher internal standards of manufacturers." FDA thus believes that even when the written specifications for a product are more demanding than those of generically equivalent products, the differences in specifications do not ordinarily produce a difference in product quality. Because the phrases cited in the comment have the potential to mislead consumers to believe that a product made to the specifications of one distributor is superior to equivalent products, the agency concludes that these phrases should not be allowed.

31. One comment asked for clarification of the provision in § 201.1(h) (§ 201.1(f) as proposed) which states that "No person except the manufacturer, packer, or distributor may be identified on the label of a drug or drug product". The comment stated its assumption that any one, or any combination of these three persons, may appear on the label. The comment noted that many States currently require identification on a drug product label of both the manufacturer and distributor, if the product is distributed by a person other than the manufacturer.

The applicable statute (section 502(b)(1) of the act) and regulation (21 CFR 201.1), while requiring the identification of the manufacturer, packer, or distributor, do not prohibit a firm from identifying any two or all three of these persons on the same drug label.

"Innovators and Developers"

32. Several comments urged that the regulation allow the product label to bear the name of the innovator or developer identified as such. The comments contended that while usually a product's developer (or innovator) would also be the product's distributor (even if not the product's manufacturer), to identify the developer as a distributor would not fully disclose the extent of that person's contribution.

Although the agency recognizes the valuable contribution that a product developer (or innovator) makes, and agrees that a distributor identification of a developer may be somewhat inadequate, it believes that to permit a developer to be identified as such on the product label would detract from the prominence and conspicuousness that must under section 520(c) of the act be accorded words and statements that are required to appear on the label (including statements required to appear under section 502(b)(1) of the act). Therefore, the agency rejects these comments.

33. One comment stated that § 201.1(h) (§ 201.1(f) as proposed) is deficient in that it allows the identification of the manufacturer with the option to omit the name of the packager or distributor who actually delivers the product into interstate commerce. The comment contended that if a manufacturer produces a product for several distributors who are not identified on the product label, in the event of a recall or mislabeling, it might be impossible to ascertain who was responsible for the product.

This comment incorrectly assumes that the agency has the authority to require the distributor or packer to be identified on the drug product label. No statutory provision gives the agency such authority. What is required under the Federal law is that the drug product label bear the name of the manufacturer, packer, or distributor. The choice of which of these persons or which combination of these persons are to be identified is left to the labeler of the product and to the requirements of State law.

Even without the authority to require that a drug product label identify the person who is directly responsible for introducing the product into interstate commerce, the agency believes that there are adequate mechanisms to determine who, in fact, was so responsible and thus to trace products that are subject to a recall or to an action to correct a misbranding.

Abbreviations

34. One comment urged that § 201.1(h) (§ 201.1(f) as proposed) be revised to permit a label to contain abbreviations of the phrases used to identify the packer and distributor. The comment stated that the use of an abbreviation, such as "Dist.", adequately informs consumers that the named person is not the manufacturer. A comment stated further that the failure to give any facts to support the belief that the use of abbreviations is misleading is itself grounds to invalidate the provision under *Almay, Inc.* v. *Califano*, 569 F.2d 674, 682 (D.C. Cir., 1977).

The agency agrees that abbreviations should be permitted of those phrases that § 201.1(h) allows in identifying the distributor and packer. Such abbreviations, of course, should be clear and unambiguous.

Trademark

35. Several comments noted that § 201.1(h) (§ 201.1(f) as proposed) would limit the persons identified on the drug product label to the manufacturer, packer, or distributor of the drug product. The comments urged that the owner of a trademark who licenses the trademark to another company should also be allowed to be identified on the label as the owner of the trademark. The comments argued that identification of the licensor of the trademark on the label is regarded as good trademark practice. One comment stated that a recent Canadian court decision held that a trademark owner may lose his or her rights in the trademark if the licensed product label does not state who owns the trademark. The comment claimed that other countries follow the Canadian practice. Finally, one comment suggested that along with permitting the identification of the trademark licensor, the proposal should permit the identification on the label of the licensee as a licensee.

The agency did not intend to compromise the rights of a trademark holder in its trademark. Section 201.1(h) has been revised to state that both the licensor and licensee of a trademark that appears on the drug product or product label may be appropriately identified on the drug product label.

Logos

36. Several comments recommended that proposed § 201.1(g) be deleted. That section would require, if a person's name, mark, imprint, or other identifying written, printed or graphic matter (i.e., product "logo") appeared directly on the drug product, that the label state whether the person identified on the product is the manufacturer, packer, or distributor. One comment argued that the provision would discourage the use of logos by persons who might not qualify as the manufacturer under the terms of the regulation. Another comment took issue with the stated justification for the requirement. The comment noted that the preamble justifies the proposed requirement by stating that use of a logo has the potential to mislead consumers by leading consumers to believe that the

person identified by the logo is the manufacturer. The comment stated that under the proposal the person identified on the dosage form would most likely already have his name and function on the label under the requirement of section 502(b)(1) of the act and this regulation. To require an additional statement, it was suggested, would be needlessly burdensome and a disincentive to put a "logo" on the product.

The agency has carefully considered these arguments and has concluded that proposed § 201.1(g) should be deleted. The agency believes that in the absence of § 201.1(g) there is a risk that a distributor's or packer's logo placed on a finished dosage form may be incorrectly read by consumers as identifying the manufacturer of the product. However, the agency also is sensitive to the possibility that proposed § 201.1(g) would discourage the practice of imprinting identifying marks on final dosage forms of drug products. In light of the value of the logo as a product identifier, the agency has decided not to take any action that might discourage the use of logos.

Conflict With State Laws

37. A number of comments expressed concern about the impact the proposal would have on compliance with State law labeling requirements. One comment noted that there are about 20 State laws relating to manufacturer identifications on prescription drug labeling. The comment stated that many of these laws require that the name of the manufacturer of the finished dosage form appear on the product label. The comment further pointed out that these State laws prohibit the identification of only the distributor or packer, an alternative under existing Federal law. A comment noted that a drug firm may comply with several of these State laws by using phrases such as "Manufactured for Company X by Company Y" or "Encapsulated by Company A" or "Tableted by Company B". The comment stated that the proposal would prohibit the use of these terms which, it argued, clearly indicate the relationship to the drug product of the companies named. Because several of the States have enacted legislation defining who qualifies as the manufacturer of the finished dosage form, the comment argued that any further activity by Federal regulation unnecessarily conflicts with the provisions enacted by the various States.

The agency does not believe that this regulation will conflict with State laws governing the content of drug labeling. A conflict would result from a difference in Federal and State regulation making it impossible to comply with both. The examples of differences between State and Federal law cited in the comment do not demonstrate that conflict.

As finalized, § 201.1 does not prohibit the use of the phrases cited in the comments.

38. One comment claimed that the provision in § 201.1(h) (§ 201.1(f) as proposed) that states that no person, except the manufacturer, packer, or distributor may be identified on the drug product label might be read to conflict with State laws which require the identification of the manufacturer, and, if different, the name of the packer or distributor. The comment suggested that § 201.1(h) might be construed to require drug companies to violate State law and argued that in the absence of any Congressional intent to preempt the field, FDA would not have authority to require compliance with the cited provisions. The comment argued that these State laws are important because they ensure that pharmacists will be able to identify the actual manufacturer, if refills of a prescription must be filled with the product of the same manufacturer.

The agency advises that this comment misreads § 201.1(h). That section does not prohibit the identification on drug product labels of both the manufacturer and distributor or packer or indeed of all three persons. What that section does require is that the drug product label bear the name of at least one of the three persons named. Section 201.1(h) is thus not inconsistent with State laws that require that drug labels bear the name of both the manufacturer and distributor, where a product is distributed by a person other than the manufacturer.

Drug Listing and Registration

39. Several comments complained that it would be difficult if not impossible to comply with the proposed changes in the regulations governing drug establishment registration.

The proposal would revise § 207.20 regulations to provide that no owner or operator may register an establishment, if any part of the establishment is registered by another owner or operator. A comment noted that under present practice, several different corporate subsidiaries may operate out of the same establishment (an establishment being a place of business under one management at one general physical location). The comment stated that local law may dictate such a structuring of business organization: "If a company wishes to take advantage of tax preferences in locations such as Puerto Rico it is necessary to establish separate manufacturing corporations for each new product or group of products it will manufacture in the Commonwealth; therefore, one physical facility may have two or more corporations manufacturing drug products at that facility."

The revision to § 207.20 was intended to permit the easy identification of the person who actually performed the § 201.1(b) manufacturing operations that serve as the basis for the manufacturing claim on drug product labels. Without such revision several persons could register the same manufacturing facilities and the connection between the person claiming to be manufacturer and the establishment at which the § 201.1(b) operations were performed would be made obscure and uncertain.

It should be emphasized that one plant may house several establishments as long as each establishment is physically distinct and separate from the others in the plant. If, as the comment says, each "separate manufacturing corporation" occupies a distinct part of the Puerto Rican facility, each could separately register. In such a case the amendment to § 207.20 makes the operation of two or more related companies in the same plant no more difficult that it has been in the past.

The revision to § 207.20 has been made on the assumption that few establishments are registered in two or more firm names so that compliance with this provision will not significantly disrupt or burden the drug industry. If, in fact, this provision does result in economic hardship for a drug firm that has not adopted the multiple registration device as a basis for deceptive labeling, the agency will sympathetically consider a petition to waive the requirements of the provision.

40. One comment addressed the proposed amendment to § 207.26. The amendment would require that all name changes in establishment registrations made within 6 months of a previous registration change be accompanied by a statement that the change was not made for the purpose of changing the name of the manufacturer of a drug under § 201.1.

The comment recommended that this section should exempt changes to allow firms to conform to the changes in § 207.20 and to maintain current label designations.

