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Weekly List of Public Laws
This is a listing of public bills enacted by Congress and approved by the President, together with the law number, the date of approval, and the U.S. Statutes citation. Subsequent lists will appear every Wednesday in the FEDERAL REGISTER and copies of the laws may be obtained from the U.S. Government Printing Office.

S. 433..................... Pub. Law 93-523
Safe Drinking Water Act
(Dec. 16, 1974; 88 Stat. 1660)
S. 1353..................... Pub. Law 93-524
Vessels, net tonnage for waste materials
(Dec. 18, 1974; 88 Stat. 1694)
S. 3906........................ Pub. Law 93-525
Flying units of the Air Force, aeronautical ratings for command
(Dec. 18, 1974; 88 Stat. 1695)
S. 4016........................ Pub. Law 93-526
Presidential Recordings and Materials Preservation Act
(Dec. 19, 1974; 88 Stat. 1695)
The following bill was vetoed by the President: S3537, to modify section 204 of the Flood Control Act of 1965 (79 Stat. 1085); Weekly Compilation of Presidential Documents, Vol. 10, No. 51.
The purpose of this publication by the Cost Accounting Standards Board is to adopt modifications to Part 331, Contract Procurement Practices, and Part 351, Basic Requirements, of its rules and regulations. These modifications will provide an exemption from Cost Accounting Standards Board requirements for certain national defense contracts and subcontracts of $500,000 or less.

Public Law 91-379 requires that Cost Accounting Standards must be used in all negotiated prime contract and subcontract national defense procurements with the United States in excess of $100,000, with certain stated exceptions. From time to time the Board refers to rules, regulations and standards to be in keeping with the United States in excess of $100,000, where the contractor already has received a covered contract in excess of $500,000 or less. These gaining reasons in support of this suggestion generally based their comments on simplification of administration. These commentators felt that it would be difficult for the Government or prime contractors, when awarding a prime contract or subcontract in excess of $100,000 to determine whether the contractor or subcontractor had in existence a prior $500,000 covered contract.

In view of the foregoing, the Board considers the proposed exemption increasing the minimum contract amount requiring compliance with Cost Accounting Standards Board rules, regulations and standards to be in keeping with the purposes sought to be achieved by Pub. L. 91-379 and to be an appropriate exercise of the authority granted to the Board by section 719(h) (2) of that law.

This section of the FEDERAL REGISTER is published under 50 U.S.C. 518. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.
In considering the advantages of the exemption as proposed compared to its assessment of the administrative difficulties foreseen by commentators, the Board is persuaded that its proposal relative to coverage of awards in excess of $100,000 should not be changed.

**Exemption based on sales.** A number of commentators urged that the Board establish an exemption based on sales, using the figure of $500,000 as a threshold. The reasoning given was that the circumstances are such that these existing contracts would have been exempt if awarded after the effective date of the proposed regulation. The Board has no authority to modify existing contractual agreements between the government procurement agencies and their contractors. However, it has the authority to examine various limitations but considers the definitions of "defense contractor" and "defense subcontractor" contained in § 331.30(b) and (c) to be modified to reflect the Board's intent.

The Board has given lengthy consideration to the use of a sales basis for the establishment of a minimum threshold for compliance with its rules, regulations, and standards. The Board did not use at this time due to the nature of the problems involved in administering an exemption based on sales. In either of the situations suggested by commentators, the contractor would be placed in the position of examining a contractor's total sales, including those made in its commercial business. Examination of a company's records concerning its total sales is not presently performed by the Government, who are now and will be required to monitor the activities and present new and unique problems to both parties as well as requiring substantial additional effort on the part of Government representatives.

An exemption based on sales would require a measurement period during which a contractor's status with respect to compliance with standards would be determined. Contractors under which sales were recorded during this period would not be subject to standards. If the volume of sales during the measurement period exceeded a stated threshold, a contractor would then be required to comply with Government standards under contracts received in subsequent periods. Thus, the contracts that brought the contractor under the Board's representation requirements would be affected, while those received at a later time would be.

The Board has decided that the administrative problems involved with an exemption based on sales should be considered before establishing such a threshold. The Board would continue to study these problems and investigate whether exemptions based on criteria other than a minimum contract amount would be appropriate and consistent with the purposes of Pub. L. 91-370.

**Retroactivity.** Several commentators requested that the Board modify its proposal so as to provide retroactive exemption to existing contracts where the circumstances are such that these existing contracts would have been exempt if awarded after the effective date of the proposed regulation.

The Board has authority to examine various limitations but considers the definitions of "defense contractor" and "defense subcontractor" contained in § 331.30(b) and (c) to be modified to reflect the Board's intent.

As the Board stated in its September 27 publication, its contract requirements have been applied to business units, such as profit center, division, subsidiary, or similar unit of a company, which perform the contract, even in those cases where the contract was entered into on behalf of the overall company rather than the business unit. This application of the Board's requirements to the performing business unit is well established and unchallenged, and clarification of the definitions of "contractor" and "subcontractor" does not appear necessary.

**Effective date.** Several commentators raised questions concerning the effective date of the eligibility for this exemption in relation to awards received prior to an effective date of January 1, 1975, and on which notification of final acceptance of all items or work to be delivered on that contract or subcontract has not been received, is a contractor who has "already received a contract or subcontract in excess of $500,000," as that phrase is used in § 331.30(b)(3). Therefore, today's publication requires that a contractor meeting this test will be required to comply with standards on all covered prime contracts or subcontracts in excess of $100,000 received after January 1, 1975, under the provisions of § 331.30.

**(Sec. 102.84 Stat. 1106 (50 U.S.C. App. 2169)).**

In view of the foregoing, the following additions and changes to Part 331 and Part 351 of the Defense contract regulations are being made effective January 1, 1975.

1. Amend § 331.30(a), *Applicability, exemption, and waiver*, by adding after the words, "in excess of $100,000," the following, "except as provided in paragraph (b) of this section."
2. Amend the same § 331.30 by adding the following new paragraph (b) (8).

These amendments would have the following effect:

§ 331.30 Applicability, exemption, and waiver.

(a) The head of each relevant Federal agency shall cause or require the clause set forth in § 331.50 captioned Cost Accounting Standards to be inserted in all negotiated defense contracts in excess of $100,000, except as provided in paragraph (b) below, other than contracts entered into by the agency where the price is based on: (1) established catalog or market prices of commercial items sold in substantial quantities to the general public, or (2) prices set by law or regulation. Additionally, all solicitations, likely to result in a contract in which the clause set forth in § 331.50 must be inserted, shall be provided with the notice set forth in § 331.40 captioned Disclosure Statement—Cost Accounting Practices and Certification.

(b) * * *

(8) Any contract or subcontract of $500,000 or less, unless it is a contract or subcontract in excess of $500,000 and (ii) has not received notification of final acceptance of all items of work to be delivered on that contract or subcontract and on all other contracts or subcontracts awarded after January 1, 1975, which were subject to the cost accounting standards clause. For the purposes of this paragraph (b) (8), an intercorporate transfer shall be considered to be a subcontract. Notwithstanding this exemption, any contractor entitled to an exemption under this paragraph (b) (8) may elect to comply with the cost accounting standards clause. The contractor may elect to comply in connection with the receipt of its first contract or subcontract awarded after January 1, 1975, which but for this paragraph (b) (8) would be subject to the clause. A contractor who does not elect to comply with the clause in connection with the receipt of the first contract or subcontract of that type on which notification of final acceptance of all items of work to be delivered has not been received.

3. Amend § 331.40, Solicitation notice, by adding after the words in the first sentence of paragraph (a), “law or regulation,” the following, “and except for contracts which may be exempt under the provisions of 4 CFR 331.30(b),”.

This amendment would have the following effect:

§ 331.40 Solicitation notice.

DISCLOSURE STATEMENT—COST ACCOUNTING PRACTICES AND CERTIFICATION

(a) Any contract in excess of $100,000 resulting from a solicitation, except contracts where the price negotiated is based on: (1) established catalog or market prices of commercial items sold in substantial quantities to the general public, or (2) prices set by law or regulation, and except for contracts which may be exempt under the provisions of 4 CFR 331.30(b), will be subject to the requirements of the Cost Accounting Standards Board. Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of the Cost Accounting Standards Board must, as a condition of contracting, submit a disclosure statement as required by this part. The disclosure statement must be submitted as a part of the offeror’s proposal under this solicitation unless the agency determines that the proposal is for a subcontract awarded after January 1, 1975, which were subject to the cost accounting standards clause. For the purposes of this paragraph (b) (8), an intercorporate transfer shall be considered to be a subcontract. Notwithstanding this exemption, any contractor entitled to an exemption under this paragraph (b) (8) may elect to comply with the cost accounting standards clause. The contractor may elect to comply in connection with the receipt of its first contract or subcontract awarded after January 1, 1975, which but for this paragraph (b) (8) would be subject to the clause. A contractor who does not elect to comply with the clause in connection with the receipt of the first contract or subcontract of that type on which notification of final acceptance of all items of work to be delivered has not been received.

4. Amend § 331.50, Contract clause, by adding after “law or regulation” in subsection (d) (2), the following: “and except for the requirement that shall not apply to the contractors who enter into negotiated national defense contracts other than contracts where the price negotiated is based on (1) established catalog or market prices of commercial items sold in substantial quantities to the general public, or (2) prices set by law or regulation. A separate disclosure statement must be submitted covering the practices of each of the contractor’s profit centers, divisions, or similar organizational units when the total price of any contract exceed $100,000, except as provided in 4 CFR 331.30(b), except where such costs are based on (1) established catalog or market prices of commercial items sold in substantial quantities to the general public or (2) prices set by law or regulation. If the cost accounting practices under contracts are identical for more than one organizational unit, then only one statement need be submitted for those units, but each such organizational unit must be identified. A disclosure statement will also be required for each corporate or group office whose costs are allocated to one or more corporate segments performing contracts covered by Pub. L. 91-379.

This amendment would have the following effect:

§ 331.50 Contract clause.

(d) The contractor shall include in all negotiated subcontracts which he enters into the clause set forth in paragraph (b) of this section, and shall require such inclusion in all other subcontracts of any tier, except that the requirement shall apply only to negotiated subcontracts in excess of $100,000 where the price negotiated is not based on:

(1) Established catalog or market prices of commercial items sold in substantial quantities to the general public, or

(2) Prices set by law or regulation, and except that the requirement shall not apply to negotiated subcontracts otherwise exempt from the requirement to accept the cost accounting standards clause by reason of § 331.30(b) of Title 4, Code of Federal Regulations (4 CFR 331.30(b)).

This amendment would have the following effect:

§ 331.50 Contract clause.

(d) The contractor shall include in all negotiated subcontracts which he enters into the clause set forth in paragraph (b) of this section, and shall require such inclusion in all other subcontracts of any tier, except that the requirement shall apply only to negotiated subcontracts in excess of $100,000, except as provided in 4 CFR 331.30(b), where the price negotiated is not based on:

(1) Established catalog or market prices of commercial items sold in substantial quantities to the general public, or

(2) Prices set by law or regulation, and except that the requirement shall not apply to negotiated subcontracts otherwise exempt from the requirement to accept the cost accounting standards clause by reason of § 331.30(b) of Title 4, Code of Federal Regulations (4 CFR 331.30(b)).

This amendment would have the following effect:

§ 331.50 Contract clause.

(d) The contractor shall include in all negotiated subcontracts which he enters into the clause set forth in paragraph (b) of this section, and shall require such inclusion in all other subcontracts of any tier, except that the requirement shall apply only to negotiated subcontracts in excess of $100,000, except as provided in 4 CFR 331.30(b), where the price negotiated is not based on:

(1) Established catalog or market prices of commercial items sold in substantial quantities to the general public, or

(2) Prices set by law or regulation, and except that the requirement shall not apply to negotiated subcontracts otherwise exempt from the requirement to accept the cost accounting standards clause by reason of § 331.30(b) of Title 4, Code of Federal Regulations (4 CFR 331.30(b)).

5. Amend section 351.40, Filing requirement, by inserting in the first sentence of paragraph (a) after the figures “$100,000”, the following, “except as provided in 4 CFR 331.30(b),”.

§ 351.40 Filing requirement.

(a) This amendment would have the following effect:

§ 351.10 Filing requirement.

(a) The requirements of this part are applicable to all contractors who enter into negotiated national defense contracts with the United States in excess of $100,000, except as provided in 4 CFR 331.30(b), other than contracts where the price negotiated is based on (1) established catalog or market prices of commercial items sold in substantial quantities to the general public, or (2) prices set by law or regulation. A separate disclosure statement must be submitted covering the practices of each of the contractor’s profit centers, divisions, or similar organizational units when the total price of any contract exceed $100,000, except as provided in 4 CFR 331.30(b), except where such costs are based on (1) established catalog or market prices of commercial items sold in substantial quantities to the general public or (2) prices set by law or regulation. If the cost accounting practices under contracts are identical for more than one organizational unit, then only one statement need be submitted for those units, but each such organizational unit must be identified. A disclosure statement will also be required for each corporate or group office whose costs are allocated to one or more corporate segments performing contracts covered by Pub. L. 91-379.

This amendment would have the following effect:

§ 351.10 Instructions and information.

The following instructions and information shall be used by persons completing disclosure statements.

INSTRUCTIONS AND INFORMATION

(a) This disclosure statement has been designed to meet the requirements of Pub. L. 91-379, and persons completing it are to describe their contract cost accounting practices, either in the clause set forth in this section or in the instructions set forth in this section. For timing of requirement to file a disclosure statement, see § 351.40. A statement should be submitted by all defense contractors who enter into negotiated national defense contracts with the United States in excess of $100,000 other than contracts where the price negotiated is based on (1) established catalog or market prices of commercial items sold in substantial quantities to the general public, or (2) prices set by law or regulation.
or regulation, or contracts exempt under the provision of 4 CFR 331.30(b). A separate disclosure statement must be submitted covering the practice of each of the contractors, profit centers, divisions, or similar organizational units, whose costs included in the total price of any contract exceed $100,000, except where such costs are based on (1) established catalog or market prices of commercial items sold in substantial quantities to the general public, or (2) prices set by law or regulation, or contracts exempt under the provisions of 4 CFR 331.30(b). If the cost accounting practices under contracts are identical for more than one organizational unit, then only one statement need be submitted for those units, but each such organizational unit must be identified. A disclosure statement will also be required for each corporate or group office when costs are allocated to one or more corporate segments performing contracts covered by Pub. L. 91-370, but only Part VIII of the statement need be completed.

**Title 21—Food and Drugs**

**CHAPTER II—DRUG ENFORCEMENT ADMINISTRATION, DEPARTMENT OF JUSTICE**

**PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES**

**Removal of Naloxone and Its Salts From Control**

A notice was published in the Federal Register, on July 10, 1974 (39 FR 25327) proposing the removal of naloxone and its salts from Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91-515). All interested persons were given 30 days after publication to submit their objections, comments, or requests for hearing. In view of the fact that no comments, objections, or requests for a hearing were received as to the proposed order, and based upon the investigation of the Drug Enforcement Administration and upon the scientific and medical evaluation and recommendation of the Secretary of Health, Education, and Welfare, received pursuant to section 201(b) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(b)), the Administrator of the Drug Enforcement Administration finds that naloxone and its salts have a currently accepted medical use in the United States and do not have at this time a potential for abuse or abuse liability to justify the control or exemption control in any schedule under the Act. Therefore, under the authority vested in the Attorney General by section 201(a) of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 811(a)), and delegated to the Administrator of the Drug Enforcement Administration by § 0.100 of Title 28 of the Code of Federal Regulations, the Administrator hereby orders that § 1308.12(b)(1) of Title 21 of the Code of Federal Regulations be amended to read as follows:

§ 1308.12 Schedule II.

(b) * * *

(i) Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding naloxone and its salts, but including the following:

- Raw opium
- Opium extract
- Opium fluid extract
- Powdered opium
- Granulated opium
- Tincture of opium
- Aromorphine
- Codeine
- Ethylmorphine
- Etorphine hydrochloride
- Hydromorphone
- Metadone
- Morphine
- Oxycodone
- Oxymorphone
- Thebaine

This order is effective December 24, 1974.

Dated: December 18, 1974.

John R. Bartels, Jr.,
Administrator,
Drug Enforcement Administration.

**PART 1033—CAR SERVICE**

**Demurrage and Free Time on Freight Cars**

December 19, 1974.

At a Session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 17th day of December 1974.

Upon further consideration of Service Order No. 1201 (39 FR 40501), because of substantial reductions in carloadings during the Christmas-New Year period, and for other good cause appearing:

It is ordered, That:

§ 1033.1201, Service Order No. 1201 be, and it is hereby, suspended until further order of the Commission.

Effective date. This amendment shall become effective at 7 a.m., December 21, 1974.

Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 394, as amended; (49 U.S.C. 1, 12, 15, and 17(2)). Interprets or applies Secs. 1(10-17), 18(4), and 17(3), 40 Stat. 101, as amended, 54 Stat. 911; (49 U.S.C. 1(10-17), 15(4), and 17(2)).

It is further ordered, That a copy of this amendment 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; and that notice of this amendment 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 it with the Director, Office of the Federal Register.

By the Commission, Division 3.

Robert L. Oswald, Secretary.

**PART 1035—CAR SERVICE**

**Demurrage and Free Time at Ports**

December 19, 1974.

At a Session of the Interstate Commerce Commission, Railroad Service Board, held in Washington, D.C., on the 17th day of December 1974.

Upon further consideration of Service Order No. 1201 (39 FR 40501), because of substantial reductions in carloadings during the Christmas-New Year period, and for other good cause appearing:

It is ordered, That:

§ 1033.1201, Service Order No. 1201 be, and it is hereby, suspended until further order of the Commission.

Effective date. This amendment shall become effective at 7 a.m., December 21, 1974.

Secs. 1, 12, 15, and 17(2), 24 Stat. 379, 383, 394, as amended; (49 U.S.C. 1, 12, 15, and 17(2)). Interprets or applies Secs. 1(10-17), 18(4), and 17(3), 40 Stat. 101, as amended, 54 Stat. 911; (49 U.S.C. 1(10-17), 15(4), and 17(2)).

It is further ordered, That a copy of this amendment 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; and that notice of this amendment 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 it with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board.

Robert L. Oswald, Secretary.
PART 1915—IDENTIFICATION OF SPECIAL HAZARD AREAS

List of Communities With Special Hazard Areas

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**North Carolina**

- Sampson: Clinton, city of...

- North Carolina Offices of Water and Air Resources, Department of Natural and Economic Resources, P.O. Box 2767, Raleigh, N.C. 27611. North Carolina Insurance Department, P.O. Box 2767, Raleigh, N.C. 27611.
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**Legislation:** 43 Fed. Reg. 4397 (Dec. 6, 1974);

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<td>City Planning Commission, Department of Natural Resources, P.O. Box 460, Madison, Wis. 53701.</td>
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<td>City Planning Commission, Department of Natural Resources, P.O. Box 460, Madison, Wis. 53701.</td>
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Effective date of identification of areas which have special flood hazards.


Issued: December 11, 1974.

J. ROBERT HUNTER,
Acting Federal Insurance Administrator.
Title 5—Administrative Personnel
CHAPTER I—CIVIL SERVICE COMMISSION

PART 213—EXCEPTED SERVICE

Miscellaneous Revisions

Supart C of Part 213 is amended to show that under the provisions of § 213.3101b, 85 positions are no longer excepted under Schedule C.

§ 213.3303 Executive Office of the President.

(a) Office of Management and Budget.

(2) One Special Assistant to the Deputy Director.

(d) Office of the Special Representative for Trade Negotiations.

(4) [Revoked]

(5) [Revoked]

(j) Special Action Office for Drug Abuse Prevention.

(1) [Revoked]

(3) [Revoked]

(4) [Revoked]

(5) [Revoked]

(k) Office of Economic Opportunity.

(13) [Revoked]

(14) [Revoked]

§ 213.3304 Department of State.

(a) Office of the Secretary.

(2) Four Private Secretaries to the Secretary.

(13) [Revoked]

(u) Office of the Counselor.

(1) [Revoked]

§ 213.3305 Treasury Department.

(a) Office of the Secretary.

(37) [Revoked]

§ 213.3306 Department of Defense.

(a) Office of the Secretary.

(2) One Private Secretary to the Deputy Secretary of Defense and one Private Secretary to each of the following: the Director of Defense Research and Engineering; the Principal Deputy Director of Defense Research and Engineering; the Deputy Directors of Defense Research and Engineering (Tactical Warfare Programs), (Strategic Systems), (Research and Technology), the Director Advanced Research Projects Agency; the Assistant Secretaries of Defense (Manpower and Reserve Affairs), (International Security Affairs), (Public Affairs), (Installations and Logistics), (Comptroller), (Systems Analysis), (Intelligence), and (Legislative Affairs); the General Counsel; the Assistant to the Secretary of Defense (Atomic Energy); and the Military Assistant to the Secretary of Defense.

§ 213.3307 Department of the Army.

(b) [Revoked]

§ 213.3310 Department of Justice.

(b) Office of the Deputy Attorney General.

(1) One Confidential Assistant (Private Secretary) to the Deputy Attorney General.

(k) Board of Immigration Appeals.

(2) Three Members of the Board.

(o) Office of the U.S. Attorney.

(1) Secretary and Confidential Assistant to the U.S. Attorney (23 positions).

(s) Law Enforcement Assistance Administration.

(1) [Revoked]

(4) [Revoked]

§ 213.3312 Department of the Interior.

(a) Office of the Secretary.

(1) Eight Confidential Assistants to the Secretary.

(2) Four Special Assistants to the Secretary.

(29) [Revoked]

(31) One Confidential Assistant to the Assistant Secretary for Management.

§ 213.3313 Department of Agriculture.

(a) Office of the Secretary.

(6) [Revoked]

(b) Rural Electrification Administration.

(4) One Assistant to the Administrator.

(h) Agricultural Stabilization and Conservation Service.

(4) Three Confidential Assistants to the Administrator.

§ 213.3314 Department of Commerce.

(a) Office of the Secretary.

(16) One Confidential Assistant to the Director, Office of Foreign Direct Investment.

(18) [Revoked]

(b) [Revoked]

§ 213.3315 Department of Labor.

(a) Office of the Secretary.

(5) [Revoked]

(6) One Assistant to each Assistant Secretary of Labor appointed by the President, except the Assistant Secretary for Manpower.

(11) [Revoked]

(18) [Revoked]

§ 213.3316 Department of Health, Education, and Welfare.

(a) Office of the Secretary.

(4) [Revoked]

(6) Five Confidential Assistants to the Under Secretary.

(8) [Revoked]

(9) [Revoked]

(13) Four Assistants to the Secretary.

(15) Two Private Secretaries to the Secretary.

(24) [Revoked]

(c) Office of Education.

(1) One Special Assistant to the Commissioner of Education.

(5) [Revoked]

(6) [Revoked]

(9) [Revoked]

(k) Office of the Assistant Secretary for Planning and Evaluation.

(13) [Revoked]

(1) Social Security Administration.

(2) [Revoked]

(n) Office of the Assistant Secretary for Human Development.

(4) [Revoked]

(o) Social and Rehabilitation Service.

(10) [Revoked]

(q) Office of the Special Assistant to the Secretary for Civil Rights.

(1) One Special Assistant to the Special Assistant.

§ 213.3337 General Services Administration.

(a) Office of the Administrator.

(4) Three Confidential Assistants to the Assistant Administrator.
### RULES AND REGULATIONS

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### PART 213—EXCEPTED SERVICE

**Department of Transportation; Correction**

In the Federal Register of August 10, 1973 (38 FR Doc. 73-16524), appearing on page 21621, § 213.3394(f) (1) was revoked in error. Section 213.3394(f) (1) reads as follows:

§ 213.3394 Department of Transportation

(f) Urban Mass Transportation Administration.

(1) One Assistant Administrator for Public Affairs.


**PART 775—FEED GRAINS**

Subpart—Feed Grain Program for Crop Years 1974–1977

1976 National Feed Grain Allotment

On July 17, 1974, a notice of proposed rule making was published in the Federal Register (39 FR 20150) stating that the Secretary of Agriculture proposed to make determinations and issue regulations relative to the 1976 national feed grain allotment. Interested persons were invited to submit written data, views, and recommendations regarding the determinations. The comments and recommendations received have been duly considered.

The regulations governing the Feed Grain Program for Crop Years 1974–1977 issued July 12, 1974 (39 FR 25663) are amended by adding a new § 775.4a. The purpose of this section is to determine and proclaim the 1975 national feed grain allotment.

Pursuant to section 105(b) (2) of the Agricultural Act of 1949, as amended by the Agriculture and Consumer Protection Act of 1973, Pub. L. 93-86, 57 Stat. 221, 231 (1973), the Secretary is required, prior to January 1 of each calendar year, to determine and proclaim for the crop produced in such calendar year a national acreage allotment for feed grains.
which shall be the number of acres he determines, assuming the basis of the estimated national average yield of the feed grains included in the program for the crop for which the determination is being made, will produce the quantity (less imports) of such feed grains that he estimates will be utilized domestically and for export during the marketing year for such crop. If the Secretary determines that carryover stocks of any of the feed grains are excessive or an increase in stocks is needed to assure a desirable carryover, he may adjust the feed grain allotment by the amount he determines will accomplish the desired decrease or increase in carryover stocks.

The determination in § 775.4a of the 1975 national feed grain allotment is based on the acreages, yields, and use set out therein. The determination has been made on the basis of the latest available statistics of the Federal Government. Compliance with the feed grain allotment is not a condition of eligibility for participation in the program, and feed grain acreage on the farm may vary widely from the farm feed grain allotment. Hence, in determining the national allotment, an adjustment for the purpose of increasing carryover stocks to a more desirable level was not considered necessary, and no such adjustment was made.

Part 775 is amended by adding a new § 775.4a to read as follows:

§ 775.4a 1975 national feed grain allotment.

Based on estimated utilization (less imports) for the 1975-1976 marketing year of 5.924 billion bushels of corn, 875 million bushels of sorghum, and 445 million bushels of barley and estimated national yields of 83.9 bushels per acre for corn, 60.0 bushels per acre for sorghum, and 45.5 bushels per acre for barley, the combined acreage of corn, sorghum and barley needed to produce a quantity of feed grains equal to estimated utilization is determined to be 89.0 million acres and a 1975 national feed grain allotment of 89.0 million acres is hereby proclaimed.

(See 106, 63 Stat. 1054, as amended; 87 Stat. 231: (7 U.S.C. 1441) note)

Effective date: December 24, 1974.

Signed at Washington, D.C. on December 18, 1974.

EARL L. BUTZ,
Secretary.

[FR Doc.74-39660 Filed 12-23-74; 8:45 am]

CHAPTER XVIII—FARMERS HOME ADMINISTRATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER A—GENERAL REGULATIONS

[FmHA Instruction 424.1]

PART 1804—PLANNING AND PERFORMING DEVELOPMENT WORK

Subpart A—Planning and Performing Development Work

In page 37992 of the Federal Register of October 25, 1974, there was published a notice of proposed rulemaking, amending § 1804.4 by adding a new paragraph (g) (5) concerning actions to be taken during the warranty period and redesignating the present paragraph (g) (5) as (g) (6). Also, under consideration was a program identified as Appendix B of this subpart entitled, "Notifying Borrowers of Expiration of 1-Year Warranty Period," which will notify borrowers of the expiration of the 1-year warranty period. If construction deficiencies exist, borrowers will request the County Supervisor to conduct an inspection.

Interested persons were given 30 days to submit written comments, suggestions, or objections regarding the proposed revised guidelines. No written comments, suggestions, or objections have been received and the proposed regulations are hereby adopted without change and are set forth below.

Effective date. This amendment is effective on December 24, 1974.


F. W. NAYLOR, Jr.,
Acting Administrator.

1. As amended, § 1804.4(g) (5) reads as follows:

§ 1804.4 Performing development.

(5) Inspection of development work.

* * * * *

(g) Inspection of development work.

(5) Guarantee—warranty period. In all cases where Form FmHA 424-19 has been executed, the following actions will be taken:

(i) The County Supervisor will assist borrowers as provided in Subpart C of this Part, "Handling Construction Complaints.''

(ii) Borrowers will be notified of the warranty expiration date prior to the 11th month of the warranty period. Appendix B describes the action that will be taken.

2. Appendix B, as added reads as follows:

Appendix B—Notifying Borrowers of Expiration of 1-Year Warranty Period

1 Purpose. This Appendix outlines the procedures for notifying borrowers of the expiration of the 1-year warranty period for defects in materials or workmanship when Form FmHA 424-19, "Builder's Warranty," has been signed by a warrantor.

2. Policy. Each borrower will be notified of the expiration date of Form FmHA 424-19 and the name and address of the warrantor with instructions for notifying the warrantor of any complaints that may exist. Ordinarily, notification will be given by letter; however, if complaints have been received or known construction defects exist, an onsite inspection will be made by the County Supervisor or construction inspector to determine the nature and seriousness of the defects.

3. Implementation, alternatives and action to be taken. The County Supervisor will take the following action prior to the expiration of the 1-year Builder's Warranty:

(a) A letter notifying the borrower of the expiration date of the Builder's Warranty will be mailed to the borrower early in the 10th month of the warranty period.

(b) If the County Supervisor does not hear from the borrower within 30 days, he can reasonably assume that no complaints exist or that any complaints have been satisfied, unless he has information to the contrary.

(c) If the borrower notifies the County Supervisor that any complaint has not been satisfied, an onsite construction inspection shall be made as early as possible but not later than the 11th month of the 1-year Builder's Warranty period. The results of the inspection visit will be recorded on Form FmHA 424-12, "Inspection Report." If the borrower complaints are justified, the case should be handled in accordance with Subpart C of this Part, "Handling Construction Complaints.''

(7. U.S.C. 1989); (42 U.S.C. 1480); delegation of authority by the Sec. of Agri, 7 CFR 2.75; delegation of authority by the Asst. Sec. for Rural Development, 7 CFR 2.70.)

[FR Doc.74-39660 Filed 12-23-74; 8:45 am]

CHAPTER XVIII—FARMERS HOME ADMINISTRATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—LOANS AND GRANTS PRIMARILY FOR REAL ESTATE PURPOSES

[FmHA Instruction 444.4]

PART 1822—RURAL HOUSING LOANS AND GRANTS

Subpart C—Farm Labor Housing Loan Policies, Procedures, and Authorizations

Revision of Eligibility Requirements

On page 37849 of the Federal Register of October 25, 1974, there was published a notice of proposed rulemaking to revise § 1822.64 of Subpart C of Part 1822. The purpose of this revision is to clarify eligibility requirements an applicant must meet to obtain a Labor Housing loan, and provides that the financial condition of individual members of associations of farmers be considered in determining whether credit is available from other sources.

Interested persons were given 30 days in which to submit written comments, suggestions, or objections regarding the proposed revision. No comments, suggestions, or objections have been received and the proposed regulations are hereby adopted without change and are set forth below.

Effective date. This revision is effective on December 24, 1974.


F. W. NAYLOR, Jr.,
Acting Administrator.

Section 1822.64 is revised to read as follows:

§ 1822.64 Eligibility requirements.

(a) Eligibility of applicant. To be eligible for an LH loan the applicant must:

1. Be an individual farm owner or an organization, as those terms are defined

1 Appendix A reserved.
Title 9—Animals and Animal Products

CHAPTER I—ANIMAL AND PLANT HEALTH INSPECTION SERVICE, DEPARTMENT OF AGRICULTURE

SUBCHAPTER C—INTERSTATE TRANSPORTATION OF ANIMALS (INCLUDING POULTRY) AND ANIMAL PRODUCTS

PART 76—HOG CHOLERA AND OTHER COMMUNICABLE SWINE DISEASES

Definition of "State" Amended and the United States Virgin Islands Declared Hog Cholera Free

Notice is hereby given in accordance with the administrative procedure provisions in 5 U.S.C. 553, that the Animal and Plant Health Inspection Service is amending §§76.1(f) and 76.2(g) of Chapter I of Title 9 of the Code of Federal Regulations to include the Virgin Islands of the United States as a hog cholera free State.

Statement of considerations. A systematic surveillance for the detection of hog cholera has been in effect in the United States Virgin Islands for many years. Hog cholera has not been found to exist in the United States Virgin Islands since it was introduced from the United States through vaccinated swine imported in 1941. That outbreak was promptly contained and vaccination has not been practiced since 1964. A continued surveillance for hog cholera in the Virgin Islands of the United States by diagnosticians from the Commonwealth of Puerto Rico for the investigation of suspected hog cholera remains in effect.

Accordingly, Part 76 is amended as follows:

1. §76.1 is amended to read:

§76.1 Definitions.

(i) State. Any State, Puerto Rico, the United States Virgin Islands, or the District of Columbia.

§76.2 [Amended]

2. §76.2(g) is amended by adding thereto the United States Virgin Islands.

Effective date. The foregoing amendments shall become effective December 18, 1974.

The amendments change the definition of "State" to include the United States Virgin Islands and declare that area to be hog cholera free under the regulations of this Part 76.

The amendments do not change the requirements under the regulations in 9 CFR Part 76 with respect to the interstate movement of swine or swine products. They have the effect of relieving restrictions on indemnity payments under the regulations in 9 CFR Part 56 and should be made effective promptly in order to be of maximum benefit to affected persons. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to the amendments are impracticable, unnecessary, and contrary to the public interest, and good cause is found for making them effective less than 30 days after publication in the Federal Register.