FDA rejects this comment. Assuming that at present some establishments are, in fact, registered in two or more names, the delay in effective date to April 10, 1981, should give drug firms sufficient time to ensure that, by the effective date, no establishment is registered in more than one name. Thus, in the 1-year

interval, it would not be impossible to conform to the amended provisions. The extended effective date should also give firms sufficient time to exhaust current label inventories.

Scope

Drug Components

41. A number of comments asked for clarification of the regulation as it affects the labeling of bulk drug components, i.e., ingredients intended for use in the manufacture of drug products. Several comments suggested that regardless of the usefulness of the proposal in ensuring truthful and nondeceptive labeling of drug products (i.e., finished dosage forms), the proposed definition of manufacturer would not be suitable to the labeling of drug components. The comment stressed two primary points:

a. The manufacturing operations listed in § 201.1(b) pertain to the manufacture of final dosage forms but not the manufacture of components—the manufacture of components involves synthesizing, purifying, and finishing steps that are not listed in § 201.1(b).

b. Consumers of drug components—chiefly pharmaceutical houses that manufacture final dosage forms—are sophisticated buyers who are unlikely to be mislead by inaccurate labeling practices.

One comment addressed the same issue and complained that a person who takes a drug in bulk form and then performs incoming quality control inspection on the bulk drug, performs all appropriate identity and stability studies, and processes the drug into vials, although subject to good manufacturing practices, is not able under the proposal to designate itself as sole manufacturer. The comment stated that preventing the person from identifying itself as manufacturer is not consistent with the regulatory responsibilities imposed upon it by FDA.

The agency has carefully considered these comments and has concluded that the provisions in § 201.1 (b), (c), (d), and (e) that define the conditions under which a person may be represented as manufacturer for purposes of section 502(b)(1) of the act should not apply to manufacturer designations on drug component labels. As noted in the comments, the manufacturing operations listed in § 201.1(b) are not relevant to the processes involved in the production of drug components. Moreover, the agency is not aware of any regulatory problem in connection with the identification on drug component labels of the name of the manufacturer, packer, or distributor.

As finalized, the regulation states that a person who takes a bulk drug component and performs all the operations listed in § 201.1(b) that are necessary to produce a finished dosage form would be able to designate itself as sole manufacturer of the finished dosage form.

This action exempts drug components from § 201.1 (b), (c), (d), (e), and (f). It should be noted that drug components remain subject to the other provisions of § 201.1.

Radiopharmaceuticals

42. One comment urged that the regulation should not apply to radiopharmaceuticals. The comment claimed that these drugs are unlike other prescription drugs in that they are not dispensed pursuant to prescription but are administered directly to the patient by a professional as part of a total medical diagnostic procedure. Therefore, the comment argued, the economic goals addressed by the regulation are irrelevant because the pharmacist is not involved in drug product selection. Further, the comment argued that the goal is irrelevant to radiopharmaceuticals because the labeling information is directed only at the professional and is never seen by the consumer. Finally, the comment suggested that the regulation would make it more difficult to identify a single person to be contacted for further information about the drug product, and that this result would be especially unfortunate in the case of radiopharmaceuticals with their relatively short half-lives.

The primary purpose of this regulation is to ensure that the representation on the drug product label as to the manufacturer, packer, or distributor truthfully and nondeceptively reveals the connection between the person or persons named and the drug product. This purpose is served by the proper labeling of all drug products, including radiopharmaceuticals. That users of radiopharmaceuticals are professionals rather than lay consumers is not significant in determining whether radiopharmaceuticals should be subject to the standards of accurate and nondeceptive labeling. The agency believes that all users of drug products will benefit by nondeceptive labeling.

As revised, § 201.1(h)(3) permits the identification of a person or persons to whom inquiries about the drug product can be addressed. The identification of such person should make it easier for consumers to solicit and obtain relevant information about all drug products, including radiopharmaceuticals.

OTC Drug Products

43. One comment asked that OTC drug products be exempted from the requirements of the regulation. The comment claimed that the impetus for the proposed revisions to § 201.1 came from concern over the accuracy of labeling for prescription drug products and contended that any possible benefit that might come from extending the proposal to cover OTC drugs was outweighed by a number of disadvantages. In particular, the comment argued that the regulation as proposed would significantly increase label costs for many OTC manufacturers, that it would cause consumer confusion as to who was responsible for the labeled product and who should be contacted for information about the product, and that it would, in many instances, result in the "cluttering" of the drug product label with the names of a number of joint manufacturers.

The agency does not agree that OTC drug products should be exempted from the requirements of this regulation. The agency believes that the need for truthful and nondeceptive labeling information is as important for consumers of OTC drug products as it is for consumers of prescription drug products.

FDA believes that the changes that have been made to the regulation should significantly reduce, if not eliminate, the disadvantages attributed to the proposal. In particular, the changes described in paragraph 2 of this preamble should make it more likely that product labels can be written to avoid the "clutter" and confusion that might result from identifying a number of persons as joint manufacturers. These changes along with the extended effective date should also minimize whatever label costs may result from compliance with revised § 201.1.

Biological Drugs

44. One comment claimed that the regulation would impose labeling requirements on biological products that are inconsistent with present biological drug product regulatory requirements and asked that biological products be exempted from the regulation.

The agency believes that the current regulations and statutes that specifically govern biological products provide adequate assurance that the firm that is represented on the product label as manufacturer has been actually and substantially involved in the manufacture of the product. Section 351(a)(2) of the Public Health Service Act (42 U.S.C. 262(a)(2)), which relates

specifically to biological products, requires that each product be plainly marked with the name, address, and license number of the manufacturer. Thus the labels of biological products unlike the labels for other human drug products (and veterinary drugs) must bear the name of the manufacturer. In addition, § 610.63 of the regulations requires that, if two or more establishments participate in the manufacture of a biological product, the name of each firm appear on the package label. There are, however, a limited number of product licenses that include approval of one step in the manufacturing process done by a contractor. In these few instances the agency has decided that control obligations imposed on the licensee over the one manufacturing step done by a contractor are such that in the opinion of the agency, divided manufacturing responsibility labeling pursuant to § 610.63 is unnecessary. Finally, the licensing of biological drug product establishments as well as the product licensing of a biological products provide an ultimate mechanism to ensure that the person (or persons) claiming to be manufacturer have exercised complete control over the manufacturing process. In light of these specific provisions, the agency concludes that biological products should be exempted from the requirements of § 201.1.

Medical Devices

45. One comment stated that the regulation would establish a precedent which will be claimed by FDA to apply to medical devices. Another comment noted that the definition of manufacturer in the regulation governing the registration and listing of medical devices includes the person developing specifications for a product that is subsequently fabricated to those specifications by another person. The comment asked whether device specifications are so unlike specifications for drugs as to warrant different treatment.

This regulation responds to problems associated with identifying the manufacturer, packer, or distributor on drug product labels. FDA is not aware of comparable problems with respect to medical devices. In the absence of a perceived problem, FDA will not extend the principles established in this final rule to the regulation of the labeling of medical devices.

The agency emphasizes that the definition of "manufacturer" contained in this rule applies only to the labeling of drug products for purposes of section 502(a) and (b)(1) of the act. It does not affect the definition of "manufacturer" for purposes of listing and registration of drugs or medical devices.

Animal Drugs

46. Two comments stated their assumption was that the proposal was directed at human drugs alone and not intended to cover animal drugs. One comment noted that the Congressional hearings held in late summer 1978 to consider the man-in-the-plan policy were concerned with the labeling of human drugs. The comment suggested that the thrust and focus of the proposed regulation was directed to human drugs consistent with this Congressional concern. Two comments suggested that this assumption was reinforced by the fact that the conforming amendments published along with the proposed changes to § 201.1 refer only to Part 314 (21 CFR Part 314) relating to new drug applications and do not refer to Part 510 (21 CFR Part 510) relating to new animal drug applications.

The agency agrees that the focus of the Congressional hearings was with the labeling of human drug products. However, section 502(b)(1) of the act and § 201.1 of the regulation clearly apply to both human and animal drugs. Moreover, the proposed revision to § 201.1 made no distinction between human and animal drugs and on its face did apply to both. Therefore, FDA believes that adequate notice was given in the proposed regulation of agency intent that the revisions to § 201.1 would apply to animal drugs as well as human drugs.

The proposed regulation inadvertently did not contain a conforming amendment to provide for the submission of revised labeling in supplemental new animal drug applications. A conforming amendment to the relevant section of Part 510 (§ 514.8(a)(6)(ii)) will be proposed shortly.

47. One comment, which assumed that the proposal did in fact apply to animal drugs, asserted that it would not accomplish its "stated purpose" to inform the consumer of the responsible party in the event that the consumer encountered a difficulty with the product. The comment asserted that if the manufacturer who does not distribute the product is identified on the animal drug label, the user may initially contact the manufacturer in the event that he or she has a problem with the product and that this result would delay the response of the nonmanufacturing responsible party to the problem. Moreover, the comment argued that since the holder of an approved new animal drug application must assure FDA that any contract manufacturer involved in the production of the product meets the conditions of original approval, it would be misleading to imply by the proposed revision that the nonsponsor manufacturer has the primary responsibility for manufacturing controls as well as safety and efficacy of the product.

As indicated in paragraph 3 above, if there is any potential for confusion regarding who should be contacted for information about the labeled product, the label may specifically identify a person as the source of such information.

If the holder of an NADA (or NDA) for a product is not the manufacturer of that product, the agency believes that it would be false and misleading under section 502 of the act to identify the holder as the manufacturer regardless of the responsibilities borne by the holder. It should be noted that this final regulation does not change the responsibilities of either the sponsor or subcontractor with respect to manufacturing controls or the safety and efficacy of products whose manufacture may be contracted out.

48. One manufacturer complained that employees of the Bureau of Veterinary Medicine had advised the firm that it had to list the manufacturer on the animal drug label and that the listing of the packer or distributor was optional. The comment observed that the listing of the name of the manufacturer was optional.

The agency agrees that the relevant provisions of the statute and this regulation require that the drug product label bear the name and place of business of the manufacturer, packer, or distributor. Thus the choice of which person or persons are to be identified is left to the firms involved. Any informal advice given by the agency to the contrary is in error.

Economic Impact

Anticompetitive Effect

49. As noted earlier a number of comments argued that the proposal would have a substantial anticompetitive effect on the drug industry. The comments suggested that the major drug companies perceived marketing disadvantages in identifying themselves as a joint manufacturer or distributor and therefore might decide to stop contracting out certain drug manufacturing operations and invest the capital necessary to acquire the appropriate hardware and equipment for in-house production. The result, these comments claimed, would be to force

out of business (through economic failure or take-over by larger companies) many small, third-party contract lyophilizers, sterilizers, and aerosol fillers.

To assist the agency in its consideration of this argument, in the Federal Register of June 26, 1979 (44 FR 37234) the agency published a notice reopening the comment period on the proposal to solicit the information needed to evaluate the claimed anticompetitive effect. Evidence was particularly solicited on (1) the extent of and incentives for contract manufacturing, (2) how the proposed changes might reduce such incentives, (3) the extent to which this might lead to reduced use of contract manufacturing, and (4) how costs, competition, and prices might be affected. The notice contained specific questions intended to elicit evidence and comments sufficiently relevant and factual to help the agency determine whether the proposal would have an anticompetitive effect. Of the 20 additional responses received, 3 came from trade associations, 1 from a professional association, 11 from contract manufacturers or packagers, 2 from over-the-counter drug firms, and 3 from small to medium size drug firms. For the convenience of the discussion, the FDA response in paragraph 51 below follows the summary (in paragraph 50) of all significant comments received on the anticompetitive issue. The comment summaries parallel the organizational structure that was used in the June 26, 1979 notice.

What are the incentives for, and what is the extent of, the use of contract manufacturing currently?

50a. The comments suggested that the use of contract manufacturing proceeds mainly from two interrelated business motives: (1) capturing economies of scale not available to individual low-volume operations, and (2) avoiding capital outlays and other expenses for specialized plant, equipment, methods, and expertise in processes that individual firms may not be able to operate efficiently, use fully, or perhaps even afford. These factors, several comments pointed out, may permit small drug firms to avail themselves of specialized production facilities, expertise and experience without which they may not be able to compete successfully with larger firms. And, it was argued, even for larger firms, contract manufacturing permits economic production of products whose volume for the individual firm make them unattractive to produce in-house.

Other comments claimed that contract manufacturing was also of value as (1) an efficient means to handle the production of seasonal items and to handle unanticipated demand for a product customarily made in-house, (2) an efficient mode for pilot plant production of new products in their lower-volume, market-testing stages, and (3) a means of transportation cost savings to large firms through packaging at multiple subcontractor locations. Other comments stressed the value of contract manufacturing in the production of such drug products as penicillin which, if manufactured in-house, could cross-contaminate other products of a diversified manufacturer, and the quality control advantages of a double check by the contractor and the marketer.

A number of comments observed that contract manufacturing was widely and intensively used.

How and to what extent would the proposed changes reduce incentives for the use of contract manufacturing?

b. A number of comments stated that drug marketers have been traditionally reluctant to identify other firm names on product labels and have also resisted identifying themselves as distributors rather than as manufacturers. Several comments reiterated the complaints made in response to the proposal and stated that the changes would confuse consumers as to who was responsible for the product and whom to contact for product information. Moreover, the comments claimed that the revised label information could be "unsettling" to consumers who would suffer losses of product-brand association and consequently lessened confidence in brand-name products. Several comments also argued that the effect of the proposal might be to mislead rather than inform drug product users, who might assume that the products of different marketers made by the same contract manufacturer are identical when they are not.

Several comments contended that the proposal would increase the labeling costs associated with contract manufacturing, which in turn would serve as a disincentive to further use of contract manufacturing. The comments claimed that compliance with the proposed changes would entail destruction of label inventories and purchases of new plates and expenditures on new label runs when contract manufacturers were changed. One comment observed that large marketers may use two or three contract fillers to produce a single product and contended that the proposal would mean increased printing costs as separate label inventories would have to be maintained. A comment also noted that compliance with the proposed revisions would increase the risk of labeling errors.

The operational complexities as well as the costs of these changed labeling requirements, it was suggested, would reduce the incentive to use multiple contractors and to freely shift among contractors, both of which were presented as major advantages of the present system because they produce flexibility, competition, and therefore efficiency, in the production of drug products.

Considering both the incentives for use of contract manufacturing and possible reductions of these incentives associated with adverse marketing reactions, to what extent is it likely drug firms would withdraw from contract manufacturing?

c. Many comments contended that a substantial number of drug companies would reduce their reliance on contract manufacturers if the proposal were adopted. One comment stated that the amount of reduction would depend on "each company's assessment of the extent to which consumers are likely to misperceive that established, known companies use unknown companies in manufacturing their products." Several contract manufacturers said that they had been informed by marketing drug firms that their business relationships would be reduced and possibly ended if the proposal were adopted.

How and to what extent would manufacturing costs, competition, and prices of drug products be affected by withdrawals from contract manufacturing in varying degree?

d. Many comments asserted that production costs would be substantially increased for drug firms that decided to perform in-house the operations formerly contracted out. The comments stated that such firms would be compelled to invest in the capital equipment necessary to begin in-house production. Several comments argued that, given smaller volume productions and less intensive use of equipment, in-house production would be costlier per unit volume than production by subcontractors.

Several comments suggested that the loss of business by contract manufacturers would drive some or many of them out of business and that their reduced numbers would have the direct effect of lessening competition. Other commentors thought it probable that larger drug firms would tend to purchase the assets of contract manufacturers. One comment stated that such a trend already exists but that the proposed rule would accelerate it.

A comment suggested that the cost of obtaining approval to market new drugs would discourage subcontractors from trying to enter product markets on their own. For many products, a comment argued, marketers would be unwilling either to continue to contract out their manufacturing, or to make the investment necessary to begin in-house production. This would be especially true, one comment claimed, for low-volume products as these products are particularly susceptible to production cost increases. The result, it was claimed, would be to reduce product competition for many products.

Several comments stressed that the proposed changes would put smaller firms to a competitive disadvantage as these firms frequently cannot afford the cost associated with in-house production, whereas larger firms will often be capable of handling a variety of manufacturing processes internally. A comment suggested that, if the proposal were adopted, a smaller company would have no choice but to accept the "marketing disadvantages" that result from identifying the subcontractor as the manufacturer or, alternatively, identifying the small firm as distributor.

Finally, a comment observed that smaller contract manufacturers might be placed at a disadvantage if drug companies who use contract manufacturers prefer to identify larger, "more reputable" contractors on product labels.

Agency Analysis of Claimed Anticompetitive Effect

51. In publishing the June 26, 1979 notice, the agency stated that it did not have available the kinds of information required to meaningfully assess the argument that the proposed rule would have an anticompetitive effect on the drug industry. By reopening the comment period, FDA hoped that the drug firms and trade association that had originally raised the anticompetitive argument would support it with the kind of factual and analytic data that only the drug industry could readily obtain. FDA regrets that that kind of data have not been submitted. In the absence of such data, the agency has been obliged to assess the anticompetitive arguments in terms of the plausibility of their economic rationale. The agency concludes that the revisions to § 201.1 issued today should not significantly affect the competitive structure of the drug industry.

The agency of course agrees with the almost universal observation that the use of contract manufacturing services in certain situations can offer a highly flexible, efficient, and cost-saving alternative to in-house manufacturing. The agency will also concede that a firm that has previously been able to market a product while claiming to be its manufacturer may suffer some marketing disadvantages when it is no longer able to represent itself as the product's manufacturer. From this, however, it does not follow that, on balance, the economic interests of such firms lie on the side of curtailing the use of contract manufacturing and shifting to in-house manufacturing. For such a shift to be in a firm's economic interest, the marketing disadvantages that result from disclosure of the actual manufacturer (or the identification of the firm as the distributor rather than the manufacturer) would have to outweigh the cost disadvantages associated with in-house manufacturing. However, as several comments noted, such shifting would be likely to result in significant cost increases for firms making the shift and would inevitably increase prices as these cost increases were passed on to consumers. And the comments fail to demonstrate—or indeed even to establish grounds for a presumption—that the marketing disadvantages would be sufficiently great to induce firms currently using contract manufacturing services to abandon or reduce their use of these services and accept the cost penalties stated to be involved. (The fact that many drug marketers already acknowledge the subcontractor as the actual manufacturer suggests a truly limited marketing disadvantage in accurate manufacturer identifications.)

Even if some firms using contract manufacturing services did shift to in-house manufacture, it is not clear that, having made the shift, they could successfully compete in marketing their product. In other words, a further condition is also essential to the anticompetitive argument: that many or most of the firms now using contract services could make such a shift successfully in a competitive market. That is, for there to be the possibility of an anticompetitive effect, the firms involved, acting independently, would not only have to adopt unnecessarily costly modes of production but would also have to succeed in passing on the cost increments in product prices despite lower-priced competition from firms who market the same drug products without claiming to be their manufacturers. If, as the anticompetitive arguments imply, the present market is a competitive one, and if contract arrangements are part of its efficiencies, it is hardly plausible that it could be transformed into a less competitive, higher-priced market by the individual decisions of numerous firms. The ability to do so would suggest a degree of market control and concerted action that would belie the existence of a competitive market in the first place. For these reasons, the agency finds the anticompetitive arguments offered by commentors unpersuasive.

While the agency has not been persuaded that the proposed rule would have a significant anticompetitive effect on the drug industry, the comments have influenced the agency's consideration of the need to make the final rule more flexible. A number of the changes made in the final rule (particularly those described in paragraph 2 above) should reduce whatever tendency might have existed under the propsal to reduce the incentives for use of contract manufacturing services.