Done at Washington, D.C., this 18th day of December, 1974.

J. M. Hjel, Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[F.R. Doc. 74-29908 Filed 12-23-74; 8:45 am]

PART 76—HOG CHOLERA AND OTHER COMMUNICABLE SWINE DISEASES

Hog Cholera Eradication and Free States

This amendements deletes the Commonwealth of Puerto Rico from the list of Hog Cholera Eradication States in 9 CFR 76.2(f), as amended, and adds said State to the list of Hog Cholera Free States in § 76.2(g) upon the basis of a determination that such State qualifies for hog cholera free status under § 76.2(g) of the regulations contained in 9 CFR Part 76.

Accordingly, Part 76 is amended, pertaining to the interstate movement of swine and swine products from such Eradication or Free States remain applicable to the Commonwealth of Puerto Rico.

The removal of the Commonwealth of Puerto Rico from the list of Hog Cholera Eradication States and the addition of this State to the list of Hog Cholera Free States affects the Federal indemnities payable under other regulations (9 CFR Part 56, as amended) for swine slaughtered because of hog cholera in the Commonwealth of Puerto Rico.

Accordingly, Part 76, Title 9, Code of Federal Regulations, as amended, restricting the interstate movement of swine and certain products because of hog cholera and other communicable swine diseases, is hereby amended in the following respects:

(1) The reference to the Commonwealth of Puerto Rico in paragraph (f) is deleted, and paragraph (g) is amended by adding thereto the name of said State.

(See 4-7, 22 Stat. 32, as amended; secs. 1 and 2, 32 Stat. 761-762, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; sec. 1, 75 Stat. 481; secs. 3 and 11, 78 Stat. 130, 132; 9 CFR Part 76, as amended; secs. 1, 121, 123, 126, 134b, 134f, 76 FR 28464, 28477, 38 FR 19141)

Effective date. The foregoing amendment shall become effective December 18, 1974.

The amendment does not change the requirements under the regulations in 9 CFR Part 76 with respect to the interstate movement of swine or swine products. It has the effects of relieving restrictions on indemnity payments under the regulations in 9 CFR Part 56 and should be made effective promptly in order to be of maximum benefit to affected persons. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.
proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions in 5 U.S.C. § 553, it is found upon good cause that notice and other public procedure with respect to the amendments and revisions is impracticable, unnecessary and contrary to the public interest, and good cause is found for making it effective less than 30 days after publication in the Federal Register.

Done at Washington, D.C., this 18th day of December 1974.

J. M. HR.
Deputy Administrator, Veterinary Services, Animal and Plant Health Inspection Service.

[FR Doc. 74-39907 Filed 12-23-74: 8:45 am]

Title 10—Energy
CHAPTER II—FEDERAL ENERGY ADMINISTRATION
PART 210—GENERAL ALLOCATION AND PRICE RULES
PART 211—MANDATORY PETROLEUM ALLOCATION REGULATIONS

Limitation of Refinery Fuel Use of Propane and Butane. Clarification of Special Restrictions of Propane and Butane for SNG Use, Gas Utility Use and Industrial Use

The Federal Energy Administration hereby amends, effective immediately, the Mandatory Petroleum Allocation Regulations concerning the allocation of propane and butane to limit their use as refinery fuel. In addition, the special restrictions on the use of propane and butane contained in § 211.10(g) (8) and former § 211.10(g) (9) have been clarified and expanded to include refinery fuel use.

The allocation and pricing of propane and butane has been a matter of continuing concern to the FEA. Recently, FEA has been advised that several refiners have anticipated allocation fractions for propane and butane during the first quarter of 1975 which represent substantial reductions from the allocations implemented by the same refiners during the last allocation quarter of 1974. FEA is concerned that these reductions are due, in part, to the fact that refiners are using these products directly and in mixtures of other allocated and non-allocated products in increasing amounts as refinery fuel, since they have become relatively inexpensive fuels for this use. This situation was not anticipated when 10 CPR 211.81(a) (2) was promulgated excluding from Subpart D of the Mandatory Petroleum Allocation Regulations "propane in mixtures of light hydrocarbons produced in a refinery and used in that refinery for use other than as feedstock."

The present diversion of propane or butane directly or indirectly in other mixtures for use as a refinery fuel threatens substantial disruption of traditional propane and butane supply patterns for other traditional uses. Accordingly, the present and butane produced in a refinery for use in that refinery will be allocated in the same manner as propane and butane produced in a gas processing plant pursuant to Subpart D. An addition has been placed upon the use of propane or butane from any source, without regard to whether it has been subject to refining or processing or is contained in other mixtures. In particular, the use of propane or butane for refinery fuel in excess of certain volumes has been prohibited.

The revised regulations add a new definition for "refinery fuel use" and exclude refinery fuel use from the definition of "energy production." A definition of "natural gas liquids" has also been added. The definitions of "propane," "propane-butane mix" have been revised. An allocation level of one hundred percent of base period use subject to the allocation fraction for refinery fuel use of propane, butane and natural gas liquids has also been added to Subparts D and E of Part 211.

Refiners which use allocated products (including propane and butane) for refinery fuel use or other uses do so in their capacity as either an end-user or wholesale purchaser-consumer. They must as suppliers, therefore, allocate these products to themselves in their capacities as wholesale purchaser-consumers or end-users. Other producers of these products to refiners for refinery fuel use will also allocate to refiners in accordance with the revised regulations.

FEA has separately and combined §§ 211.10(g) (8) and 211.10(g) (9) making it clear that end-users and wholesale purchaser-consumers of propane or butane may not accept or use these fuels for excess one hundred percent of their base period use for synthetic natural gas feedstock use, gas utility use or other industrial use. Refinery fuel use has been similarly restricted; therefore, refiners may not use these fuels directly or indirectly from any source in a period which corresponds to a base period to exceed one hundred percent of their base period use for refinery fuel use.

Sections 211.81 and 211.91 have been revised to indicate that the propane and butane allocation subparts exclude the propane and butane content of natural gas liquids and refinery gas from direct allocation. However, the restriction placed upon the use of the propane and butane content of natural gas liquids and refinery gas under § 211.10(g) (8) is emphasized.

Finally, § 210.34 of Part 210 and § 211.1 of Part 211 have been revised to delete reference to the term "refinery gas" in those sections. In so doing, the FEA intends to avoid possible confusion as to FEA's position regarding the component elements of refinery gas. The exemption originally provided for refinery gas was intended to clarify FEA's position that the methane and ethane content of gas produced in the refining of crude oil for use as refinery fuel was not subject to either allocation or usage restrictions under the regulations. FEA intended, however, to restrict the use of the propane and butane content of refinery gas and other mixtures even though such mixtures contained ethane, or other non-allocated products prior to processing. The possibility that §§ 210.34 and 211.1 as previously written were susceptible to contrary interpretation was anticipated. Therefore, the amendments to § 211.81 of Subpart D and § 211.91 of Subpart E make it clear that FEA allocates propane, butane, and propane-butane mixtures, as such, and that with respect to mixtures that contain non-allocated products, FEA restricts the use of the propane and butane contained in those mixtures.

FEA has concluded that these amendments and revisions are being issued on an emergency basis, an opportunity for oral presentation of views is not possible prior to the implementation of these amendments and revisions. A public hearing, however, will be held beginning at 9:30 a.m. on January 9, 1975 at the Federal Building, Room 3000, 12th and Pennsylvania Avenue, N.W., Washington, D.C., to receive comments from interested persons. The hearing will be continued through January 10, 1975, if necessary. Any person who has an interest in the subject matter of the hearing, or who is a representative of a group or class of persons which has an interest in the subject of the hearing, may make a written request for an opportunity to make oral presentation. Such a request should be directed to Executive Communications, FEA, and must be received before 4:30 p.m., e.s.t., December 31, 1974. Such a request may be hand delivered to Room 3309, Federal Building, 12th and Pennsylvania Avenue, N.W., Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday.
Comments should be identified on the outside envelope and on documents submitted to Executive Communications, FEA, with the designation “Limitation on Refinery Fuel Use.” Fifteen copies should be submitted. All comments received by January 6, 1975, and all relevant information, will be considered by the Federal Energy Administration.

Any information or data considered by the person furnishing it to be confidential and which is submitted in writing, one copy only. The FEA reserves the right to determine the confidential status of the information or data and treated it according to its determination. (Emergency Petroleum Allocation Act of 1973, Pub. L. 93-159; Federal Energy Administration Act of 1974, Pub. L. 93-275; E.O. 11790 (39 FR 23185)).

In consideration of the foregoing, Parts 210 and 211 of Chapter II, Title 10 of the Code of Federal Regulations, are amended as set forth below, effective immediately.


ROBERT E. MONTGOMERY, JR.,
General Counsel,
Federal Energy Administration.

§ 210.34 Petroleum refinery products.

(a) Petroleum refinery products such as petroleum wax, petroleum coke, asphalt and road oil which are not crude oil, refined petroleum products, or residual fuel oils are exempt from the provisions of Parts 211 and 212 of this chapter.

§ 211.10 Supplier’s method of allocation.

(8) Limitation on purchaser’s rights including special restrictions on propane and butane.

Unless directed by FEA no supplier shall supply and no end-user or wholesale purchaser-consumer shall accept quantities of allocated product which exceed one hundred (100) percent of the end-user’s or wholesale purchaser-consumer’s current requirements, provided, that (1) no supplier shall supply and no end-used or wholesale purchaser-consumer shall accept or use quantities of propane or butane (including the propane and butane content of natural gas liquids and refinery gas) in excess of one hundred (100) percent of base period use for synthetic natural gas feedstock use, gas utility use, or any industrial use except for the purpose of increasing inventories for such uses to the levels allowed under § 211.86(g) or § 211.96(d) and provided further, That (ii) no supplier shall supply and no end-user or wholesale purchaser-consumer shall accept or use quantities of propane or butane (including the propane and butane content of natural gas liquids and refinery gas) in excess of one hundred (100) percent of base period use for refinery fuel use.

§ 211.51 Definitions.

§ 211.10 Supplier’s method of allocation.

(a) Petroleum refinery products such as petroleum wax, petroleum coke, asphalt and road oil which are not crude oil, refined petroleum products, or residual fuel oils are exempt from the provisions of Parts 211 and 212 of this chapter.

2. Section 211.10 is amended in paragraph (a) (3) to read as follows:

§ 210.34 Petroleum refinery products.

(a) Petroleum refinery products such as petroleum wax, petroleum coke, asphalt and road oil which are not crude oil, refined petroleum products, or residual fuel oils are exempt from the provisions of Parts 211 and 212 of this chapter.

(b) Exclusions.

(3) Petroleum refinery products such as petroleum wax, petroleum coke, asphalt and road oil which are not crude oil, refined petroleum products, or residual fuel oils are excluded from this part.

§ 211.10 Supplier’s method of allocation.

(g) Allocations fractions greater than one.

§ 211.10 Supplier’s method of allocation.

(8) Limitation on purchaser’s rights including special restrictions on propane and butane.

§ 211.10 Supplier’s method of allocation.

(8) Limitation on purchaser’s rights including special restrictions on propane and butane.

Unless directed by FEA no supplier shall supply and no end-user or wholesale purchaser-consumer shall accept quantities of allocated product which exceed one hundred (100) percent of the
constitutes greater than ten (10) percent of the mixture by weight. Included within the definition of propane is the propane content of natural gas liquids and refinery gas when used for refinery fuel use.

“Propane-butane mix” means any mixture consisting exclusively of propane and butane.

“Refinery fuel use” means the use of an allocated product as fuel in the refining of petroleum products.

5. Section 211.81 is revised to read as follows:

§ 211.81 Scope.

(a) This subpart is applicable to all suppliers, including producers, and purchasers of propane.
(b) This subpart provides for the mandatory allocation of all propane produced in or imported into the United States, except bottled propane, and the propane content of natural gas liquids and refinery gas. Restrictions on the use of the propane content of natural gas liquids and refinery gas are specified in §211.10(g) (8) of this Part.
(c) This subpart provides for a state set-aside.

§ 211.82 [Amended]

6. Section 211.82 is amended by deleting the definitions of “butane” and “propane-butane mix.”

7. Section 211.83 is amended in paragraph (c) by deleting the word “and” in subparagraph (2) (vi); by replacing the period (.) after subparagraph (2) (v) with a semicolon (:) and by adding a new paragraph (c) (2) (vi) to read as follows:

§ 211.83 Allocation levels.

(c) Allocation levels subject to an allocation fraction. * * *

(vi) Refinery fuel use.

* * *

(2) *

8. Section 211.91 is revised to read as follows:

§ 211.91 Scope.

(a) This subpart is applicable to all suppliers and purchasers of butane and natural gasoline.
(b) This subpart provides for the mandatory allocation of all butane and natural gasoline produced in or imported into the United States, except bottled butane, and the butane content of natural gas liquids and refinery gas. Restrictions on the use of the butane content of natural gas liquids and refinery gas are specified in §211.10(g) (8) of this Part.
(c) This subpart does not provide for a state set-aside.

PART 212—MANDATORY PETROLEUM PRICE REGULATIONS

Changes in the Price Regulations for Natural Gas Liquids and Natural Gas Liquid Products

On September 6, 1974, the Federal Energy Administration issued a Notice proposing a number of significant changes in the Mandatory Petroleum Price Regulations (39 FR 32718, September 10, 1974). Comments were invited from interested persons by September 27, 1974, and more than 80 comments were received. A public hearing on the proposal was held September 30 and October 1, 1974, at which approximately 20 interested persons presented statements. The FEA has previously amended its regulations with respect to the possibility of formulating the price of natural gas liquids and products produced from natural gas liquids, including propane, and is today adopting new regulations designed to promote new regulations designed specifically to cover the prices of natural gas liquids and products produced from natural gas liquids, including propane, and is today adopting new regulations on this subject, to be effective January 1, 1975.

Action on all other revisions to the price regulations proposed in the September 10 Notice is deferred until a later date. However, those possible revisions continue to be under active consideration by FEA for decision in this proceeding.

I. Background.

Proposing a number of significant changes in the Mandatory Petroleum Price Regulations and rewriting these new regulations could have an unanticipated impact on various entities and interests. Accordingly, although the regulations issued today will provide the basic framework for FEA regulation of prices of natural gas liquids and natural gas liquid products, the FEA is aware that revisions to these regulations may well be called for.

A principal aspect of the regulations adopted today is that they serve to allocate costs of producing propane and other natural gas liquid products to the refiners' price rules of the FEA on the basis of the differences between the operating costs of a gas plant and a refinery. The comments received in the proceeding have underscored those differences between gas processing and crude oil refining, and have made even more apparent the difficulty of formulating refiners' price rules applicable to a very complex sector of the petroleum industry. In the regulations adopted today, the FEA seeks to apply a set of rules to this sector of the industry which is as simple and as generalizable as possible. The FEA is fully aware, however, that these new regulations could have an unanticipated impact on various entities and interests. Accordingly, although the regulations issued today will provide the basic framework for FEA regulation of prices of natural gas liquids and natural gas liquid products, the FEA is aware that revisions to these regulations may well be called for.

The alternative to a cost-based price regulatory system would be a system of administered prices at various levels of distribution. Under such a system, prices would be established for natural gas liquid products that would approximate the prices of crude petroleum derived products, on a BTU equivalency basis. To the extent that demand for natural gas liquid products is exaggerated by their relatively low prices in comparison with similar products produced from crude oil, such a price system could be expected to return demand to more normal levels. Such a system would also minimize the price disparity problem, which is particularly acute in the marketing sector of the propane industry. Single prices at given levels of distribution would, however, necessarily involve inequities for producers and processors having different costs, and those with the lowest costs, might be in a position to reap “windfall” profits. Further, in order for any administered ceiling price system at various levels of distribution to stimulate additional supplies, the price level at the lowest level would have to be set at or near the level needed to provide sufficient incentive for additional production, which would be
prices to be charged for products produced in new plants. The FEA is also seeking an appropriate price incentive for the expansion of existing gas processing facilities. At the same time, the FEA is issuing an emergency amendment to its allocation regulations to govern the use of propane as a refinery fuel, to insure that undue volumes of propane are not consumed for this purpose, and the regulations today are a necessary compromise among the conflicting considerations which must be taken into account. As stated in the September 10 Notice, the fundamental objective is to permit prices that will be as low as reasonably possible without adversely affecting the availability of the product. The adverse effects of price disparities stemming from the differing costs of crude oil and natural gas on the distribution sector of the industry, and the added demand for natural gas liquid products priced at less than the prices for BTU equivalent crude petroleum derived products, were also among the problems adverted to by the FEA in its September 10 Notice. A further important consideration in this proceeding is that the FEA must ensure, to the maximum extent practicable, that its regulations do not have an undue adverse impact on any particular segment of the industry, and that established relationships and operations in the industry are not unnecessarily disrupted.