52. In addition to the comments that suggested that the proposed charges would have an anticompetitive effect on the drug industry, a number of comments were submitted that argued that the direct economic consequences of the proposed regulation would be substantial. The comments contended that if the proposal were adopted, considerable present stocks of labels would have to be destroyed and the products relabeled to comply with the requirements of the regulation. One comment noted that for labeling which may be prepared 6 to 9 months in advance and which is silk screened on glass or on plastic product containers, a labeling change caused by a manufacturing breakdown or scheduling difficulty would require that the misbranded containers be destroyed. Several comments recommended that in light of the direct and indirect cost impacts of the proposal, the agency should file a meaningful economic impact statement.

The agency agrees that there may be some direct cost impacts resulting from adoption of the final rule. The agency considered this impact when determining an appropriate effective date.

In light of the delayed effective date, the agency believes that drug firms will have ample time to exhaust their label inventories so that the need to destroy present stocks of labels and to relabel will be negligible.

For products with silk-screened labeling, the agency also agrees that manufacturing breakdowns, etc., could cause additional labeling costs. Some of these costs, the agency believes, are the unavoidable result of a policy that demands that the information on drug product labels be truthful and nondeceptive. Moreover, many of the potential costs attributable to the

proposal should be avoidable under the more flexible and accommodating final rule. Finally, the agency believes that any cost impact that remains can be significantly reduced by skillful management of such contract arrangements, reduced label inventories, and so on.

In preparing the regulatory analysis assessment the agency considered the direct costs that would result from the proposed rule and concluded that these costs were "quite limited." This conclusion did not take into account all direct costs associated with the proposed rule or include all possible indirect costs, particularly with respect to the possible influence of the proposal on the competitive structure of the drug industry. However, in light of the change in the regulation, including the extended effective date, the agency believes that the regulation should not cause a significant economic impact and concludes that there is no reason to revise the initial regulatory analysis assessment.

Effective Dates

53. Several comments objected to the proposed effective date provisions. The proposal stated that the final rule would be effective 60 days after publication in the **Federal Register** (except for proposed § 201.1(f) (1) and (2) which would be effective 12 months after publication). The comments suggested that the 60-day effective date provision would force substantial relabeling, create significant losses in printed labels on hand, possibly disrupt the supply of critical drugs, and significantly increase the demand on existing printing facilities and equipment. As a result, the comments claimed, expenses associated with the labeling of drug products would substantially increase. Comments argued that a 12-month effective date provision would avoid the difficulties attributed to the 60-day provision. Comments asserted that the preamble's justification for a 12-month effective date for proposed § 201.1(f) would apply equally as well to the other provisions of the rule. A comment stated that extending the effective date to 12 months for the entire proposal would be consistent with FDA's policy respecting the permissible time allowed for labeling changes where no apparent safety issue is involved. In addition, several comments urged that instead of basing the effective date on the date of introduction or delivery for introduction into interstate commerce the provision should be based on the date of manufacture or packaging. One comment stated that this revision would ensure a smooth changeover to the new policy for both the manufacturers and for FDA.

For the reasons stated in the comments, FDA has decided to make all provisions of this final rule effective April 10, 1981, for drugs and drug products initially introduced or initially delivered for introduction into interstate commerce. The agency is confident that the delayed effective date should give ample time to exhaust present stocks of labels and to ensure that, on the effective date, all drugs and drug products introduced into or delivered for introduction initially into interstate commerce are labeled in compliance with the provisions of this final rule.

54. In the **Federal Register** of June 26, 1979 (44 FR 37434), FDA issued a final regulation which revised the requirements for the content and format of prescription drug labeling. Section 201.100(e) of that regulation required that all labeling bear conspicuously the name and place of business of the manufacturer, packer, or distributor as required for the label of the drug under § 201.1. As finalized, § 201.1(e) was scheduled to become effective June 26, 1980, or when printing plates were revised in the normal course of business, whichever occurred first. As noted above, the effective date for revised § 201.1 is April 10, 1981. Because the changes to drug labeling mandated by § 201.100(e) are so closely related to the changes that must be made to drug labels under § 201.1, the agency concludes that a single effective date for both final rules is appropriate. The effective date for § 201.100(e) is therefore extended to April 10, 1981. Of course, FDA encourages all drug firms to comply voluntarily with the revised labeling requirements as soon as practicable and before the effective date.

55. One comment stated that FDA has in the recent past issued several final rules which require labeling changes for prescription drugs. The comment noted that each of these regulations (in particular the final rules describing drug current good manufacturing practice and the rule defining prescription drug dispensing container requirements) has a different effective date. The comment argued that compliance with a variety of different effective dates is costly and asked that the effective dates for all of these rules be made uniform.

While the regulations cited in the comment have already become effective, and therefore are no longer candidates for a uniform effective date, as described above, FDA has established a uniform effective date for § 201.100(e) and this final regulation. The agency strongly believes that under certain circumstances uniform effective dates are a desirable means to reduce the costs and burdens associated with labeling revisions. FDA is considering developing a more formal policy concerning uniform effective dates for labeling changes required by regulation for drugs for human use.

Miscellaneous

Trade Correspondence

56. In the 1940's FDA issued two informal opinions regarding who could properly claim to be manufacturer of a drug product: Trade Correspondence 107 issued February 29, 1940, and Trade Correspondence 302 issued August 20, 1940. As these opinions are not consistent with the provisions of this final regulation, they are no longer applicable and are hereby revoked.

Place of Business

57. Section 201.1(i) currently requires that the statement of the place of business of the manufacturer, packer, or distributor include the street address, city, State, and ZIP Code on the product label (the street address may be omitted if it is shown in a current city directory or telephone directory). This section clearly describes what must be included in the address of a domestic manufacturer, packer, or distributor. The section has not specifically stated what must be included in the address of a foreign manufacturer, packer, or distributor. To clarify what must be included, the agency has added a provision in § 201.1(i) stating that for a foreign manufacturer, packer, or distributor, the statement of the place of business shall include the street address, city, and country and any applicable mailing code.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 502, 701(a), 52 Stat. 1050–1051 as amended 1055 (21 U.S.C. 352, 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Title 21 of the Code of Federal Regulations is amended as follows:

PART 201—LABELING

1. By revising § 201.1 to read as follows:

§ 201.1 Drugs; name and place of business of manufacturer, packer, or distributor.

(a) A drug or drug product (as defined in § 320.1 of this chapter) in finished package form is misbranded under section 502(a) and (b)(1) of the act if its label does not bear conspicuously the name and place of business of the manufacturer, packer, or distributor.

This paragraph does not apply to any drug or drug product dispensed in accordance with section 503(b)(1) of the act.

(b) As used in this section, and for purposes of section 502(a) and (b)(1) of the act, the manufacturer of a drug product is the person who performs all of the following operations that are required to produce the product: (1) Mixing, (2) granulating, (3) milling, (4) molding, (5) lyophilizing, (6) tableting, (7) encapsulating, (8) coating, (9) sterilizing, and (10) filling sterile, aerosol, or gaseous drugs into dispensing containers.

(c) If no person performs all of the applicable operations listed in paragraph (b) of this section, no person may be represented as manufacturer except as follows:

(1) If the person performs more than one half of the applicable operations listed in paragraph (b) of this section and acknowledges the contribution of other persons who have performed the remaining applicable operations by stating on the product label that "Certain manufacturing operations have been performed by other firms."; or

(2) If the person performs at least one applicable operation listed in paragraph (b) of this section and identifies by appropriate designation all other persons who have performed the remaining applicable operations, e.g., "Made by (Person A), Filled by (Person B), Sterilized by (Person C)"; or

(3) If the person performs at least one applicable operation listed in paragraph (b) of this section and the person is listed along with all other persons who have performed the remaining applicable operations as "joint manufacturers." A list of joint manufacturers shall be qualified by the phrase "Jointly Manufactured By ————," and the names of all of the manufacturers shall be printed together in the same type size and style; or

(4) If the person performs all applicable operations listed in paragraph (b) of this section except for those operations listed in paragraph (d) of this section.

(d) The Food and Drug Administration finds that it is the common practice in the drug industry to contract out the performance of certain manufacturing operations listed in paragraph (b) of this section. These operations include: (1) Soft-gelatin encapsulating, (2) aerosol filling, (3) sterilizing by irradiation, (4) lyophilizing, and (5) ethylene oxide sterilization.

(e) A person performs an operation listed in paragraph (b) of this section only if the operation is performed, including the performance of the appropriate in-process quality control operations, except laboratory testing of samples taken during processing, as follows:

(1) By individuals, a majority of whom are employees of the person and, throughout the performance of the operation, are subject to the person's direction and control;

(2) On premises that are continuously owned or leased by the person and subject to the person's direction and control; and

(3) On equipment that is continuously owned or leased by the person.

(f) The name of the person represented as manufacturer under paragraph (b) or (c) must be the same as the name of the establishment (as defined in § 207.3(b) of this chapter) under which that person is registered at the time the labeled product is produced. In addition, the name shall meet the requirements of paragraph (g) of this section.

(g) The requirement for declaration of the name of the manufacturer, packer, or distributor shall be deemed to be satisfied, in the case of a corporation, only by the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation. A separately incorporated subsidiary shall use its actual corporate name and not the name of its parent company. However, if it chooses, a separately incorporated subsidiary may also identify its parent corporation. Abbreviations for "Company," "Incorporated," etc., may be used and "The" may be omitted. In the case of an individual, partnership, or association, the name under which the business is conducted shall be used.

(h)(1) Except as provided in this section, no person other than the manufacturer, packer, or distributor may be identified on the label of a drug or drug product.

(2) The appearance on a drug product label of a person's name without qualification is a representation that the named person is the sole manufacturer of the product. That representation is false and misleading, and the drug product is misbranded under section 502(a) of the act, if the person is not the manufacturer of the product in accordance with this section.

(3) If the names of two or more persons appear on the label of a drug or drug product, the label may identify which of the persons is to be contacted for further information about the product.

(4) If a trademark appears on the drug or drug product label or appears as a mark directly on the drug product (e.g., tablet or capsule), the label may identify the holder or licensee of the trademark. The label may also state whether the person identified holds the trademark or is licensee of the trademark.

(5) If the distributor is named on the label, the name shall be qualified by one of the following phrases: "Manufactured for ————", "Distributed by ————", "Manufactured by ———— for ————", "Distributor: ————", "Marketed by ————". The qualifying phrases may be abbreviated.

(6) If the packer is identified on the label, the name shall be qualified by the phrase "Packed by ————" or "Packaged by ————". The qualifying phrases may be abbreviated.

(i) The statement of the place of business shall include the street address, city, State, and ZIP Code. For a foreign manufacturer, the statement of the place of business shall include the street address, city, country, and any applicable mailing code. The street address may be omitted if it is shown in a current city directory or telephone directory. The requirement for inclusion of the ZIP Code shall apply to consumer commodity labels developed or revised after July 1, 1969. In the case of nonconsumer packages, the ZIP Code shall appear either on the label or the labeling (including the invoice).

(j) If a person manufactures, packs, or distributes a drug or drug product at a place other than the person's principal place of business, the label may state the principal place of business in lieu of the actual place where such drug or drug product was manufactured or packed or is to be distributed, unless such statement would be misleading.

(k) Paragraphs (b), (c), (d), (e), and (f) of this section, do not apply to the labeling of drug components.

(l) A drug product is misbranded under section 502(a) of the act if its labeling identifies a person as manufacturer, packer, or distributor, and that identification does not meet the requirements of this section.

(m) This section does not apply to biological drug products that are subject to the requirements of section 351 of the Public Health Service Act, 42 U.S.C. 262.

PART 207—REGISTRATION OF PRODUCERS OF DRUGS AND LISTING OF DRUGS IN COMMERCIAL DISTRIBUTION

2. By revising § 207.20(a) to read as follows:

§ 207.20 Who must register and submit a drug list.

(a) Owners or operators of all drug establishments, not exempt under

section 510(g) of the act or Subpart D of this Part 207, that engage in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs are required to register and to submit a list of every drug in commercial distribution (except that listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments). Such owners or operators are required to register and to submit a list of every drug in commercial distribution (except that listing information may be submitted by the parent, subsidiary, and/or affiliate company for all establishments when operations are conducted at more than one establishment and there exists joint ownership and control among all the establishments), whether or not the output of such establishment or any particular drug so listed enters interstate commerce, except that drug listing is not required at this time for the manufacturing, preparation, propagation, compounding, or processing of an animal feed (including a feed concentrate, a feed supplement, and a complete animal feed) bearing or containing an animal drug. No owner or operator may register an establishment, if any part of the establishment is registered by any other owner or operator.

* * * * *

3. By revising § 207.26 to read as follows:

§ 207.26 Amendments to registration.

Changes in individual ownership, corporate or partnership structure location or drug-handling activity, shall be submitted by Form FD–2656 (Registration of Drug Establishment) as amendment to registration within 5 days of such changes. A change in a registered establishment's firm name within 6 months of the registration of the establishment is required to be supported by a signed statement of the establishment's owner or operator that the change is not made for the purpose of changing the name of the manufacturer of a drug product under § 201.1 of this chapter. Changes in the names of officers and directors of the corporations do not require such amendment but must be shown at time of annual registration.

PART 314—NEW DRUG APPLICATIONS

4. By revising § 314.8(a)(6)(ii) to read as follows:

§ 314.8 Supplemental applications.

(a) * * *

(6) * * *

(ii) There are no changes from the conditions of the approved application except for a different and suitable proprietary name of the drug (if one is used) and the name and address of the distributor as used on the label and labeling. The name of the distributor shall be accompanied by a qualifying phrase permitted under § 201.1(h) of this chapter.

* * * * *

Effective date. This regulation shall be effective April 10, 1981, for drugs and drug products initially introduced or initially delivered for introduction into interstate commerce. It also extends the effective date of § 201.100(e) (21 CFR 201.100(e)), which requires that prescription drug labeling bear the name and place of business of the manufacturer, packer, or distributor, to April 10, 1981.

(Secs. 502, 701(a), 52 Stat. 1050–1051 as amended, 1055 (21 U.S.C. 352, 371(a)))

Dated: April 8, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11061 Filed 4–11–80; 8:45 am]

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federal register

Tuesday
April 15, 1980

Part IV

Department of Energy

Economic Regulatory Administration

Electric Power System Permits and Reports Applications; Administrative Procedures and Sanctions

DEPARTMENT OF ENERGY

Economic Regulatory Administration

10 CFR Part 205

[Docket No. ERA-R-80-03]

Electric Power System Permits and Reports Applications; Administrative Procedures and Sanctions

AGENCY: Economic Regulatory Administration.

ACTION: Notice of proposed rulemaking and public hearings.

SUMMARY: The Economic Regulatory Administration (ERA) of the Department of Energy (DOE) hereby gives notice of a proposal to implement the provisions of Section 202(e) of the Federal Power Act and Executive Order 10485, as amended by Executive Order 12038. Section 202(e) of the Federal Power Act specifies that the export of electric energy shall be authorized provided that the proposed transmission will not impair the sufficiency of electric supply within the United States or impede or tend to impede the coordination in the public interest of facilities subject to the jurisdiction of the DOE. Section 202(e) further provides the authority to impose such terms and conditions on the export authorization as may be appropriate. Executive Order 10485, dated September 3, 1953, as amended by Executive Order 12038, dated February 3, 1978, establishes the procedures and standards for issuance of a Presidential Permit authorizing the construction, connection, operation and maintenance of electrical transmission facilities at international boundaries.

In accordance with the DOE Organization Act and pursuant to the DOE Delegation Order No. 0204–4, the ERA has been delegated the responsibility by the Secretary of the DOE for the regulation of international electricity exports. It is anticipated that the rules proposed herein will supersede 18 CFR 32.30–32.38 and 32.50–32.52, which ERA has been following pursuant to Section 705 of the DOE Organization Act (42 U.S.C. Section 7295).

DATES: Comments on this proposed rule are invited and should be submitted on or before May 9, 1980. Requests to speak at the public hearing are due by April 22, 1980. Hearing date: April 29, 1980.

ADDRESSES: Mail all comments to: Department of Energy, Docket Control Center, Docket No. ERA–R–80–03, Department of Energy, Office of Public Hearing Management, Room 2313, 2000 M Street, N.W., Washington, D.C. 20461. Requests to speak at the Public Hearing should be addressed to: Office of Public Hearing Management, Docket No. ERA–R–80–03, Room 2313, 2000 M Street, N.W., Washington, D.C. 20461.

FOR FURTHER INFORMATION CONTACT:

James M. Brown, Jr., System Reliability and Emergency Response Branch, Department of Energy, Room 4110, 2000 M St., N.W., Washington, D.C. 20461, (202) 653–3825.

Lise Courtney Howe, Office of General Counsel, Department of Energy, Room 5E–064, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, (202) 252–2900.

ERA Docket Room, Room 2313, 2000 M Street, N.W., Washington, D.C. 20461.

SUPPLEMENTARY INFORMATION:

Background and Purpose

On October 1, 1977, the authority to regulate exports of electricity was transferred to and vested in the Secretary of Energy pursuant to Sections 301 and 402(f) of the DOE Organization Act. Responsibility for the review and consideration of such applications to export electricity was delegated to the Administrator of the Economic Regulatory Administration by the DOE Delegation Order No. 0204–4 (42 FR 60726). Prior to this, authority resided with the Federal Power Commission under Section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

The Economic Regulatory Administration advises that it is herein proposing regulations relating to applications for authorization to transmit electric energy to a foreign country and regulations relating to applications for construction, operation, maintenance or connection at an international boundary of facilities for the transmission of electric energy. The new regulations will be incorporated into 10 CFR 205.300 through 205.309, and 205.320 through 205.326, respectively. The final amended rulemakings will supersede 18 CFR 32.30 through 32.38, and 32.50 through 32.52.

Proposed Rule

The proposed rule changes:

1. *Changes to the rule governing authorizations to export electric energy (10 CFR 205.300 to 205.309).* The ERA is expanding the data to be submitted in applications for authorization to export electric energy. Changes made to the existing rules are as follows:

a. All references to "the Commission" have been changed to read "ERA" in accordance with Section 402(f) of the DOE Organization Act (42 U.S.C. Section 7172) and the DOE Delegation Order 0204–4.

b. The definition of who shall apply under § 205.300 of the proposed rule has been changed to specify that the rule is applicable only to electric utilities subject to jurisdiction under Part II of the Federal Power Act. This rewording eliminates confusion caused by the current regulations which state that any "owner of a source of supply of electric energy shall apply" even though the basis for the regulation is Part II of the Federal Power Act.

c. The time of filing prior to initiation of the export has been increased from 30 days to six months to provide sufficient time to publish a **Federal Register** notice inviting public comments and to accomplish the environmental assessment as required by the National Environmental Policy Act.

d. Minor changes have been made in § 205.302 concerning requirements for the contents of an application (previously 18 CFR 32.32(d)). The requirement that a copy of the rates proposed to be charged for the exported electric energy has been removed from this section and placed in § 205.303 as Exhibit A. Additional information is being requested such as the legal name of all partners of the applicant (Section 205.302(b)). Information required concerning electricity to be exported has been expanded to include the address of any other Federal, state or local government agency which may have jurisdiction over the action to be taken in this application. This information will enable the ERA to coordinate the export authorization process with other interested government agencies.