The principal features of the revised cost-based system with respect to the pricing of natural gas liquids being adopted today are: (1) The continuation of May 15, 1973 as the reference point from which increased costs and lawful prices are to be determined, but with an adjustment of May 15, 1973 selling prices of natural gas liquid products at the first sale level to at least 8.5 cents per gallon for propane, 9 cents per gallon for butane, and 10 cents per gallon for natural gasoline; (2) provision for the addition of up to 0.5 cents per gallon to May 15, 1973 selling prices for increased non-product costs incurred in processing natural gas liquids; (3) provision for the cost-based system with respect to the processing of crude oil and products derived therefrom, to reflect increased product costs, incurred since May 15, 1973, or during the month of May, 1973, as the costs against which current product costs are determined, to afford a larger percentage net-back. The FEA has determined that it would be administratively impracticable to seek to regulate, in effect, the supply-and-demand contractual arrangements under which “net-backs” are determined. Accordingly, FEA regulations will not address the manner in which the net-back revenues are allocated among purchasers. To provide specifically that the manner in which net-back revenues are allocated shall not constitute a basis upon which a first sale price may be increased.

The new Subpart K of Part 212 adopted today applies to all sales other than resale of natural gas liquids and natural gas liquid products by all entities. Including producers, royalty owners, gas processors, refiners, and resellers. The definition of “refiner” set forth in §212.31, which includes those entities which refine crude oil and which process natural gas to obtain natural gas liquids or natural gas liquid products, has not been changed. However, the applicability sections of Subpart E (Refiners) and Subpart K (Natural Gas Liquids) provide that where a refiner that refines crude oil and which processes natural gas is involved in a transaction in which a specified per unit price is not determined until the natural gas liquid products are sold separately—with royalty owners, producers, and gas processors then receiving portions of the sales revenues as determined by contractual arrangement.

In order to clarify the applicability of FEA price regulations to these various transactions, two new definitions have been added to the regulations. The term “net-back sale” is used to refer to the first transaction with respect to which a specified per unit (e.g., cents-per-gallon) price is determined. “Net-back sale” is used to refer to transactions with respect to which a specified per unit price is not determined, but as to which the transferor of the product is entitled to receive a percentage of the ultimate sales revenues of the product or products involved. The parties to sales are to make clear that FEA regulations apply to all transactions—both “first sales” and “net-back sales.” As to “net-back sales,” entities such as royalty owners, producers, and gas processors may not receive greater “net-back” revenues per gallon than were received on May 15, 1973, unless the related “first sale” is to be treated as a “net-back sale” and the contractual terms are revised to afford a larger percentage net-back. The FEA has determined that the period which preceded the initiation of the Phase IV controls, the Council determined that the month of May, 1973, as the most appropriate reference point to determine historical margins under a system of price controls designed to “freeze” prices at a time that approximate the period during which market forces appeared to have been operating relatively free of the effects of price controls, particularly with respect to crude oil, which was chosen by the Cost of Living Council as the best single date to apply price controls to natural gas liquids. The Bureau of Labor Statistics estimated this May 15, 1973 margin (i.e., the difference between May 15, 1973 selling prices and May 15, 1973 selling prices) and to provide for a dollar-for-dollar pass through of increased product costs.
a substantial departure from more typical market conditions, and reflected the fact that some firms had changed their prices, while others had not. The price spread May 15, 1973 was 7.5 cents per gallon, in contrast to 6.5 cents per gallon after the Council's Phase I freeze, of August, 1971.

The FEA also recognizes that May 15, 1973 propane prices reflect a seasonal demand reduction for that product, in many instances. To date, the FEA has received several requests for exceptions to the price regulations, citing the inequity of determining current lawful prices on the basis of a typically low price per gallon on that date, or 8.5 cents per gallon. This provision should help insure that all processors of natural gas will have margins comparable to historical levels—thus providing a continuing incentive to produce natural gas liquid products.

The FEA has determined that the arithmetic average of the prices for propane on May 15, 1973 represents a price level that is more representative for purposes of determining allowable prices, than the individual prices of each firm. Therefore, firms that are selling at lower prices than the arithmetic average price, which is more representative of the essentially free market price range by August had been reduced to 11.7 cents per gallon, which further indicates that prices were in a state of transition on May 15, 1973.

Permitting the use of this adjusted May 15, 1973 “free market” price for propane is analogous to the crude oil trading price regulation, which does not limit each producer of crude oil to a price based on the price actually charged by that producer in sales of its crude oil on May 15, 1973. Rather, producers’ prices for domestic crude oil are based on “the highest posted price” of crude oil sold at that field (“the highest posted price” of crude oil sold at that field “free market” (10 CFR 212.73(b)).

Thus, in order to obviate the necessity of dealing with this problem through exceptions on a case-by-case basis, and in light of the fact that average prices for propane were at a level of somewhat more than 8.5 cents per gallon on May 15, 1973, the FEA has determined that, in dealing with the higher price at which propane was lawfully priced in transactions on May 15, 1973, for use in the price rule, a seller of propane in a first sale transaction may use the higher of either the adjusted arithmetic average price per gallon on that date, or 8.5 cents per gallon. This provision should help insure that all processors of natural gas will have margins comparable to historical levels—thus providing a continuing incentive to produce natural gas liquid products.

The FEA has further determined that, in view of the fact that prices for butane and high pressure natural gasoline historically exceeded the price of propane by an average of 0.5 cents per gallon for butane and 1.5 cents per gallon for natural gasoline, the May 15, 1973 prices which may be used for these two products for purposes of the price regulations will be the higher of the actual price on that date for each product, or 9 cents per gallon for butane and 10 cents per gallon for natural gasoline.

These provisions with respect to adjusted May 15, 1973 prices are intended to remove inequities that have resulted from non-representative May 15, 1973 prices. Although not intended primarily as a measure to reduce current price disparities, this provision should also tend to alleviate the price disparity problems in the marketing sector of the propane industry.

IV. Non-product cost allowance. The FEA recognizes that processors of natural gas liquids may be incurring increased non-product costs of operations, such as rent, labor, interest, etc., which cannot be accounted for as increased natural gas shrinkage costs. The FEA does not, however, have sufficient data to determine the extent of these increased non-product costs on a plant-by-plant, or industry-wide basis.

The FEA has concluded that the differences in gas plant operations from those of crude oil refinery operations justifies the treatment of non-product costs. Particularly in view of the large number of gas plants and the fact that many of them are not under the ownership of a single legal entity, the FEA has concluded that regulations to provide for the computation and the pass-through of increased non-product costs on a plant-by-plant, or even a firm-by-firm basis, in the manner of the recently amended non-product cost pass-through regulations which are generally applicable to refiners (4212.87), is impracticable and would present an unreasonable administrative burden if applied to all gas plants. In view of the foregoing, the FEA has determined that actual increased non-product costs of operating gas processing plants may be passed through in prices charged for natural gas liquids, provided that not more than 0.5 cents per gallon will be permitted to be added to the May 15, 1973 selling price of natural gas liquid products, in recognition of increased non-product costs incurred since that date.

Gas plant operators will be required to maintain records to justify non-product cost increases, just as they will be required to do with respect to product cost increases, and the pass through of increased non-product costs by refiners that process natural gas and refine crude oil will be subject to profit margin limitations of Subpart E.

Any firm that has increased non-product costs of gas processing that would justify a price increase of more than 0.5 cents per gallon may request permission to charge higher prices, on a case-by-case basis through the exceptions process.

V. Increased cost of natural gas shrinkage. For natural gas processing, the equivalent of increased product cost is the increase in the cost of the “shrinkage” which occurs in the natural gas stream from which the liquids are extracted, as a result of the extraction of the liquids. This cost of such shrinkage is the reduction in sales revenues received from the natural gas because of the reduced volume of the gas after processing. Where the price permitted to be charged for natural gas has increased since May 15, 1973, an increased cost of “shrinkage” resulting from extraction of the liquids has been the result. The FEA has determined that this cost increase is the equivalent of increased product cost, and shall therefore be permitted to be passed through in sales of natural gas liquids.

The cost of shrinkage shall be computed based on the contractual terms in effect for the sale of natural gas during the time period for which shrinkage cost is being measured. Thus, in those cases where the natural gas processed is sold under contracts whereby the price is based on BTU value, the cost of “shrinkage” is to be computed based on the reduction in sales revenues from natural gas because of reduced BTU value attributable to gas processing. Where the natural gas processed is or was sold under contracts at prices based on the volume of gas, the cost of “shrinkage” is to be computed based on the reduction in sales revenues from natural gas sales because of reduced volume attributable to gas processing.

Thus, any selling prices for natural gas liquid products which exceed the adjusted May 15, 1973 price for the product, plus the 0.5 cents per gallon allowed for increased non-product costs, must be justified by increased natural gas shrinkage costs. The pass-through of increased shrinkage costs will permit continuing price disparities, particularly as long as the wide disparity in prices being charged for interstate sales and for intrastate sales of natural gas persists. However, use of this type of regulation will permit the full cost of processing higher priced natural gas to be passed through and, to the extent that
the prices of natural gas begin to move closer to the prices of crude oil, on a BTU basis, the problem of price disparities between derived products and natural gas liquid products will be alleviated, without the need for any action by FEA.

Gas plant operators will be required to maintain records to establish the amount of increased shrinkage costs attributable to the gas they process. The total increased shrinkage cost attributable to the entire volume of natural gas processed must be allocated to the total volume of natural gas liquids to which those costs are attributable. For each month, increased shrinkage costs may be allocated to the prices charged for those liquids in a first sale, without regard to which entity actually retains title to the natural gas, and therefore "incurs" an increased shrinkage cost by virtue of reduced natural gas sales revenues. This approach avoids the complexities inherent in attempting to allocate the shrinkage costs pursuant to the wide variety of contractual terms that are in existence, and is consistent with the application of a "first sale" price rule which leaves the parties free to "back" sale arrangements free to allocate the revenues from first sales of natural gas liquid products as they see fit.

Because the amount of increased shrinkage costs and volumes of natural gas liquids to which those costs are attributable are relatively stable, such costs may be added to prices on a current basis. This will contribute to administrative simplicity for processors who will simply be required, for each month, to establish the increased shrinkage costs for that month and charge the prices charged in that month. Increased shrinkage costs not recovered in one month may be carried forward for recovery in a subsequent month.

Where different volumes of natural gas processed in the same gas plant are subject to separate contracts for sale, and different increased shrinkage costs attributable to the gas they process. The total increased shrinkage cost attributable to the entire volume of natural gas processed must be allocated to the total volume of natural gas liquids to which those costs are attributable. In such a case, the amount of increased shrinkage costs attributable to all natural gas processed in a plant may be allocated to the total volume of liquids extracted from that volume of gas, or the total amount of increased shrinkage costs attributable to all natural gas processed in a plant may be allocated to the total volume of liquids extracted from that gas. Whatever method of cost allocation is used, no more than a volumetrically proportional share of the available increased costs may be allocated to prices charged for particular products.

VI. Unequal application among classes of purchaser of increased costs to determine prices for propane. FEA price regulations require generally that the amount of increased product costs used in determining prices charged for a particular product be equally applied to the May 15, 1973 selling price to each class of purchaser of that product. In the September 10 Notice, the FEA proposed an amendment to this requirement, for all products, in order to restore a measure of pricing flexibility that is not currently available under the price regulations. The September 10 Notice proposed to eliminate the equal application requirement, except in the case where it is necessary to protect the independent sector of the market. The FEA has not yet completed its analysis of this proposal as to the pricing of covered products in general, but it has concluded that a revision to its regulations in this regard for propane prices is appropriate at this time, in light of the special considerations which affect the prices of this product.

In revising the equal application of increased cost requirement for propane prices, the FEA will, as proposed in its September 10 Notice, afford protection for independent marketers by requiring that the increased increment of increased product cost be applied to prices charged to any class of purchaser that includes an independent marketer. In addition, that same restriction will be extended to the May 15, 1973 selling price, may be computed on the basis of the adjusted May 15, 1973 prices, the FEA will, as proposed in its analysis of this proposal as to the pricing of covered products in general, but it has concluded that a revision to its regulations in this regard for propane prices is appropriate at this time, in light of the special considerations which affect the prices of this product.

Although no limitation was proposed on the amount of difference in amounts of increased product costs that could be applied to the May 15, 1973 selling price to different classes of purchaser under this revision, the FEA has concluded that there should be such a limitation, at least, for propane. Accordingly, under the new regulation, the greatest amount of increased product cost added to the May 15, 1973 selling price of propane to any other class of purchaser by more than 100 percent. Thus, if a seller had May 15, 1973 weighted average selling prices of 9 cents per gallon to a class of purchaser that included an independent marketer, and of 11 cents per gallon to the May 15, 1973 selling price of propane to the May 15, 1973 selling price of propane to the other class of purchaser by more than 100 percent. Thus, if a seller had May 15, 1973 weighted average selling prices of 9 cents per gallon to a class of purchaser that included an independent marketer, and of 11 cents per gallon to the May 15, 1973 selling price of propane to the other class of purchaser would be 10 cents per gallon, which would result in a selling price in this example to that class of purchaser of 21 cents per gallon.

These revisions to the price regulations for propane are intended to help preserve reasonable price levels for propane used by residential users, and at the same time to help forestall some of the excessive demand for this product from so-called "non-traditional" users, which could be intensified by the availability to such users of the product at costs which are based solely on natural gas prices, and which would therefore typically be less than prices for BTU equivalent crude petroleum derived fuels. This provision builds on a distinction that propane available through imports, by facilitating the pass through of the higher cost of imported product, especially to industrial and utility users of propane, which are in a better position to meet the higher cost of imported product than are residential users.

VII. Separate calculation of revenues from natural gas liquid product sales by refiners that refine crude oil and process natural gas. The FEA has become aware of the significant problem currently faced by independent natural gas processors that do not refine crude oil in obtaining new supplies of natural gas for processing. Since natural gas producers and royalty owners traditionally receive a percentage of the revenue from the liquid products, they seek to commit their natural gas to the processor that has the highest lawful selling price for those products. In order to maximize their return, and since the highest selling price is often above the price at which they can sell the liquid products, they seek to commit their natural gas to the processor that has the highest lawful selling price for those products. In order to maximize their return, and since the highest selling price is often above the price at which they can sell the liquid products, the FEA has concluded that there should be such a limitation, at least, for propane. Accordingly, under the new regulation, the greatest amount of increased product cost added to the May 15, 1973 selling price of propane to any other class of purchaser by more than 100 percent. Thus, if a seller had May 15, 1973 weighted average selling prices of 9 cents per gallon to a class of purchaser that included an independent marketer, and of 11 cents per gallon to the May 15, 1973 selling price of propane to the other class of purchaser would be 10 cents per gallon, which would result in a selling price in this example to that class of purchaser of 21 cents per gallon.

This provision necessarily overrides any contractual provisions that are inconsistent with it. It should be noted, also, that any contractual provisions that depend upon "posted" or "market" prices would be generally inoperative, since the operation of the FEA cost-based price regulations in general, but it has concluded that a revision to its regulations in this regard for propane prices is appropriate at this time, in light of the special considerations which affect the prices of this product.
butane, and 13.5 cents per gallon for natural gasoline may be used. The additional 3.5 cents per gallon with respect to May 15, 1973 prices, to be used in computing lawful prices for natural gas liquid products produced in new gas plants is intended to provide an incentive for the construction of new plants and to stimulate new gas supply. Comments are requested with respect to this provision of the regulations, and if this incentive is not regarded as sufficient, data to support the decrease in any further incentive should be submitted.

The maximization of extraction of liquids from existing plants, through providing price incentives for plant modernization and expansion, is also an objective of the FEA. The FEA does not have on hand sufficient data to determine whether increased extraction can be appropriately measured, or what kind of incentives to achieve further liquid extraction would be. It may be possible, for example, to provide by regulation that the percentage of propane extracted from the natural gas produced by a particular plant is increased by a certain percentage, a special additional price per gallon of product produced in that plant could be charged. Comments are also requested on this issue.

IX. Relationship to allocation regulations. The cost-based regulations adopted today continue to relate the prices of natural gas liquid products to the prices of the natural gas from which they are extracted. To the extent that natural gas prices are regulated at less than the equivalent BTU prices of crude oil, natural gas liquids will have levels which represent generally a lower price per BTU than fuels derived from crude petroleum.

The argument that natural gas liquid products are derivatives of crude petroleum or natural gas, or any firm which refined by a refiner, except as provided when it is produced.

Notwithstanding the provisions of § 212.83(b), for purposes of this special propane rule, cost of crude petroleum shall not include the cost of natural gas liquids and:

(A) May not apportion to propane a greater percentage of increased cost of crude petroleum purchased or landed in the twelve month period July 1, 1974, through June 30, 1975, than the percentage that the volume of propane sold during the twelve month period August 1, 1974, through July 31, 1975, which was produced by that refiner from crude petroleum is to the total volume of all products (including other than covered by the price regulations during the same twelve month period, which were produced by that refiner from crude petroleum. Notwithstanding § 212.83(b), for purposes of this special propane rule, cost of crude petroleum shall not include the cost of natural gas liquids.