In addition the applicant will be required to submit a description of the facilities to which the electric energy will be delivered in the foreign country, including the name of the owner(s) and the location of the facility(s) and to provide a discussion of the impact of the proposed electricity export on the applicant's present and prospective system, considering overall system reliability, fuel use and system development. The requirement for the applicant to provide this data is necessary so that the ERA can satisfy the requirement in Section 202(e) of the Federal Power Act that the authorization be issued unless "the proposed transmission would impair the sufficiency of electric supply within the United States or would impede or tend to impede the coordination of facilities subject to jurisdiction of the commission."

e. Under § 205.303 the exhibits required have been modified from the requirements in 18 CFR 32.51. As stated above, Exhibit A requires that the proposed rates be filed together with similar information regarding such service if provided within the United States. This exhibit is a consolidation of

provisions found in 18 CFR 32.32(d) and 18 CFR 32.33, Exhibit A. Exhibit C has been amended to delete the scale requirement for the general or key map, while the applicant is now requested to identify the border crossing point by Presidential Permit number.

The requirement (Exhibit E) to show corporate relationships or existing contracts between the applicant and other corporations or governments has been made more specific; however, it is similar to the language found previously in 18 CFR 32.51(c).

The requirement to provide copies of articles of incorporation and bylaws of the applicant company has been deleted.

To ensure the maximum benefits to consumers in the United States each applicant will be required to develop a plan for informing any electric utility with a service area border common with the applicant's prior to any electricity transactions with the foreign utility. Diversity exchanges and emergency transfers are exempted from this requirement (Exhibit F). This new requirement will in part fulfill the coordination review required by the statute and will ensure protection of the public interest.

f. In § 205.304, the exemption from filing certain information in applications for the export of less than 1,000,000 kilowatt hours annually, which was found in 18 CFR 32.34, has been revised to correspond to the new filing requirements. The exemption remains so that low quantity exports authorization applications are simplified.

g. After reviewing the rules pursuant to the DOE's responsibilities under the National Environmental Policy Act of 1969 [42 U.S.C. Section 4321 *et seq.*], the DOE has determined that the proposed action does not constitute a Federal action significantly affecting the quality of the human environment. Therefore, no environmental assessment or environmental impact statement was prepared and a finding of no significant impact to that effect is hereby issued.

2. *Changes to the regulations for applications for Presidential Permits authorizing construction, connection, operation and maintenance of electric energy transmission facilities at international boundaries (10 CFR 205.320 to 205.326).* These proposed regulations are an expansion of 18 CFR 32.50 *et seq.*, so as to require an application to include more technical and environmental data. The majority of changes are found in § 205.321 concerning the required contents of the application. The application is subdivided into four major subsections:

1. Information about the applicant;
2. Information regarding the facility;
3. Environmental data; and
4. Alternatives to the project.

Changes made in the regulations are as follows:

a. All references to "the Commission" have been changed to read "ERA" in accordance with Section 402(f) of the DOE Organization Act (42 U.S.C. Section 7122) and the DOE Delegation Order 0204–4.

b. The applicant, under § 205.321(a)(2) of the proposed rule, must now include the legal names of all partners and show, under § 205.321(a)(6), that the proposed facility is within its corporate powers and that the applicant has complied with the applicable state laws.

c. The information required in § 205.321(b)(1), (2) and (3) of the proposed regulations is considerably more detailed than that which has previously required. Applicant is requested to provide a technical description of the proposed transmission line(s). Applicant is also required to distinguish facilities already constructed from those proposed to be constructed.

If the applicant proposes to operate the facility at more than 138 kilovolts, additional technical data, such as power transfer capability, effect on power system reliability, system power flow plots, stability analysis, for the applicant and his Fuel Use Regional area are required. Also, data on television and radio interference that may be caused by the proposed transmission line are required to be filed under § 205.321(b)(3). These additional data are required because power system facilities above 138 kilovolts will normally have a significant impact on the adequacy of the bulk power system. Consequently, this required information is necessary to assess adequately the impact of the proposed facility. Facilities operated at less than 138 kilovolts are generally local area feeder lines and will usually have minimal impact on the bulk power system.

d. A major subsection on environmental data has been added to assist the DOE in making a determination as to the necessity for an environmental impact statement in compliance with the National Environmental Policy Act (Pub. L. No. 91–190, 42 U.S.C. Section 4321 *et seq.*) and 10 CFR Part 208.

General environmental data on the border crossing and the connecting transmission line are required in § 205.321(c). The applicant shall provide information on the type of land to be used for the facility and whether the facility will cross or impact upon floodplains, wetlands, or national historic sites. Details regarding right-of-way widths for transmission lines must be included. The environmental data shall also include a list of local threatened or endangered species.

e. Section 205.321(d) requires a brief description of alternatives to the proposed facility and a discussion of whether the alternatives would have a lesser or greater environmental economic impact.

f. A requirement that each application shall be signed and verified by an officer of the applicant is added in § 205.321(a)(7).

g. After reviewing the rules pursuant to DOE's responsibilities under the National Environmental Policy Act, DOE has determined that the proposed action does not constitute a Federal action significantly affecting the quality of the human environment. Therefore, no environmental assessement or environmental impact statement was prepared and a finding of no significant impact to that effect is hereby issued.

3. *General changes pertinent to both rules occur in the sections concerning transferability, form and style, annual reports and filing fees.*

a. Section 205.305(a) covering transferability remains basically unchanged from 18 CFR 32.35 except that the section which read "shall continue in effect temporarily for a reasonable time thereafter * * *." now reads "shall continue in effect temporarily * * *.", and where it read "provided notice is promptly given in writing * * *.", it now reads "provided notice is given to ERA in writing within 30 days * * *.". A section similar to § 205.305(a) is also added as § 205.322(a). Under § 205.322(c), changes to facilities authorized by permit must have prior approval from ERA and, under subsection (d), permits may me modified or revoked by the President of the United States, or by the Administrator of ERA after public notice and may be amended by ERA upon proper application thereto. A new § 205.305(b) has been added which provides that in the event of a proposed transfer the transferor and transferee will file a joint application, pursuant to §§ 205.300–204.304, and include a statement of reasons for the transfer. A similar section has been added to § 205.322(b).

b. ERA proposes the requirement of an original and ten conformed copies of an application under § 205.307 governing applications for export authorization and § 205.323 governing Presidential Permit applications. 18 CFR 32.37 required that an original and six copies be filed; 18 CFR 32.50 required an original and eight copies.

c. Section 205.308(a) requires persons authorized to export electric energy to file supplements, notices of succession in ownership or operation, notices of cancellation and certificates of concurrence with respect to such energy within 30 days of the action. Applicants are also required to submit an annual report to ERA showing the gross amount of kilowatt hours of energy received or delivered, the cost and revenue associated with the transfer (Section 205.308(d) and § 205.324). Subsections 205.308 (b) and (c) provide that persons authorized to export electric energy shall file a certified copy of the current rate schedule for that energy.

Accordingly, such rates may take effect upon filing with ERA. This departure from FPC procedure is proposed in order to avoid unnecessary United States Federal agency review of rates which generally are the result of arms-length bargaining between two utilities and subject to review by the appropriate governmental agency in the importing nation.

d. The filing fees of $500 and $150 established in §§ 205.309 and 205.325 are identical to fees currently in effect.

e. Requirements that each application must be accompanied by the proper fee in order to be accepted and processed and information on how fee payment is to be made are added in § 205.309 and § 205.325.

Public Hearing and Comment Procedures

1. *Written Comments.* You are invited to participate in this proceeding by submitting information, opinions or arguments, with respect to the proposals set forth in this Notice. Comments should be submitted by 4:30 p.m., e.s.t., May 9, 1980, to the address indicated in the "Addresses" section of this Notice and should be identified on the outside envelope and on documents submitted, with the designation "Procedures for Electricity Export Authorization and Presidential Permit Authorization," Docket No. ERA–R–80–03.

Five copies should be submitted. All comments received will be available for public inspection in the DOE Freedom of Information Office, GA–152, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, and the ERA Office of Public Information, Room B–110, 2000 M Street, N.W., Washington, D.C. 20461, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except holidays.

Any information or data submitted which is considered to be confidential must be so identified and submitted in writing, one copy only. DOE reserves the right to determine the confidential status of such information or data and to treat it according to its determination.

2. *Public Hearings.*

a. *Procedures for request to make oral presentation.* The times and places for the hearing are indicated in the "Dates" and "Addresses" sections of this Notice. If you are interested in this proposed rule or represent a person, group or class of persons that has an interest, you may make a written request for an opportunity to speak at the public hearing. Requests to speak must be sent to the address shown in the "Addresses" section and must be received by April 22, 1980.

You should provide a phone number where you may be reached through the day before the hearing. If you are selected to participate in the hearing, you will be so notified on or before April 25, 1980, for the April 29 hearing. You should submit 25 copies of your statement by 4:30 p.m. on April 28, 1980, to Public Hearing Management, U.S. Department of Energy, Room 2313, 2000 M Street, N.W., Washington, D.C. 20461.

b. *Conduct of the hearing.* We reserve the right to schedule participants' presentations and to establish the procedures governing the conduct of the hearing. ERA may limit the length of each presentation, based on the number of persons requesting to be heard. ERA encourages groups that have similar interests to choose one appropriate spokesperson qualified to represent the views of the group.

An official of the ERA will be designated to preside at the hearing. It will not be a judicial-type hearing. Questions may be asked only by those conducting the hearing. At the conclusion of all initial oral statements, each person who has made an oral statement may be given the opportunity, if time permits, to make a rebuttal statement. Rebuttal statements, if allowed, will be given in the order in which the initial statements were made and will be subject to time limitations.

If you wish to ask a question at the hearing, you must submit it in writing to the presiding officer on the day of the hearing. The presiding officer will determine whether time limitations permit it to be presented for answer.

The presiding officer will announce any further procedural rules needed for the proper conduct of the hearing.

ERA will have a transcript made of the hearing, and ERA will retain the entire record of the hearing, including the transcript, and make it available for inspection at the DOE Freedom of Information Office, Room GA–152, Forrestal Building, 1000 Independence Avenue, S.W., Washington, D.C. 20585, and the ERA Office of Public Information, Room B–110, 2000 M Street, N.W., Washington, D.C. 20461, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday. A copy of the transcript may be purchased from the reporter.

In consideration of the foregoing, the Department of Energy proposes to add Subpart W of Part 205 of Chapter II, Title 10, Code of Federal Regulations, to read as set forth below.

Issued in Washington, D.C., on April 7, 1980.

Hazel R. Rollins,

Administrator, Economic Regulatory Administration.

It is proposed to amend Part 205, Chapter II of Title 10, Code of Federal Regulations by adding Subpart W—Electric Power System Permits and Reports Applications containing §§ 205.300–205.309 and 205.320–205.326 as follows:

PART 205—ADMINISTRATIVE PROCEDURES AND SANCTIONS

Subpart W—Electric Power System Permits and Reports

Application for Authorization to Transmit Electric Energy to a Foreign Country

Sec.

Application for Presidential Permit Authorizing the Construction, Connection, Operation, and Maintenance of Facilities for Transmission of Electric Energy at International Boundaries

Authority: Department of Energy Organization Act, Pub. L. No. 95–91, 91 Stat. 565 (42 U.S.C. Section 7101). Federal Power Act, Pub. L. 66–280, 41 Stat. 1063, (16 U.S.C. Section 792 et seq.). Department of Energy Delegation Order No. 0204–4 (42 FR 60726). EO 10485, 18 FR 5397, 3 CFR, 1949–1953 Comp., p. 970; as amended by EO 12038, 43 FR 4957, 3 CFR 1978 Comp., p. 136.

Subpart W—Electric Power System Permits and Reports

Application for Authorization to Transmit Electric Energy to a Foreign Country

§ 205.300 Who shall apply.

(a) An electric utility or other entity subject to jurisdiction under Part II of the Federal Power Act who proposes to transmit any electricity from the United States to a foreign country is a necessary party to an application for this authorization sought under Section 202(e) of the Federal Power Act. The application shall be submitted to the Office of Utility Systems of the Economic Regulatory Administration (ERA).

(b) In connection with an application under §§ 205.300 through 205.309, attention is directed to the provisions of §§ 205.320 through 205.326, of this subpart, concerning applications for Presidential Permits for the construction, connection, operation, or maintenance, at the borders of the United States, of facilities for the transmission of electric energy between the United States and a foreign country in compliance with Executive Order 10485, as amended by Executive Order 12038.

§ 205.301 Time of filing.

Each application should be made at least six months in advance of the initiation of the proposed electricity export.

§ 205.302 Contents of application.

Every application shall contain the following information set forth in the order indicated below:

(a) The exact legal name of the applicant;

(b) The exact legal name of all partners;

(c) The name, title, post office address, and telephone number of person to whom correspondence in regard to the application shall be addressed;

(d) The state or territory under the laws of which the applicant is organized or incorporated, or authorized to operate. If the applicant is authorized to operate in more than one state, all pertinent facts should be included;

(e) The address of any other Federal, state or local government agency which may have any jurisdiction over the action to be taken in this appliaction and a brief description of that authority;

(f) Description of the facilities to which the electric energy will be delivered in the foreign country, including the name of the owners and the location of the facilities;

(g) Discussion of the impact of the proposed electricity export on the applicant's present and prospective electric power supply system, considering overall system reliability, fuel use and system stability. Applicant shall explain why the proposed electricity export will not impair the sufficiency of electric supply and will not impede or tend to impede the coordination of electric utility planning or operation within the applicant's service area and within the appropriate Fuel Use Electric Region;

(h) The original application shall be signed and verified under oath by an officer of the applicant having knowledge of the matters set forth therein.

§ 205.303 Required exhibits.

There shall be filed with the application and as a part thereof the following exhibits:

Exhibit A. Copy of the agreement or proposed agreement under which the electricity is to be transmitted and all other applicable written instruments regarding the terms and conditions proposed to be charged to the foreign purchaser together with similar information regarding such service if rendered in the United States.

Exhibit B. A showing, including signed opinion of counsel, that such export of electricity is within the corporate power of the applicant, and that the applicant has complied or will comply, with all pertinent Federal and state laws. This showing shall identify the Presidential Permit to be used for the proposed export.

Exhibit C. A general map showing the applicant's overall system and a detailed map highlighting the location of the facilities used or the proposed facilities to be used for the generation and transmission of electric energy to be exported and the point or proposed point of transfer of such energy. The detailed map shall identify the border crossing points by Presidential Permit number whenever possible.

Exhibit D. If an applicant resides or has its principal office outside the United States, such applicant shall designate by irrevocable power of attorney an agent residing within the United States upon whom service of notice and process with respect to transmission of electric energy may be had; a verified copy of such power of attorney shall be furnished with the application.

Exhibit E. A statement of any corporate relationship or existing contract between applicant and any other person, corporation, or foreign government, which in any way relates to the control or fixing of rates for the purchase, sale or transmission of electric energy and which may serve in any way to restrict or prevent competing U.S. companies from extending their activities.

Exhibit F. An explanation of the methodology to be employed to inform other United States electric utilities of the available capacity and energy which may be in excess of applicant's requirements before delivery of such capacity to the foreign purchaser. Diversity exchange and emergency situations are exempted from this requirement. Those materials required by this section previously filed by the applicant with the ERA, since the establishment of the Department of Energy, may be incorporated by reference.

§ 205.304 Other information.

Where the application is for authority to export less than 1,000,000 kilowatt hours annually, applicants need not furnish the information called for in §§ 205.32(g) and 205.303 (Exhibit C). Applicants, regardless of the amount of electric energy to be exported, may be required after filing the application to furnish such supplemental information as the ERA may deem pertinent.

§ 205.305 Transferability.

(a) An authorization to transmit electric energy from the United States to a foreign country granted by order of ERA under Section 202(e) of the Federal Power Act shall not be transferable or assignable. The ERA order granting the authorization may, however, provide that the authorization shall continue in effect temporarily in the event of the involuntary transfer by operation of law (including such transfers to receivers, trustees, or purchasers under foreclosure or judicial sale) pending the making of an application for permanent authorization and decision thereon, provided notice is given to the ERA in writing within 30 days accompanied by a statement that the physical facts relating to sufficiency of supply, rates, and nature of use remain substantially the same as before the transfer and as stated in the initial application for such authorization.

(b) In the event of a proposed voluntary transfer, including transfer of authority to export electricity, the transferee and the transferor shall file jointly an application pursuant to this subsection, setting forth such information as required by Sections 250.300 through 304, together with a statement of reasons for the transfer.

(c) The ERA may at any time subsequent to the original order of authorization, after opportunity for hearing, issue such supplemental orders to the original order as it may find necessary or appropriate.

§ 205.306 Authorization not exclusive.

No authorization granted pursuant to Section 202(e) of the Act shall be deemed to prevent authorization from being granted to any other person or

entity to transmit electric energy for the same use, or to prevent any other person or entity from making application for such authorization.

§ 207.307 Form and style; number of copies.

An original and ten conformed copies of an application under §§ 205.300 through 205.309 must be filed and must conform in all other respects to the requirements of Section 205.4 through 205.9 of this chapter.

§ 205.308 Filing schedule and annual reports.

(a) Persons authorized to transmit electric energy from the United States shall file all supplements, notices of succession in ownership or operation, notices of cancellation, and certificates of concurrence with respect to such energy at least 30 days prior to taking such actions.

(b) Person authorized to transmit electric energy from the United States shall also file with the ERA annually by February 15, a certified copy of the current rates charged for the exported energy together with a copy of the rates charged by that person for similar service rendered in the United States.

(c) A change in the tariff arrangement does not require change in the authorization. However, persons authorized to transmit electric energy from the United States shall file with the ERA a certified copy of the changed rate schedule and/or terms for informational purposes related to the determination that such exports are not inconsistent with the public interest, pursuant to Section 202(e) of the Federal Power Act. Such changes may take effect upon the date of filing of informational data with ERA.

(d) Persons receiving authorization to transmit electric energy from the United States shall submit to the ERA, by February 15 each year, a report covering each month of the preceding calendar year detailing the gross amount of kilowatt-hours of energy, by authorized category, received or delivered, and the cost and revenue associated with each category.

§ 205.309 Filing procedures and fees.

Applications shall be addressed to the Office of Utility Systems of the Economic Regulatory Administration. Every application shall be accompanied by a fee of $500.00. Fee payment shall be by check, draft, or money order payable to the Treasurer of the United States.

Application for Presidential Permit Authorizing the Construction, Connection, Operation, and Maintenance of Facilities for Transmission of Electric Energy at International Boundaries

§ 205.320 Who shall apply.

(a) Any person, firm, co-operative, corporation or other entity who operates an electric power transmission or distribution facility crossing the border of the United States, for the transmission of electric energy between the United States and a foreign country, shall have a Presidential Permit, in compliance with Executive Order 10485, dated September 3, 1953, as amended by Executive Order 12038, dated February 3, 1978. Such applications should be filed with the Office of Utility Systems of the Economic Regulatory Administration.

Note.—Executive Order 12038, dated February 3, 1978, amended Executive Order 10485, dated September 3, 1953, to delete the words "Federal Power Commission" and "Commission" and substitute for each "Secretary of Energy". Executive Order 10485 revoked and superseded Executive Order 8202 dated July 13, 1939.

(b) In connection with applications hereunder, attention is directed to the provisions of §§ 205.300 to 205.309, of this subpart concerning applications for authorization to transmit electric energy from the United States to a foreign country pursuant to Section 202(e) of the Federal Power Act.

§ 205.321 Contents of application.

Every application shall be accompanied by a fee prescribed in § 205.325 of this subpart and shall provide in the order indicated the following:

(a) Information regarding applicant.