(B) May apportion to the increased cost of propane purchased or landed in the twelve month period of July 1, 1974, through June 30, 1975, and

(C) May apportion to the increased cost products attributable to propane produced from natural gas as determined pursuant to the provisions of § 212.83(b) Subpart, and

(D) May not apportion to any increased cost products incurred prior to July 1, 1974, and not recovered through July 31, 1974.

* * * * *

(v) Exception to equal application rules for propane. Notwithstanding the provisions of paragraphs (c) (1) (i) and (ii) of this section, a refiner may comply with the provisions of this paragraph by applying unequal amounts of increased costs to the weighted average May 15, 1973 selling price of propane to classes of purchaser of propane, provided, That the highest amount of increased cost applied to the weighted average May 15, 1973 selling price to any class of purchaser shall not exceed by more than 100 percent the amount of increased cost applied to the weighted average May 15, 1973 selling price to any other class of purchaser of propane, and (ii) of this section, a refiner may comply with the provisions of this paragraph by applying unequal amounts of increased costs to the weighted average May 15, 1973 selling price of propane in sales to any other class of purchaser, which includes either an independent marketer, as defined in § 311.51 of this Chapter, or a purchaser that uses the product for residential use, as defined in § 311.51 of this Chapter, than is applied to the weighted average May 15, 1973 selling price of propane to sales to any other class of purchaser.

5. Section 212.93 is amended by redesignating paragraphs (f) and (g) as (g) and (h), respectively, and by adding a new paragraph (f) to read as follows:

§ 212.93 Price rule.

(f) Exception to equal application rules for propane. Notwithstanding the provisions of this section by applying unequal amounts of increased costs to the weighted average May 15, 1973 selling price of propane to classes of purchaser of propane, provided, That the highest amount of increased cost...
cost applied to the weighted average May 15, 1973 selling price to any class of purchaser, and provided further, that no greater increased product cost shall be applied to the weighted average May 15, 1973 selling price of propane in sales to any class of purchaser which includes either an Independent marketer, as defined in § 211.51 of this Chapter, or a purchaser that uses the product for residential use, as defined in § 211.51 of this Chapter, than is applied to the weighted average May 15, 1973 selling price of propane in sales to any other class of purchaser.

6. A new Subpart K is added to Part 212 to read as follows:

Subpart K—Natural Gas Liquids

§ 212.141 Applicability and relationship to other subparts.

§ 212.142 Definitions.

§ 212.143 General price rule.

§ 212.144 Adjusted May 15, 1973 first sale price.

§ 212.145 Increased non-product costs.

§ 212.146 Increased product costs.

§ 212.147 Allocation of increased product costs.

§ 212.148 Increased product costs for natural gas liquid products from gas plants that began operation after May 15, 1973.

§ 212.149 Net-back calculations.

§ 212.150 Records required to be maintained.


Subpart K—Natural Gas Liquids

§ 212.141 Applicability and relationship to other subparts.

(a) Scope. This subpart applies to all sales of natural gas liquids and natural gas liquid products, including transfers between affiliated entities, by all firms, including gas plant operators, producers of natural gas, natural gas royalty owners, and refiners except sales by resellers or retailers, which are subject to Subpart F of this part.

(b) Relationship to other subparts.

(1) Gas plant operators. Refiners that only refine liquid hydrocarbons from oil and gas field gases and do not refine crude petroleum shall determine their maximum lawful prices pursuant to this Subpart K and are not also subject to Subpart E.

(2) Crude oil refiners which are also gas plant operators—(i) General. Refiners that refine liquid hydrocarbons from oil and gas field gases, and also refine crude petroleum, shall determine their May 15, 1973 selling prices and increased costs for natural gas liquids and for natural gas liquid products produced in gas plants and sold to this subpart, but shall determine their maximum lawful selling prices pursuant to Subpart E.

(ii) Calculation of increased product costs. Such refiners shall calculate the increased product costs of all natural gas liquids (except natural gas liquids which are separated from natural gas at the well head of an oil well, and purchased as crude oil) and the increased product costs attributable to natural gas liquid products pursuant to §§ 212.147 and 212.148, and shall add the amount of increased product costs so determined to the amount of increased product costs incurred in each month of measurement and determined to be allocable to products charged for special products under the refiner's cost allocation formula of § 212.83(c) (1), provided that the amount of such increased product costs allocable to propane prices is limited to the amount provided for § 212.147(c) and § 212.148(c) (l). (iii) Calculation of increased non-product costs. Such refiners shall calculate increased non-product costs attributable to natural gas liquid products pursuant to §§ 212.145 in prices charged for covered products pursuant to § 212.97(b), provided that the inclusion of such increased non-product costs determined pursuant to § 212.97(b) shall not be allocable to prices charged for covered products under the net-back calculation of § 212.83(c).


Subpart K—Natural Gas Liquids

§ 212.141 Applicability and relationship to other subparts.

(a) Scope. This subpart applies to all sales of natural gas liquids and natural gas liquid products, including transfers between affiliated entities, by all firms, including gas plant operators, producers of natural gas, natural gas royalty owners, and refiners except sales by resellers or retailers, which are subject to Subpart F of this part.

(b) Relationship to other subparts—

(1) Gas plant operators. Refiners that only refine liquid hydrocarbons from oil and gas field gases and do not refine crude petroleum shall determine their maximum lawful prices pursuant to this Subpart K and are not also subject to Subpart E.

(2) Crude oil refiners which are also gas plant operators—(i) General. Refiners that refine liquid hydrocarbons from oil and gas field gases, and also refine crude petroleum, shall determine their May 15, 1973 selling prices and increased costs for natural gas liquids and for natural gas liquid products produced in gas plants and sold to this subpart, but shall determine their maximum lawful selling prices pursuant to Subpart E.

(ii) Calculation of increased product costs. Such refiners shall calculate the
of the actual May 15, 1973 selling prices for natural gas liquid products which were used to determine first sale prices of natural gas liquid products, first sale prices of not more than $.065 per gallon for propane, not more than $.09 per gallon for butane and not more than $.10 per gallon for natural gasoline, provided that the first sale price of natural gas liquids shall be reduced by same percentage or amount from these adjusted first sale prices for natural gas liquid products as it was from the actual May 15, 1973 selling prices of natural gas liquid products, which served as the reference for determining the May 15, 1973 first sale price of natural gas liquids.

Imputed May 15, 1973 first sale prices for natural gas liquid products from new gas plants where groundbreaking did not occur until January 1, 1975, or thereafter. For purposes of determining lawful prices of natural gas liquid products from new gas plants where groundbreaking did not occur until January 1, 1975, or thereafter, a firm may use as the weighted average price at which natural gas liquid products were sold in transactions on May 15, 1973, prices of not more than $.12 per gallon for propane, not more than $.125 per gallon for butane, and not more than $.135 per gallon for natural gasoline.

§ 212.145 Increased non-product costs. The first sale price of natural gas liquid products may be increased by an amount which is not in excess of $.065 per gallon in excess of the amount otherwise permitted to be charged pursuant to the provisions of this subpart, to reflect increased non-product cost increases which have been incurred since May 15, 1973; provided, That, records are maintained to show the increased non-product costs attributable to gas plant operations, under the customary accounting procedures generally accepted and consistently applied by the firm concerned, are sufficient to justify the amount of the price increase on a dollar-for-dollar basis through May 15, 1973.

§ 212.146 Increased product costs. (a) The first sale price of natural gas liquids or natural gas liquid products may be increased in each month as provided in § 212.147 to reflect, on a dollar-for-dollar basis, increased product costs since May, 1973 attributable to the production of such natural gas liquids or natural gas liquid products.

(b) Increased product costs are (1) the difference between the weighted average cost per gallon of natural gas liquids purchased in a first sale in the month of May 1973, and the weighted average cost per gallon of natural gas liquids sold in a first sale in the current month multiplied by the number of gallons of natural gas liquids purchased in the current month, plus (2) the difference between the weighted average cost per thousand cubic feet (MCF) of natural gas processed in the month of May 1973, and the weighted average cost of natural gas shrinkage per thousand cubic feet (MCF) of natural gas processed in the current month, multiplied by

\[ V_x \times \left( \frac{V_y}{V_x} \right) \]

where:

\[ V_x = \text{The total volume of all natural gas liquid products and ethane derived from that volume of natural gas and sold in the current month, and} \]
\[ V_y = \text{The total volume of all ethane derived from that volume of natural gas and sold in the current month.} \]

§ 212.147 Allocation of increased product costs. (a) Exclusion of increased product costs attributable to ethane. The total amount of increased product costs attributable to a given volume of natural gas shall be reduced each month by an amount equal to the product of the increased product costs multiplied by

\[ \left( \frac{V_y}{V_x} \right) \]

(b) Aggregation of increased product costs. Where increased product costs are measured with respect to particular volumes of natural gas or natural gas liquids processed in a gas plant in a month are different, (i) the increased product costs measured with respect to a particular volume of natural gas may be allocated to the particular sales volumes of natural gas liquid products which is produced therefrom; or, in the alternative, (ii) the total amount of increased product costs measured with respect to the total amount of natural gas and natural gas liquids processed in a gas plant in a month may be allocated to the total sales volume of natural gas liquid products from all volumes of natural gas and natural gas liquids processed in that gas plant.

(c) Increased product costs allocable to propane. The total amount of increased product costs allocable to the price of propane derived from a particular volume of natural gas shall not exceed the amount of increased product cost determined pursuant to paragraphs (a) and (b) of this subsection to be allocatable to that volume of natural gas and allocable to the sales volume of natural gas liquid products derived therefrom, multiplied by

\[ \left( \frac{V_y}{V_x} \right) \]

where:

\[ V_x = \text{The total volume of all natural gas liquid products and ethane derived from that volume of natural gas and sold in the current month,} \]
\[ V_y = \text{The total volume of propane derived from that volume of natural gas and sold in the current month.} \]

(d) Allocation of increased product costs among classes of purchaser. In computing maximum lawful prices for sales of natural gas liquid products other than propane, the amount of increased product cost allocable to such products pursuant to this section shall be equally applied to each class of purchaser. The total amount of increased product costs allocable to natural gas liquid products may be apportioned among natural gas liquid products purchased, in whatever amounts are deemed appropriate. In computing maximum lawful prices for sales of propane, unequal amounts of increased product costs may be allocated to different classes of purchaser, provided, That the highest amount of increased product cost applied to the weighted average May 15, 1973 selling price to any class of purchaser shall not exceed 100 percent the amount of increased product cost applied to the weighted average May 15, 1973 selling price to any other class of purchaser.

That no greater amount of increased product cost can be applied to the weighted average May 15, 1973 selling price of propane in sales to any class of purchaser which includes an independent marketer, as defined in § 211.51 of this Chapter, or a purchaser that uses the product for residential use, as defined in § 211.51 of this Chapter, than is applied to the weighted average May 15, 1973 selling price of propane to any other class of purchaser.

(e) Carry-forward of unrecovered increased product costs. Increased product cost that has been calculated pursuant to this section and not recovered in sales revenues in the current month may be carried forward for recovery in a subsequent month, provided, That such unrecovered increased product costs shall be allocated to prices as provided in this section, and, provided further, That to the extent any sales revenues in any current month recover in excess of the amount of increased product costs calculated pursuant to this section, such amounts shall be subtracted from the amount of increased product costs otherwise available to be allocated to prices in the following month.

§ 212.148 Increased product costs for natural gas liquids produced in a gas plant that began operation after May 15, 1973. For purposes of determining increased product costs attributable to natural gas liquid products produced in a gas plant that began operation after May 15, 1973, a firm shall use a May 15, 1973 price of natural gas of 23 cents per thousand cubic feet (MCF) for 1000 BTU per cubic foot natural gas.

§ 212.149 Net-back calculations. For purposes of calculating net-back revenues, revenues from sales of natural gas liquid products shall exclude any amounts that represent recoupment of increased cost of crude oil, provided for pursuant to Subpart E.

§ 212.150 Records required to be maintained. Prices otherwise permitted to be charged pursuant to this subpart to reflect increased product costs and increased non-product costs shall not be charged unless records adequate to demonstrate such increased product costs.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
This interpretation of a stripper well lease contains with industry usage and the congressional intent in providing for a stripper well lease exemption in the Emergency Petroleum Allocation Act of 1973 (Pub. L. 93-159, EPAA) was to assure economic viability and continued production of crude petroleum. The legislative history of this exemption reveals that Congress understood the "stripper well" concept in the same way that the FEA, in the early 1970s, defined the phrase, namely with reference to oil wells with such low production levels of crude oil that the producer received only a marginal return over cost of production.

Neither the Congress nor the FEA regulations intended to extend the "stripper well" language to encompass any production of "crude petroleum and petroleum condensates, including natural gas liquids" of wells which do not produce crude petroleum, for which the phrase "stripper well" has no real significance.

The profitability of production of natural gas from a gas well depends principally on the volumes of gas produced, and the price for which it is sold. The amounts of liquids associated with that gas, whether or not they are separated from the gas, would not, therefore, be the only appropriate factor to take into account in determining whether a price incentive was necessary to insure the continuation of gas production from a gas well.

The fact that gas well liquid production is not to be regarded as in an exemption status means that the word "wells" in the provisions of §10 CFR 210.32 may refer to gas wells obtained from Property B, since that property does not qualify as a "stripper well lease" under §210.32.

A stripper well lease is defined in §210.32(b) as "a 'property' whose average daily production of crude petroleum and petroleum condensates, including natural gas liquids, per well did not exceed 10 barrels per day during the preceding calendar year."

The provisions of 10 CFR 210.32 specifically apply, therefore, to only a property which has a "production of crude petroleum and petroleum condensates, including natural gas liquids." Firm P may, therefore, apply the provisions of the stripper well lease exemption to the production of the property where "oil wells" are producing (whether or not there is production of associated gas or casinghead gas), but may not properly claim the exemption for the natural gas liquid production of "gas wells" on a property, since these wells do not produce crude petroleum.

Thus, the first sale exemption of §210.32 applies only to the production of oil wells, which produce crude petroleum and petroleum condensates, including natural gas liquids, which are exempt.
Thus, the FEA regulations by their specific language provide that only wells "which produce crude petroleum" are to be counted in calculating average daily production for the purpose of determining whether the stripper well lease exemption applies. While injection techniques help to "produce" crude petroleum, they are not wells which themselves "produce" crude petroleum. Therefore, wells which did not actually yield or produce crude petroleum during the preceding calendar year are not production wells for this purpose. Whether the non-producing well was an "injection" well, a disposal well, a dry well, a spent well or a shut-in well will not change this result.

**ROBERT E. MONTGOMERY, JR.,
General Counsel,
Federal Energy Administration.**

**DECEMBER 19, 1974.**

[FR Doc.74-29980 Piled 12-20-74; 3:22 pm]

**[Ruling 1974-27]**

**ALLOCATION OF REFINER'S INCREASED PRODUCT COSTS TO SALES VOLUMES**

**Facts.** Firm A, a refiner subject to the Federal Energy Administration (FEA) Mandatory Petroleum Price Regulations, sells most of its covered petroleum products to domestic purchasers in arm's-length sales. Some of the covered products refined by Firm A, however, are consumed by A as refinery fuels and use as operating fuels (such as diesel fuel to power generator engines or gasoline to operate delivery vehicles). All volumes of covered petroleum products purchased by Firm A must therefore have the same incremental increased product cost assigned to them as is assigned to each product by Firm A in determining its arm's-length sales to arm's-length purchasers. The increased product costs provided for by the Act would not be realized on an equitable basis if Firm A and its affiliates were to be permitted to avoid the impact of increased product costs by Firm A in arm's-length transactions, with that increment of increased product cost to be regarded as recouped by Firm A when it uses the product, and therefore no longer available for pass-through in prices charged by Firm A.

**Issue.** How should Firm A allocate increased product costs under 10 CFR 212.83(c) with respect to these transactions?

**Ruling.** Firm A must include in its volume of covered products to which it allocates increased product costs pursuant to § 212.83(c) and for purposes of calculating increased product cost recoupment pursuant to § 212.83(c), and for purposes of determining the price of such products, all volumes of the covered products which (a) sells in arm's-length transactions; (b) refines and consumes internally; (c) transfers to affiliated entities for further processing and ultimate sale as petrochemicals or other products not subject to FEA price regulations, and some are sold for export to points outside the United States.

**How should Firm A allocate increased product costs under 10 CFR 212.83(c) with respect to these transactions?**

**Ruling.** Firm A must include in its volume of covered products to which it allocates increased product costs pursuant to § 212.83(c) and for purposes of calculating increased product cost recoupment pursuant to § 212.83(c), and for purposes of determining the price of such products, all volumes of the covered products which (a) sells in arm's-length transactions; (b) refines and consumes internally; (c) transfers to affiliated entities for further processing and ultimate sale as other than covered products; and (d) sells for export.

**All of the foregoing transactions constitute transfers for value which must be treated as part of Firm A's sales volume of covered products for purposes of allocating increased product costs pursuant to § 212.83(c), and for purposes of calculating increased product cost recoupment pursuant to § 212.83(c), so that the dollar-for-dollar pass through provisions of the price regulations are effectively carried out.**

If Firm A were to exclude from its sales measurement the internal product consumption, transfers to affiliates, and export sales, in the fact situation posed above, it would apply its increased product costs only to its arm's-length sales of these products. Such discriminatory application of increased costs only to arm's-length purchasers would violate the equal weights and equal measures product cost provisions of § 212.83(c), and would be inconsistent with the purposes of the Emergency Petroleum Allocation Act of 1973, Pub. L. 93-159, since the purpose of the Act was to ensure that increased product costs provided for by the Act would not be realized on an equitable basis if Firm A and its affiliates were to be permitted to avoid the impact of increased product costs by Firm A in arm's-length transactions, with that increment of increased product cost to be regarded as recouped by Firm A when it uses the product, and therefore no longer available for pass-through in prices charged by Firm A in arm's-length transactions.

**The uses to which Firm A may put the fuels it produces constitute clear economic value to it. Examples of these uses include, but are not limited to: (a) Refinery fuels and use as operating fuels (such as diesel fuel to power generator engines or gasoline to operate delivery vehicles). All volumes of covered petroleum products purchased by Firm A must therefore have the same incremental increased product cost assigned to them as is assigned to each product by Firm A in determining its arm's-length sales to arm's-length purchasers. The increased product costs provided for by the Act would not be realized on an equitable basis if Firm A and its affiliates were to be permitted to avoid the impact of increased product costs by Firm A in arm's-length transactions, with that increment of increased product cost to be regarded as recouped by Firm A when it uses the product, and therefore no longer available for pass-through in prices charged by Firm A.**

**By internal consumption on affiliated entity transactions of a refiner or by export sales, the revenues received in such sales must be regarded as resulting in the recoupment by Firm A of increased product costs, to the extent that the selling price of such sales is higher than the weighted average prices at which the same products were sold to the same classes of purchaser on May 15, 1973.**

**The reason for this means of accounting is that any failure to take into account sales revenues from such sales as recoupment of increased product costs would result in double recoupment of costs—once in the recoupment by Firm A of increased product costs and once in the recoupment by the refiner in arm's-length transactions, but also the volumes of these products which are accounted for in transactions of the refiner for purposes of determining cost recovery. In general, the "V" factor appearing in 212.83(c) serves to establish a proportion of increased product costs which may be allocated to covered products. The "total volume" of product, including volumes which are disposed of by internal consumption on affiliated entity transactions of a refiner or by export sales, must therefore be used when allocating increased product costs under the "V" factor of the 212.83 formula, so that no distortion in that cost allocation will result from the exclusion of such transactions.**

The rationale for this requirement is apparent, since it would obviously be unfair to permit Firm A to pass through its increased product costs only in arm's-length sales and not in transfers to its affiliates, particularly since its affiliates could well be competitors of its arm's-length purchasers in an unregulated sector of industry, such as the petrochemical sector.

The volumes of product sold in export sales by Firm A, which are exempt from the price limitations of the FEA pursuant to § 212.83, are nevertheless regulated as sales of covered products under Part 212 for purposes of determining cost recovery. Thus, although the FEA does not regulate the "prices charged for export sales of covered products," the revenues received in such sales must be regarded as resulting in the recoupment by Firm A of increased product costs, to the extent that the selling price of such sales is higher than the weighted average prices at which the same products were sold to the same classes of purchaser on May 15, 1973.

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**FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974**
Thus, Firm P's average daily production of crude petroleum and petroleum condensates, including natural gas liquids, would not include any products produced in the processing plant (so-called "plant products") whether or not the plant is an integral part of Firm P's overall operations.

The purpose of the stripper well lease exemption was to provide needed incentives to increase available supplies of crude petroleum and petroleum condensates, including natural gas liquids, but will not include other natural gas liquids which would not have been ultimately separated from the "wet" gas, and separately accounted for.

Robert E. Montgomery, Jr.,
General Counsel,
Federal Energy Administration.
December 19, 1974.

[Ruling 1974-30]

MEASUREMENT OF THE NUMBER OF BARRELS OF PRODUCTION FROM AN OIL WELL FOR THE "STRIPER WELL LEASE" EXEMPTION OF 10 CFR § 210.32

Facts. Firm P, a producer, produces crude petroleum, and petroleum condensates, including natural gas liquids, and carbon dioxide from a well, as defined in 10 CFR 210.32. Firm P transmits, to nearby storage and gathering facilities; the condensates and natural gas liquids obtained at the wellhead, along with the crude petroleum. These liquids are then eventually transmitted through a pipeline, and are all treated as crude petroleum. Firm P subsequently receives "run tickets" as evidence of the volumes of these liquids which were disposed of in this way. The casinghead gas, a natural gas which is "wet," or rich in natural gas liquids, is sold and used as refinery fuel.

Although the stripper well concept is applicable only to the production of an oil well (See FEA Ruling 1974-28), the definition of the "wet" gas obtained by oil producers in the process of crude petroleum is not defined in § 210.32 as "crude petroleum and petroleum condensates," but will include "natural gas liquids." The term "natural gas liquids" was included solely in the context of the "petroleum condensates," which often are produced at a well and which flow with the crude oil produced. The liquid hydrocarbons which it produces and sells as crude oil, without regard to the fact that its production also yields a "wet" gas, from which certain volumes of separated natural gas liquids can be extracted.

Title 12—Banks and Banking
CHAPTER I—COMPTROLLER OF THE CURRENCY, DEPARTMENT OF THE TREASURY
PART 7—INTERPRETIVE RULINGS

Customer-Bank Communication Terminals
National bankers, associations of bankers, or bank regulatory officials frequently have approached the Comptroller's Office concerning the use by national banks of mechanisms which allow bank customers electronically to initiate transactions from locations remote from the bank certain limited banking transactions. The questions raised present difficult issues concerning the interpretation of Federal law, the interaction of Federal law with state laws, and the competition between banks and other financial institutions, and the future development of electronic services which will benefit the banking public and alter traditional banking methods.

For the reasons set forth below, the Comptroller has determined both as a matter of law and as a matter of sound public policy that such off premises customer-bank communication terminals (CBCT's may be operated by national banks without regard to the restrictions contained in Federal law regulating branch banks. An interpretive ruling is being issued herewith expressing that conclusion. The Comptroller also has determined, however, that in monitoring processes and cautions should be implemented concerning the use of CBCT's in an attempt to help assure the orderly development of the nation's banking system.

Description of CBCT's.
A number of different types of CBCT's now are available or can be expected to develop in the near future. No attempt is made here to catalog every possible type of terminal. In general, these terminals permit an existing bank customer to initiate transactions resulting in a cash...
withdrawal from his account, a crediting of funds to his account, a transfer be­


tween his checking and saving accounts, and payment transfers from his account into accounts maintained by other bank customers.

Both manned and unmanned CBCT's are now in use. The CBCT typically in­
volves: (a) A card issued to and carried by the customer which is inserted into the machine; and (b) a keyboard by which the customer can operate the CBCT's. Information as to the transaction the customer wishes to accomplish is in the customer's card. The customer's card sometimes contains information as to what trans­

actions are authorized for that particular customer, and some CBCT's are capable of updating that information at the comple­tion of the transaction. The CBCT may be self-contained, or it may be con­

nected by wire (on-line) to a bank's central computer at a remote location.

Information which is not transmitted instantaneously to the central computer is recorded within the CBCT by tape or other medium. The tape is physically removed and taken to the bank for processing. All transactions conducted at a CBCT are subject to verification either by on-line communication with the bank's computer or by later examination by the bank of the tape and funds collected from the CBCT.

Unmanned CBCT's may be under con­
trol either of the bank or of a third party. When a third party is involved, however, his functions usually are related to ownership, maintenance, and servicing of the CBCT's. He is not directly involved in the transaction between the customer and the bank.

Manned CBCT's now in use always in­
volve a third party in addition to the bank and its customer. In a typical oper­
ation, the CBCT would be located in a supermarket and manned by an em­

ployee of the store. Transactions which involve receipt of funds or cash with­
drawals are verified by the employee, and are debited to or credited to an account maintained by the supermarket at the same bank. Thus the bank customer is giving funds to or receiving funds from the supermarket, and the supermarket is a retail bank, as well as an operational intermediary between the customer and the bank.

Certain devices are permissible and may be used by national banks without regard to the integrative ruling issued herewith, such as a device or teller's win­
dow which is a part of a bank's main office or of an authorized branch. See, e.g., Dunn v. First National Bank of Carterville, 344 F. Supp. 883 (N.D. Ill. 1972); Driscoll v. Northwestern National Bank, 484 F. 2d 173 (8th Cir. 1973), re­

This ruling also does not deal with the use of any device whose sole function is to verify a customer's credit standing for purposes of authorizing a credit card transaction or guaranteeing payment of a charge.

II. Historical and statutory back­
ground. Branch banks were an uncom­

only phenomena when the National Cur­
rency Act of 1863 and its replacement and revision, the National Bank Act of 1864, were passed. These Acts thus con­
tained no provision dealing with branch banks. Section 8 of the National Bank Act of 1864 required the "usual business" of a national bank, and authorized it to "establish and operate, at an office or banking house located in the place specified in its organization certificate." 13 Stat. 102. 1 As early as 1871 the Supreme Court interpreted the statute to mean that the banking house was the "comptroller's office had the case on appeal ready for Congress." 67 Cong. Rec. 2843 (1920) (Rep. Nelson). It seems clear that Congress intended to define the teller's windows as bank branches, and to authorize them within the applicable branching limitations.

Rep. McFadden's bill became the Mc­
Fadden Act of 1927, 44 Stat. 1228. The Act permitted a national bank, with the approval of the Comptroller, to estab­

lish and operate new branches within the limits of the city, town, or village in which the bank is situated, if such estab­

lishment and operation were permitted by state law to state banks. The Act fur­
ther defined "branch" as follows:

The term "branch" as used in this section shall be held to include any branch, addition, or extension of the office, or any branch place of business located in any State or Territory of the United States or in the District of Columbia at which deposits are received, or checks paid, or money lent.

The McFadden Act also imposed for the first time a limit on the branching ability of some state chartered banks. State banks which were members of the Federal Reserve System were permitted to retain and operate existing branches, but were forbidden to establish any new branches " * • * beyond the limits of the city, town, or village in which the parent bank is situated." According to Rep. Mc­
Fadden, this Act established competitive equality among all member banks of the Federal Reserve System. 68 Cong. Rec. 1492 (1927).

The branch definition of the McFadden Act never has been amended and is found at 12 U.S.C. 36(f). The only major change since the McFadden Act in the branching powers of national banks was accomplished by the Banking Act of 1933, 48 Stat. 189, which permitted a national bank to establish and operate branches at any point within the state in which the branch was situated, establishment and operation were authorized to state banks and subject to the restric­tions as to location imposed by state law upon state banks. This statute also es­
abled national banks to establish "outside" branches to be established by state member banks.

The Exclusivity of the Federal Def­
nition of "Branch". The Supreme Court in First National Bank in Plant City v. Dickinson, 396 U.S. 122, 133 (1969), re­
ected the contention that "state law definitions of what constitute 'branch"
banking' must control the content of the Federal definition of § 36(f)." Courts both before and after the Plant City decision have recognized that "what constitutes a branch of a national bank * * * is to be determined by application of the definition contained in 12 U.S.C. § 36(f)." North Davis Bank v. First National Bank of Layton, 457 F. 2d 820, 822 (10th Cir. 1972). The Comptroller agrees that state law cannot affect the definition of terms used in this federal statute, and that a resolution of whether a CBCT is a branch for purposes of federal law should be the same, for example, in California, which permits statewide branch banking, as in Texas, whose constitution prohibits branching.

The underlying structure of the National Bank Act shows the necessity of this result. The National Bank Act of 1864, 13 Stat. 510, substantially amended and replaced the National Currency Act of 1863, 12 Stat. 655. The paramount intention of both of these statutes was to " * * * give every possible support to the public credit, and to establish a uniform Currency * * * furnished by national associations, organized under a general act of Congress." Abraham Lincoln, Special Message on the Reconstruction of the War, Senate Journal, pp. 121-122 (37th Cong. 3rd Sess., Jan. 17, 1863). The first Comptroller of the Currency, Hugh McCulloch, in submitting his detailed recommendations for the amendment of the National Currency Act of 1863, pointed out that "the national banking system was expected in the seaboard areas * * * to supersede the system of banking in these states by attracting to it the capital of existing [i.e., state] banks." Annual Report of the Comptroller of the Currency, p. 10 (Nov. 28, 1865). Secretary of the Treasury Chase emphasized at page 19 of his 1865 Annual Report that the recommendations in the national banking system would " * * * induce the conversion, at the earliest practicable period, of the bank corporations of the states into national banking associations * * *." Consistent with this intention Congress gave special competitive advantages to national banks over state banks in order to induce the state banks, either to convert into national associations or go out of business altogether. When the state banking system did not disappear as expected, Congress in 1865 enacted a 10 percent tax on state bank notes, 13 Stat. 469, which was expected to eliminate the state banking system. Sections 7 and 14 of the 1865 Act specifically provided for the conversion of state chartered banks into national banking associations. The 1865 statute largely achieved the desired result: in one year the number of state chartered banks dropped from 1,089 to 349 while the number of national banks rose from 467 to 1,294.

Thus there is no general purpose in the National Bank Act to defer to state statutes regulating state chartered banks, and it is against this background that Chief Justice Burger's admonition in Plant City, supra, 396 U.S. at 133-134 must be read:

Admittedly, state law comes into play in deciding how, where, and when branch banks may be operated, Walker Bank, supra, for instance section 36(c) Congress entrusted to the States the regulation of branching as Congress thought it would be in the States to define the content of the term "branch" would make them the sole judges of their own affairs. Congress did not intend such an improbable result as appears from the inclusion in section 36 of a general definition of 'branch'.

In other words, the "branch" definition of section 36(f) cannot be varied by state law, enacted "to allow branches to itself test to be applied in the first instance to determine the extent to which state law is to be permitted to operate upon national banks in controvension of the paramount national banking supremacy over state law. See, e.g., Tiffany v. National Bank of Missouri, 18 Wall. 409 (1874); Easton v. Iowa, 188 U.S. 220 (1903).

This construction of 12 U.S.C. § 36(f) accords with the settled principle that words in a federal statute should be given a federal and nation-wide meaning. New York v. Peeling, 315 U.S. 285, 288 (1941). To construe the term "branch" as a phrase which...expected in the seaboard areas * * * to supersede the system of banking in these states by attracting to it the capital of existing [i.e., state] banks." Annual Report of the Comptroller of the Currency, p. 10 (Nov. 28, 1865). Secretary of the Treasury Chase emphasized at page 19 of his 1865 Annual Report that the recommendations in the national banking system would " * * * induce the conversion, at the earliest practicable period, of the bank corporations of the states into national banking associations * * *." Consistent with this intention Congress gave special competitive advantages to national banks over state banks in order to induce the state banks, either to convert into national associations or go out of business altogether. When the state banking system did not disappear as expected, Congress in 1865 enacted a 10 percent tax on state bank notes, 13 Stat. 469, which was expected to eliminate the state banking system. Sections 7 and 14 of the 1865 Act specifically provided for the conversion of state chartered banks into national banking associations. The 1865 statute largely achieved the desired result: in one year the number of state chartered banks dropped from 1,089 to 349 while the number of national banks rose from 467 to 1,294.

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within the most widely accepted Congressional understanding of the terms "branch bank, branch office, branch agency, additional office, or ... a branch place of business." CBCT's would seem closer to the routine off-premises activities approved by the Supreme Court in Merchante Bank v. State Bank, supra, and by Attorney General Wickersham in 1911 that was directed to the teller's window which Congress intended by the McFadden Act to authorize. 