(1) The legal name of applicant;

(2) The legal names of all partners;

(3) The name, title, post office address, and telephone number of the person to whom correspondence in regard to the applicant shall be addressed;

(4) Whether applicant company or its transmission lines are owned wholly or in part by a foreign government or directly or indirectly assisted by a foreign government or instrumentality thereof; or whether applicant company has any agreement pertaining to such ownership by or assistance from any foreign government or instrumentality thereof. If so, give full details;

(5) List all existing contracts or other arrangements that the applicant has with any foreign government, or any foreign private concerns, which relate to the purchase, sale or delivery of electric energy;

(6) A showing, including signed opinion of counsel, that the construction, connection, operation, or maintenance of such a facility is within the corporate power of the applicant, and that the applicant has complied with or will comply with applicable state laws;

(7) The original of each application shall be signed and verified under oath by an officer of the applicant having knowledge of the matters therein set forth.

(b) Information regarding the transmission lines to be covered by the Presidential Permit.

(1) A technical description providing the following information: number of circuits, with identification as to whether the circuit is overhead or underground; the operating voltage and frequency; and conductor size, type and number of conductors per phase. If the proposed interconnection is an overhead line the following additional information must also be provided: the wind and ice loading design parameters; a full description and drawing of a typical supporting structure including strength specifications; structure spacing with typical ruling and maximum spans; conductor (phase) spacing; and the designed line to ground and conductor side clearances. If an underground or underwater interconnection is proposed, the following additional information must also be provided: burial depth; type of cable and a description of any required supporting equipment, such as insulation medium pressurizing and forced cooling plants; and cathodic protection equipment. Technical diagrams which provide clarification of any of the above items should be included.

(2) A general area map with a scale not greater than 1 inch=40 kilometer (1 inch=25 miles) showing the overall system, and a detailed map at a scale of 1 inch=8 kilometers (1 inch=5 miles) showing the physical location, longitude and latitude of the facility on the international border. The map shall indicate ownership of the facilities at or on each side of the border between the United States and the foreign county. If the application covers proposed facilities in addition to those already constructed, the maps, plans, and description of the facilities shall distinguish the facilities or parts thereof which have been constructed from those to be constructed;

(3) Applications for a bulk power supply facility which is proposed to be operated at 138 kilovolts or higher shall contain the following bulk power system information:

(i) Data regarding the expected power transfer capability, using normal and short time emergency conductor ratings;

(ii) System power flow plots for the appropriate Fuel Use Electric Region for heavy summer and light spring load periods, with and without the proposed international interconnection, for the year the line is scheduled to be placed in service and for the fifth year thereafter;

(iii) Data on the line design features for minimizing television and/or radio interference caused by operation of the subject transmission facilities;

(iv) A description of the relay protection scheme, including equipment and proposed functional devices;

(v) After receipt of the system power flow plots, the ERA may require the applicant to furnish system stability analysis for the applicant's system and for the pertinent Fuel Use Electric Region.

(c) Information regarding the environmental impacts shall be provided as follows for each routing alternative:

(1) Statement of the environmental impacts of the proposed facilities including a list of each flood plain, wetland, critical widlife habitat, navigable waterway crossing, Indian land, or natural historic site which may be impacted by the proposed facility with a description of proposed activities therein;

(2) A list of Historic Places, as specified in 36 CFR Part 800, which may be eligible for the National Register of Historic Places.

(3) Details regarding the minimum right-of-way width for construction, operation and maintenance of the transmission lines and the rationale for selecting that right-of-way width.

(4) A list of local threatened or endangered wildlife or plant life.

(d) Information regarding alternatives to the interconnection.

(1) A brief description of alternatives to the facility and a discussion of the general environmental impacts of such alternatives.

(e) The original of each application shall be signed and verified under oath by an officer of the applicant, having knowledge of the matters therein set forth.

§ 205.322 Transferability.

(a) A permit issued by the ERA pursuant to Executive Order 10485, as amended, and the facility or any part thereof built pursuant to such a permit shall not be transferable or assignable. The ERA order granting the permit may however, provide that the permit shall continue in effect temporarily in the event of the involuntary transfer of the facility by operation of law (including such transfers to receivers, trustees, or purchases under foreclosure or judicial sale) pending the making of an application for a new permit and decision thereon, provided notice is given to the ERA in writing within 30 days after such transfer accompanied by a statement that the facility authorized by the permit remains substantially the same as before the transfer and as stated in the initial application for such authorization.

(b) In the event of a proposed voluntary transfer of the facility, the permittee and the party to whom the transfer would be made shall file a joint application with the ERA pursuant to this subsection, setting forth information as required by § 205.320 *et seq.*, together with a statement of reasons for the transfer. The application shall be accompanied by a filing fee pursuant to Section 205.325.

(c) No substantial change shall be made in any facility authorized by permit or in the operation thereof unless or until such change has been approved by the ERA.

(d) Permits may be modified or revoked by the president of the United States, or by the Administrator of the ERA after public notice, and may be amended by the ERA upon proper application thereto.

§ 205.323 Form and style; number of copies.

(a) All applicants shall file an original and ten conformed copies of the application and all accompanying documents required under §§ 205.321 through 205.324.

(b) All applications must conform in all other respects to the requirements of Sections § 205.4 through 205.9 of this Chapter. If the application is found to be deficient, the Administrator of the ERA, or a delegate, shall notify the applicant of the deficiencies and will request that the applicant submit revisions or additions to the application.

§ 205.324 Annual report.

Persons receiving permits to construct, connect, operate or maintain electric transmission facilities at international boundaries shall submit to the ERA, by February 15 each year, a report covering each month of the preceding calendar year, detailing by authorized category the gross amount of kilowatt-hours of energy received or delivered and the cost and revenue associated with each category.

§ 205.325 Filing procedures and fees.

Applications shall be forwarded to the Office of Utility Systems of the Economic Regulatory Administration and shall be accompanied by a filing fee of $150. The application fee will be charged irrespective of the ERA's disposition of the application. Fee payment shall be by check, draft, or money order payable to the Treasurer of the United States.

§ 205.326 Other information.

The applicant may be required after filing the application to furnish such supplemental information as the ERA may deem pertinent.

[FR Doc. 80-11269 Filed 4-14-80; 8:45 am]

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Reader Aids

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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
DOT/SECRETARY	USDA/ASCS		DOT/SECRETARY	USDA/ASCS
DOT/COAST GUARD	USDA/APHIS		DOT/COAST GUARD	USDA/APHIS
DOT/FAA	USDA/FNS		DOT/FAA	USDA/FNS
DOT/FHWA	USDA/FSQS		DOT/FHWA	USDA/FSQS
DOT/FRA	USDA/REA		DOT/FRA	USDA/REA
DOT/NHTSA	MSPB/OPM		DOT/NHTSA	MSPB/OPM
DOT/RSPA	LABOR		DOT/RSPA	LABOR
DOT/SLSDC	HEW/FDA		DOT/SLSDC	HEW/FDA
DOT/UMTA			DOT/UMTA	
CSA			CSA	

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

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

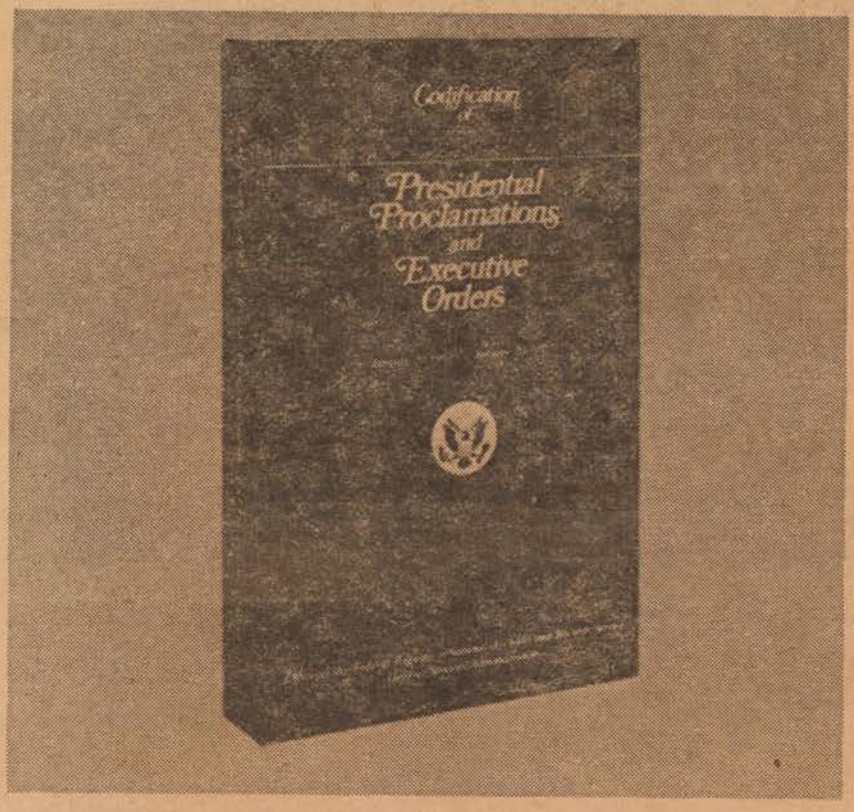
Note: There were no items eligible for inclusion in the list of **Rules Going Into Effect Today.**

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 April 14, 1980

NEW PUBLICATION NOW AVAILABLE



For those of you who must keep informed about Presidential proclamations and Executive orders, there is now a convenient reference source that will make researching certain of these documents much easier.

Arranged by subject matter, this first edition of the *Codification* contains proclamations and Executive orders that were issued or amended during the period January 20, 1961, through January 20, 1977, and which have a continuing effect on the public. For those documents that have been affected by other proclamations or Executive orders, the codified text presents the amended version. Therefore, a reader can use the *Codification* to determine the latest text of a document without having to "reconstruct" it through extensive research.

Special features include a comprehensive index and a table listing each proclamation and Executive order issued during the 1961–1977 period, along with any amendments, an indication of its current status, and, where applicable, its location in this volume.

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