Additionally, the legislative history of the McFadden Act shows a Congressional intention to permit competition and to promote public service. Rep. McFadden stated that "the main purpose of the bill is to remove certain outstanding handicaps from national banks which now stated that "the main purpose of the bill is to remove certain outstanding handicaps from national banks which now are deemed with the dual banking systems. ... to join the Federal Reserve System and thereby frequently are permitted (depending upon state law) to keep reserves in interest bearing notes or in correspondent accounts at other banks, thus substantially reducing the costs of maintaining a reserve position. State banks also sometimes are given higher lending limits or broader discretion in making loans. In other non-branching areas national banks enjoy competitive advantages in a dual banking system which is fundamentally inconsistent with complete equality between state chartered banks and national banks. Cf. First National Bank of Fairbanks v. Camp, 465 F. 2d 586, 596 (D.C. Cir.), cert. denied, 409

The Comptroller believes, moreover, that a contrary interpretation of the McFadden Act would establish an undeclared privilege in some states between national and state chartered banks. In the state of Washington, for example, traditional branches may be established only within the same county as the bank's main office, or elsewhere within the state by merger. CBCT's may be established by state banks, however, anywhere within the state. Thus, if a CBCT were a branch within the meaning of the McFadden Act, the result in the state of Washington would be that national banks could establish traditional branches statewide, although state chartered banks could not. This result seems out of harmony with the intention of the McFadden Act.

The Supreme Court in Plant City, supra, stated that "it is relevant in construing 'branch' to consider, not merely the contractual rights and liabilities created by the transaction, but all those aspects of the transaction that might give the (national) bank an advantage in its competition for customers." 396 U.S. at 130-134; See also First National Bank of Logan v. Walker Bank & Trust Co., 385 U.S. 252 (1966). The Court in Plant City, after considering both the contractual and non-contractual competitive aspects determined that "a systematic attempt to secure for national banks branching privileges which Florida denies to competing state banks' was involved in the operation of an armored car service and a receptacle which were advertised as a "mobile drive-in" providing "Full Service Banking at your doorstep," and that this operation constituted branch banking.

Consideration — as hereafter set forth—of the competitive aspects referred to by the Court in Plant City does not require CBCT's to be viewed as branches. Additionally, the contractual rights and liabilities under which a CBCT is operated shows that— even if a CBCT is considered to be a branch office, branch agency, or branch place of business—it is not receiving deposits, paying checks, or making loans within the meaning of 12 U.S.C. 361(d). Such an analysis is made in an appendix hereto, which represents the views of the Comptroller should these questions be raised. The contractual rights and liabilities reviewed in this analysis arise from the usual operating procedures of a CBCT, and have significant purposes other than structuring the technical and legal aspects of the transaction to avoid the branch banking statutes. Compare Plant City, supra, 396 U.S. at 130, 131; 89 S. Ct. 1357, 1359 (1969)
U.S. 1124 (1972). As the Supreme Court noted in Walker Bank, supra, the principle of competitive equality applied only insofar as branch banking is concerned. 385 U.S. at 261. Nevertheless, the Comptroller will urge temporary limits, as explained below, in an attempt to minimize any competitive imbalances which might result from this ruling.

Thus consideration of the competitive aspects as required by Plant City shows that the use of CBCT's will not be part of a systematic attempt to gain a competitive advantage for national banks, but instead is a necessary step to enable national banks to meet existing and potential competition from federal savings and loan associations and from state chartered institutions. The use of CBCT's by national banks also is required to bring to banking customers the benefits of existing electronic communication technology.

The Comptroller is faced with a difficult task of applying a 50 year old statute to an industry undergoing a great change as a result of modern electronic technology. Persuasive legal arguments can be made as to whether a literal interpretation of the statute is appropriate. The Comptroller believes, however, that the sound development of the country's banking system and the underlying legislative purpose of the McFadden Act are better served by concluding that CBCT's should not be defined as branches. He thus has stated that conclusion in an interpretive ruling which is published herewith.

V. Authority to operate CBCT's. It should be noted that a national bank clearly is authorized to operate a CBCT, even though a CBCT is not a branch. Sections 17 and 18 of the National Bank Act contemplate that a national bank may engage in "the business of banking" to advertise as being "one of the most usual and useful weapons" in "modern competition on Financial Structure and Consumer Response are changing rapidly, the Comptroller believes that sellers and users of these services should be given the widest latitude in determining how, when, and where CBCT's can be used efficiently.

Nevertheless, a change from traditional banking, in which geography is of supreme importance, to electronic banking in which time and distance become irrelevant, will involve competitive adjustments for many banks. The Comptroller thus is adopting the following policies:

First, any national bank wishing to establish a CBCT may not do so without giving 30 days prior written notice to the Comptroller containing the information specified in the new ruling. This will enable the Comptroller to monitor the development of CBCT's and to halt or alter their establishment if such action appears appropriate. Authority for this reporting requirement is found in 12 U.S.C. 161.

Second, each national bank should consider the impact that operation of CBCT's will have upon competing financial institutions. The Comptroller urges national banks prior to July 1, 1975, not to establish a CBCT in any state in which state law would prohibit a state chartered bank from establishing a similar facility. This urging is at the request of the Conference of State Bank Supervisors and is designed to give the legislators of such states an opportunity to consider whether they wish to place their state chartered banks in a financial competitive footing with national banks and with savings and loan associations. This urging also is consistent with the philosophy of the pending legislation arising from the consideration of the Commission on Financial Structure and Regulation that changes in the financial structure apply similarly to competing institutions. During May 1976 the Comptroller will examine the then existing situation to determine whether equitable considerations indicate further policy statements in this regard.

Third, some state laws concerning CBCT's require that these devices be shared with other financial institutions. The Comptroller is urging a singular requirement. In this regard, the antitrust laws of the United States are applicable to the operation of CBCT's. As the Department of Justice stated in a May 1974 statement to the Board of Governors of the Federal Reserve System:

The question of compulsory access to any EFT (electronic funds transfer) system will turn on fact questions, and the terms of any access will have to be tailored to the particular facts. At the outset compulsory access would not be required unless the particular facility is found to be "essential" in the sense that exclusion would impose a significant handicap.

Just as exclusion from a CBCT system sometimes might raise questions under the antitrust laws, the sharing by two or more competing CBCT systems also could raise legal difficulties if, for example, the result of that sharing was to discourage competition and innovation between two competitors each of whom independently was capable of establishing its own system. Thus the Comptroller's ruling permits, but does not require, banks to share CBCT's with others. The Comptroller urges national banks and their counsel are advised to consider the antitrust laws when questions arise concerning the sharing of these facilities.

VI. Effective date. The Administrative Procedure Act does not require notice and solicitation of comments in connection with interpretive rules. 5 U.S.C. § 553(b). Many interested persons have made their views informally known to the Comptroller even without a formal solicitation of comments, and these views have been considered. The Administrative Procedure Act also permits interpretive rules to take immediate effect. 5 U.S.C. § 553(d). Since the interpretive ruling issued herewith will not restrict any activities now being carried out by any bank, and since the Comptroller believes that substantial public benefit will result from this ruling, no reason exists to delay its effectiveness. Therefore, effective immediately upon publication, the existing 12 C.F.R. 7.7491, "Deposit Machines" is rescinded, and the new § 7.7491, "Customer-Bank Communication Terminals" accompanying this statement is adopted. The Comptroller's ruling is amended by revising § 7.7491 to read as follows:

§ 7.7491 Customer-Bank communication terminals.

(a) A national bank may make available for use by its customers one or more electronic devices or machines through which the customer may communicate to the bank a request to withdraw a new money either from his account or from a previously authorized line of credit, or an in-

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
construction to receive or transfer funds for the customer's benefit. The device may receive or dispense cash in accordance with such a request or instruction, subject to verification by the bank. Such devices may be unmanned or manned by a bona fide third party under contract to the bank. The bank for a reasonable period of time may provide one of its employees to instruct and assist customers in the operation of the device. Any transactions initiated by such a device shall be subject to verification by the bank either by direct wire transmission or otherwise.

(b) Use of such devices at locations other than the main office or a branch office of the bank does not constitute branch banking. A bank may provide insurance protection under its bonding program for transactions involving such devices.

(c) The establishment and use of these devices is subject to the following limitations:

1. Written notice must be given to the Comptroller's Office and to the office of the appropriate regional administrator 30 days before any such device is put into operation. The notice shall describe with regard to the device or machine:
   (i) The location;
   (ii) A general description of the area where located (e.g., shopping center, gasoline station, supermarket) and the manner of installation (e.g., free standing, exterior wall, separate interior booth);
   (iii) The manner of operation, including whether the device is on-line;
   (iv) All kinds of transactions which will be performed;
   (v) Whether the device will be manned, and, if so, by whose employee;
   (vi) Whether the device will be shared, and, if so, under what terms and with what other institutions and their location;
   (vii) The manufacturer and, if owned, the purchase price or, if leased, the lease payments and the name of the lessee;
   (viii) The distance from the nearest banking office and from the nearest similar device of the reporting bank; and
   (ix) The distance from the nearest banking office and nearest similar device of another commercial bank, which will not share the facility, and the name of such other bank or banks.

2. National banks are urged prior to July 1, 1975, not to establish a CBCT in any state in which state law would prohibit a state chartered bank from establishing a similar facility.

3. To the extent consistent with the antitrust laws, national banks are permitted, but not required, to share such devices with one or more other financial institutions.

**Effective date.** This section becomes effective December 24, 1974.

**Dated:** December 11, 1974.

**JAMES E. SMITH, Comptroller of the Currency.**

**APPENDIX**

Communications between customers and their banks through CBCT's involve instructions to consummate the following kinds of transactions: Cash withdrawals from demand accounts, savings accounts and credit card accounts or to savings accounts; transfers from demand to savings, or from savings to demand, or between certain accounts or to savings accounts; and automatic deposit credit for checking account deposit, and automatic withdrawal credit for checking account deposit. If the bank does not receive and accept the instructions necessary to assure safe and sound banking and prevent losses to customers and banks.

**UNMANNED AUTOMATED TERMINALS**

When an unmanned automated terminal is operated off-line, i.e., not connected by wire to the bank's computer, a deposit transaction is not consummated until the bank actually is notified of the customer's instructions and agreement. Chemicals necessary to implement the instruction are received and verified. This notification, receipt, and verification of the transaction takes place at the bank, either immediately with an on-line CBCT, or later with an off-line CBCT. In these circumstances the revolving credit agreement may be viewed as an original contract which establishes the loan relationship between the bank and the customer. Each request by the customer for a cash advance must be verified and accepted by the bank. The bank may not give credit for these funds prior to receipt and verification any more than it could give credit for items sent by mail to the bank, and accepted at the chartered banking premises. See, e.g., Bernstein v. Northwestern National Bank, 187 Pa. Super. 73, 41 A. 2d 440, In re Farmers State Bank of Amherst, 67 F.D. 81, 89-89, 286 N.W. 75, 78-79.

Funds left at an unmanned CBCT which is connected by wire to the bank's computer and operated on-line similarly do not become deposits until received and verified at the bank. The customer's instructions to receive the deposit for an on-line CBCT are similar to the instructions related to an off-line CBCT. The funds do not become deposits for any purpose—such as to create a revolving credit agreement—until the transfer has been received and accepted at the chartered banking premises. See, e.g., Bernstein v. Northwestern National Bank, 187 Pa. Super. 73, 41 A. 2d 440, In re Farmers State Bank of Amherst, 67 F.D. 81, 89-89, 286 N.W. 75, 78-79.

Funds left at an unmanned CBCT which is connected by wire to the bank's computer and operated on-line similarly do not become deposits until received and verified at the bank. The customer's instructions to receive the deposit for an on-line CBCT are similar to the instructions related to an off-line CBCT. The funds do not become deposits for any purpose—such as to create a revolving credit agreement—until the transfer has been received and accepted at the bank.

Cash withdrawals from demand CBCT's are accomplished either by the customer requesting the bank through the CBCT to deliver to the customer a pre-packaged bundle of currency in a standard amount, such as $25 or $50. A cash withdrawal from a demand account using an unmanned CBCT does not constitute a loan within the meaning of Article 3 of the Uniform Commercial Code. Nothing resembling a check is used in withdrawals using an unmanned CBCT. A check is not a negotiable instrument under the Uniform Commercial Code because a check is a written order, and a check written on an unmanned CBCT is not subject to verification. If the CBCT is on-line, the verification takes place instantaneously at the bank.

**RULES AND REGULATIONS 44421**

**COMMUNICATION BETWEEN CUSTOMERS AND BRANCH BANKING OFFICES AND NEAREST SIMILAR DEVICES OF REPORTING BANK AND BRANCH BANKING OFFICES AND NEAREST SIMILAR DEVICES OF ANOTHER COMMERCIAL BANK, WHICH WILL NOT SHARE THE FACILITY, AND THE NAME OF SUCH OTHER BANK OR BANKS.**

A maned CBCT consists of a terminal connected by wire (on-line) to the bank's computer which is connected to a branch banking office. The operator is the employee of the third party, such as a supermarket, who also is financially involved in the transaction. A bank customer presents to the operator information necessary to implement the desired transaction. The transaction instructions and information are communicated electronically to the bank, which, through transfer between the customer's and the establishment's accounts at the bank, consummates the desired transaction.

**As with on-line unmanned CBCT's, all transactions are verified instantaneously at the bank, and information is communicated, consummated at the bank. The reasoning stated above for unmanned CBCT's is equally applicable here. Additionally, the statement that the verification takes place at the CBCT. Even in this situation, however, the transaction is subject to verification to prevent unauthorized transaction resulting from an improperly altered authorization card.**
Title 12—Banks and Banking
CHAPTER II—FEDERAL RESERVE SYSTEM

PART 201—EXTENSIONS OF CREDIT BY FEDERAL RESERVE BANKS

Changes in Rates

Pursuant to section 14(d) of the Federal Reserve Act (12 U.S.C. 357), and for the purpose of adjusting discount rates with a view to accommodating commerce and business in accordance with other related rates and the general credit situation of the country, Part 201 is amended as set forth below:

1. Section 201.51 is amended to read as follows:

§ 201.51 Advances and discounts for member banks under sections 13 and 13a.
The rates for all advances and discounts under sections 13 and 13a of the Federal Reserve Act (except advances under the last paragraph of such section 13 to individuals, partnerships, or corporations other than member banks) are:

<table>
<thead>
<tr>
<th>Federal Reserve bank of</th>
<th>Rate Effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>New York</td>
<td>7% Dec. 9, 1974</td>
</tr>
<tr>
<td>Philadelphia</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>Cleveland</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>Richmond</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>Atlanta</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>Chicago</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>St. Louis</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>Minneapolis</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>Kansas City</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>Dallas</td>
<td>7% Dec. 10, 1974</td>
</tr>
<tr>
<td>San Francisco</td>
<td>7% Dec. 11, 1974</td>
</tr>
</tbody>
</table>

2. Section 201.52 is amended to read as follows:

§ 201.52 Advances to member banks under section 10(b).
(a) The rates for advances to member banks under section 10(b) of the Federal Reserve Act are:

<table>
<thead>
<tr>
<th>Federal Reserve bank of</th>
<th>Rate Effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>New York</td>
<td>8% Dec. 9, 1974</td>
</tr>
<tr>
<td>Philadelphia</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>Cleveland</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>Richmond</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>Atlanta</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>Chicago</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>St. Louis</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>Minneapolis</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>Kansas City</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>Dallas</td>
<td>8% Dec. 10, 1974</td>
</tr>
<tr>
<td>San Francisco</td>
<td>8% Dec. 11, 1974</td>
</tr>
</tbody>
</table>

(b) The rates for advances to member banks for prolonged periods and in significant amounts under section 10(b) of the Federal Reserve Act and § 201.2(e)(2) of Regulation A are:

<table>
<thead>
<tr>
<th>Federal Reserve bank of</th>
<th>Special rate Effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston</td>
<td>9% Dec. 10, 1974</td>
</tr>
<tr>
<td>New York</td>
<td>9% Dec. 9, 1974</td>
</tr>
<tr>
<td>Philadelphia</td>
<td>9% Dec. 10, 1974</td>
</tr>
<tr>
<td>Cleveland</td>
<td>9% Dec. 13, 1974</td>
</tr>
<tr>
<td>Richmond</td>
<td>9% Dec. 10, 1974</td>
</tr>
<tr>
<td>Atlanta</td>
<td>9% Dec. 10, 1974</td>
</tr>
<tr>
<td>Chicago</td>
<td>9% Dec. 10, 1974</td>
</tr>
<tr>
<td>St. Louis</td>
<td>9% Dec. 10, 1974</td>
</tr>
<tr>
<td>Minneapolis</td>
<td>9% Dec. 10, 1974</td>
</tr>
<tr>
<td>Kansas City</td>
<td>9% Dec. 10, 1974</td>
</tr>
<tr>
<td>Dallas</td>
<td>9% Dec. 10, 1974</td>
</tr>
<tr>
<td>San Francisco</td>
<td>9% Dec. 11, 1974</td>
</tr>
</tbody>
</table>

3. Section 201.53 reads as follows:

§ 201.53 Advances to persons other than member banks.
The rates for advances under the last paragraph of section 13 of the Federal Reserve Act to individuals, partnerships, or corporations other than member banks secured by direct obligations of, or obligations fully guaranteed as to principal and interest by, the United States or any agency thereof are:

<table>
<thead>
<tr>
<th>Federal Reserve bank of</th>
<th>Rate Effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston</td>
<td>10% Dec. 10, 1974</td>
</tr>
<tr>
<td>New York</td>
<td>10% Dec. 9, 1974</td>
</tr>
<tr>
<td>Philadelphia</td>
<td>10% Dec. 10, 1974</td>
</tr>
<tr>
<td>Cleveland</td>
<td>10% Dec. 13, 1974</td>
</tr>
<tr>
<td>Richmond</td>
<td>10% Dec. 10, 1974</td>
</tr>
<tr>
<td>Atlanta</td>
<td>10% Dec. 10, 1974</td>
</tr>
<tr>
<td>Chicago</td>
<td>10% Dec. 10, 1974</td>
</tr>
<tr>
<td>St. Louis</td>
<td>10% Dec. 10, 1974</td>
</tr>
<tr>
<td>Minneapolis</td>
<td>10% Dec. 10, 1974</td>
</tr>
<tr>
<td>Kansas City</td>
<td>10% Dec. 10, 1974</td>
</tr>
<tr>
<td>Dallas</td>
<td>10% Dec. 10, 1974</td>
</tr>
<tr>
<td>San Francisco</td>
<td>10% Dec. 11, 1974</td>
</tr>
</tbody>
</table>


By order of the Board of Governors, December 17, 1974.

[SEAL]

THEODORE E. ALLESON,
Secretary of the Board.

[FR Doc.74-29916 Filed 12-23-74;8:46 am]

CHAPTER VII—NATIONAL CREDIT UNION ADMINISTRATION

PART 701—ORGANIZATION AND OPERATION OF FEDERAL CREDIT UNIONS

Credit Union Service Center

On pages 32632–32633 of the September 10, 1974, edition of the Federal Register there were published proposed amendments to Part 701 (12 CFR Part 701) which would redesignate §§ 701.26 and 701.27 and add a new § 701.26.

After considering all comments submitted by interested parties, the proposed amendments, as set forth below, are hereby adopted without change.

Effective date: These amendments are effective immediately.

HERMAN NICKERSON, JR.,
Administrator.

DECEMBER 17, 1974.
Title 13—Business Credit and Assistance
CHAPTER I—SMALL BUSINESS ADMINISTRATION
[Revision 18]

PART 121—SMALL BUSINESS SIZE STANDARDS

This is revision 13 of Part 121 of Chapter I of Title 13 of the Code of Federal Regulations. Revision 13 of Part 121 reconciles revision 12, including amendments 1 through 16 thereto, in addition to incorporating the amendments to revision 12, this revision contains several clarifying and simplifying changes, the most significant of which are described below:

1. Section 121.3-2(a) has been revised by adding thereto material set forth in revision 12, §121.3-16, Interpretations, which section has been deleted by this revision.

2. Section 121.3-2(b) has been revised by adding the procedure for computing a concern’s average annual receipts for its preceding 3 fiscal years when the concern has been in business less than 3 years.

3. Section 121.3-2(c) has been revised to clarify that a concern organized for profit can qualify as a small business even if it is owned by or subject to the control of a non-profit entity.

4. Section 121.3-2(r) has been revised by adding thereto material appearing in §121.3-16 of revision 12.

5. Section 121.3-6 has been revised by adding thereto material appearing in §121.3-16 of revision 12.

6. Section 121.3-16(b) (3) (d) has been revised to make it clear that an appeal may be taken not only from the industry classification which the contracting officer has designated in the solicitation, but also from his designation of the appropriate Small Business Administration standard for such industry.

7. Section 121.3-8 has been revised by adding material appearing in §121.3-16 of revision 12.

8. Section 121.3-8 has been revised by adding material appearing in §121.3-16 of revision 12. Language has also been added to clarify procedures governing size self-certification and protest by the contracting officer.

9. Section 121.3-10 has been revised by adding material appearing in §121.3-16 of revision 12. A clause has also been added to clarify what action shall be taken where no financial assistance size standard has been established for an industry, field of operation, or activity. Finally, §121.3-10(b) has been revised to reflect the elimination from Schedule A of all industries with a 250-employee size standard.

10. Section 121.3-16, Interpretations, has been deleted and the interpretative material added to the appropriate sections of the regulations.

11. Schedule A has been revised by:
   a. Eliminating all industries with a 250-employee size standard (see new
§ 121.3-10(b) (2) which establishes a 250-employee standard for any manufacturing industry not set forth in Schedule A, and

b. Arranging the industries in numerical rather than alphabetical order. (This conforms with arrangement of Schedule B.)

12. This revision also establishes a definition of a small cable television operator for the purpose of obtaining an SBA loan. The new definition was proposed in the Federal Register on September 6, 1974 (39 FR 32334).

Part 121 of Chapter I of Title 13 of the Code of Federal Regulations is hereby revised as follows:

Sec. 121.3 Statutory provisions.
121.3-1 Purpose and method of establishing size standards.
121.3-2 Definition of terms used in this part.
121.3-3 Organization—size functions.
121.3-4 Size determinations.
121.3-5 Protest of small business status.
121.3-6 Advertisement.
121.3-7 Differentials.
121.3-8 Definition of small business for purposes of Government procurement.
121.3-9 Definition of small business for sales of Government property.
121.3-10 Definition of small business for SBA loans.
121.3-11 Definition of small business for assistance by small business investment companies or by development companies.
121.3-12 Definition of small business Government subcontractors.
121.3-13 Definition of small business for the purpose of lease guarantee.
121.3-14 Definition of small business for the purpose of Government leases of uranium prospecting or mining rights.
121.3-15 Definition of small business for the purpose of surety bond guaranty assistance.

Authority: Pub. L. 85-386, sec. 6(b), 73 Stat. 385.

§ 121.3 Statutory provisions.

(a) Small Business Act, as amended.

Sec. 8. For the purpose of this Act, a small business concern shall be deemed to be one which is independently owned and operated and which is not dominant in its field of operation. In addition to the foregoing criteria, the Administrator, in making a detailed definition, may use such criteria among others: Number of employees, and dollar volume of business. Where the number of employees is used as one of the criteria in making such definition for any of the purposes of this Act, the maximum number of employees that a small business concern may have under the definition shall vary from industry to industry to the extent necessary to reflect differing characteristics of such industries and to take proper account of other relevant factors.

(b) Small Business Act of 1958, as amended.

Sec. 103. As used in this Act—

RULES AND REGULATIONS

§ 121.3-1 Purpose and method of establishing size standards.

(a) Purpose. This part defines "small business concerns" and establishes standards, criteria, and procedures to determine which concerns are "small business concerns" within the meaning of the Small Business Act, as amended (hereinafter referred to as the "Act") and the Small Business Investment Act of 1958, as amended (hereinafter referred to as the "Investment Act").

(b) Method of establishing size standards.—(1) Use of Standard Industrial Classification Manual. The Standard Industrial Classification (SIC) Manual, as amended, prepared and published by the Bureau of the Budget (now Office of Management and Budget), Executive Office of the President, will be used by SBA as a guide in defining industries. Its use therefore is advisory and not mandatory.

(2) Size standards policy. (i) The Administrator for the purpose of Government procurement shall use the size standards policy set forth in this section. The definition of small business for each industry should be limited to that segment of the industry struggling to become or remain competitive.

(ii) It is the Small Business Administration's view that, in the absence of proof to the contrary, there is a segment of each industry wherein concerns by reason of their small size are at a competitive disadvantage. Therefore, the definition of small business for each industry should be limited to that segment of the industry struggling to become or remain competitive.

(iii) Smaller concerns often are forced to compete with middle-sized as compared with very large concerns. In consideration of this fact, the standard for each industry should be established as low as reasonably possible. It should be lowered in any case where the SBA determines that a few concerns under the size standard umbrella have, because of their size, gained undue competitive strength as compared with other concerns under the umbrella.

(iv) It is the Small Business Administration's view that concerns which, with or without assistance under the Small Business Act, have grown to a size which exceeds the applicable size standards should be assisted. Therefore, the size standard should compete for Government contracts not reserved for small business concerns or seek commercial markets in the same or related fields. Under such circumstances small business concerns should not rely on continuing assistance under the Small Business Act from the cradle to the grave, but should plan for the day on which they become obsolete and should be able to compete without assistance.

(3) Factors in formulating size standards. The following factors shall be considered in formulating industry size standards:

(i) Concentration of output; that is, the portion of the total output of an industry which is accounted for by a limited number of companies.

(ii) Coverage ratio, that is, the ratio of the industry's shipments of its primary products, to the total shipments by all industries of its primary products of the industry in question.

(iii) Specialization ratio, that is, the ratio of the industry's shipments of its primary products to its total shipments of primary and secondary products.

(iv) The total number of concerns in the industry.

(v) The size of industry leaders.

The SBA programs for which the size standard is established. In formulating industry size standards for the purpose of Government procurement, the additional factor of Government procurement history shall be used. The use of this additional factor may cause the size standards for the purpose of Government procurement and the size standards for the purpose of financial assistance to differ from one industry to the next.

(4) Product classification. For size standard purposes, a product or service shall be classified into only one industry, even though, for other purposes, it could be classified into more than one industry. In determining the SIC Industry into which particular products shall be classified for size standard purposes, consideration shall be given to all appropriate factors, including:

(i) Alphabetic indexes published by the Office of Management and Budget, Executive Office of the President; Bureau of the Census; and the Bureau of Domestic Commerce.

(ii) Description of the product under consideration.

(iii) Previous Government procurement for the same similar products.

(iv) Published information concerning the nature of companies which manufacture such products.

A product or service shall be classified in the industry whose definition best describes the principal nature of the product or service being procured. The end use of a product does not govern the
industry into which it is to be classified. In a borderline situation, the product or service shall be classified in the industry whose size standard would best serve to accomplish the purposes of the Small Business Act. In the case of a procurement for two or more items with different size standards, a bidder must qualify as a small business under the definition of a small business applicable to any item on which it bids. If the procurement requires the successful bidder to deliver all items and/or perform all services being procured, the applicable size standard is that for the industry whose products are involved in the greatest proportion of the contract price.

(5) Product classification. The SBA Regional Director or his delegatee of the SBA Region in which the principal business of the applicant concern is located, shall, determine the appropriate SIC classification, except that for procurement purposes the determination shall be made by the SBA, as specified in § 121.3-3, and for lease guarantee reinsurance purposes the determination shall be made by the Associate Administrator for Finance and Investment. Such determination shall be subject to appeal in the manner provided in § 121.3-6.

§ 121.3-2 Definition of terms used in this part.

(a) Affiliates: Concerns other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958 and companies incorporated solely for the purpose of owning stock in other concerns and companies registered under the Investment Company Act of 1940, are affiliates of each other when either directly or indirectly (1) one concern controls or has the power to control the other, or (2) a third party or parties controls or has the power to control both. In determining whether concerns are independently owned and operated, whether or not affiliation exists, and it is immaterial whether it is exercised prior to the date of the determination. It may be considered valid for the purpose of shifting control of or the power to control another concern when one or more parties have the power to control a concern in order that such concern may be treated as though they were one person.

(ii) Control through stock ownership.

(a) A party is considered to control or have the power to control a concern if he controls or has the power to control 50 percent or more of its voting stock.

(b) A party is considered to control or have the power to control a concern even though he owns, controls, or has the power to control less than 50 percent of the concern's voting stock if the block of stock he owns, controls, or has the power to control is large as compared with any other outstanding block of stock. If two or more such owners, have the power to control less than 50 percent of the voting stock of a concern and such minority block is (1) equal or substantially equal in size, and (2) by a show of such minority block outstanding, there is a presumption that each of such parties controls or has the power to control such concern; however, such presumption may be rebutted by a showing that such control or power to control, in fact, does not exist.

(c) If a concern's voting stock is distributed to the officers and directors of such concern, it is deemed to be in control of such concern.

Example. In a corporation where the officers and directors own various size blocks of stock totaling 50 percent of a concern's voting stock, or director or directors have a block sufficient to give him control or the power to control and the remaining 50 percent is held by one or more individual stockholders having a stock interest greater than 10 percent, management has the power to control.

(iv) Stock options, convertible debentures, and stock warrants. Stock options and convertible debentures exercisable at the time of or within a relatively short time after a size determination and agreements to merge in the future are considered as having a present ownership or control when the agreement or merger is executed at any time by company "A," the situation is treated as though company "A" had exercised its rights and become owner of a controlling interest in company "B" prior to the determination. Further, if, as of the date of the determination, company "A" has entered into an agreement to merge with company "B" in the future, the situation is treated as though the merger had taken place prior to the date of the determination.

(v) Voting trusts. If the purpose of a voting trust is to separate voting power from beneficial ownership of voting stock for the purpose of shifting control of or the power to control another concern or another concern may qualify as a small business within the size regulation, such voting trust shall not be considered valid for this purpose, regardless of whether or not affiliation exists, and it is not valid within the appropriate jurisdiction. However, if a voting trust is entered into for a legitimate purpose other than that described above, and if it is entered into for a legitimate purpose other than that described above, and if it is found to exist, and it is reasonable to conclude that under the circumstances, such concern is directing or influencing the power to control another concern, the operation of such other concern.

(a) Interlocking management. Officers, directors, employees, or principal stockholders of one concern serve as the working majority of the board of directors or officers of another concern.

(b) Common facilities. One concern shares common office space and/or employees and/or other facilities with another concern, particularly where such concerns are in the same or related industry or field of operation, or where such concerns were formerly affiliated.

(c) Newly organized concern. Former officers, directors, employees, principal stockholders, and/or key employees of one concern organize a new concern in the same or a related industry or field of operation, and serve as its officers, directors, principal stockholders, and/or key employees, and one concern is furnishing or will furnish the other concern with subcontract, financial or technical assistance, and/or other facilities, whether for a fee or otherwise.

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(vii) Control through contractual relationships—(a) Definition of a joint venture for size determination purposes. A joint venture, for size determination purposes, is an association of persons or concerns with interest in any degree or proportion by way of contract, express or implied, or otherwise to engage and carry out a single business venture, such as a Government contract, for joint profit for which purpose they combine their efforts, property, money, skill, or knowledge and put in their property as a corporation or partnership in the legal or technical sense of the term.

(b) Joint ventures—financial assistance. For the purpose of financial assistance to a joint venture, the parties thereto are considered as controlling or having the power to control each other and are considered as being affiliated. For the purpose of financial assistance to a concern which has requested assistance for its own use, but which is incidentally a party to a joint venture, such concern is not considered as being affiliated with the joint venture.

(c) Joint venture—procurement assistance. Concerns bidding on a particular procurement as joint venturers are considered as controlling or having the power to control each other with regard to performance of the contract, and therefore are considered as being affiliated. However, a concern which is a party to one or more joint ventures, but which is bidding on a procurement as an individual concern, is not considered as being affiliated with its joint ventures since they have no power to control its performance of the contract being bid on.

(d) Where a concern is not considered as being an affiliate of a concern with which it is participating in a joint venture, it is necessary, nevertheless, in computing annual receipts, etc., for the purpose of applying the size standard to the concern, to include such concern's share of the joint venture receipts (as distinguished from its share of the profits of such venture).

(e) Franchise and license agreements. If a concern is controlled by another concern under a franchise or a license agreement, the following policy is applicable: In determining whether the franchisor controls or has the power to control and, therefore, is affiliated with the franchisee, the restraints imposed on a franchisee by its franchise agreement shall not be considered provided that the franchisee has the right to profit from its effort and the risk of loss incurred, commensurate with ownership. Even though a franchisee may not be controlled by the franchisor by virtue of the contractual relationship between them, the franchisee may be controlled by the franchisor or others through common ownership or common management, in which case they would be considered as controlling.

(b) "Annual receipts" means the gross income (less returns and allowances, sales of fixed assets, and interaffiliate transactions) of a concern (and its domestic and foreign affiliates) from sales of products and services, interest, rents, fees, commissions, and/or from whatever other source derived, as entered on its regular books of account for its most recently completed fiscal year (whether on a cash, accrual, completed contracts, percentage of completion, or other acceptable accounting basis) and, in the case of a concern subject to U.S. Government contract, reported or to be reported to the U.S. Treasury Department, Internal Revenue Service for Federal income tax purposes: Provided, however, That whenever the concern has completed prior to the issuance of bids that the estimated value of one of the foregoing services constitutes more than 50 percent of the estimated value of the entire contract, the contract shall be classified as base maintenance but in the industry in which such service is classified.

(f) "Bona fide feed stocks" means crude and any other hydrocarbon material used as components in products to be delivered after merely filtering, cleaning, or blending.

(g) "Crude-oil capacity" means the maximum daily average crude throughput of a refinery in complete operation, with allowance for necessary shutdown time for routine maintenance, repairs, etc. It is determined by daily average crude runs to stills that can be maintained for an extended period.

(h) "Certificate of Competency" means a certificate issued by SBA pursuant to the authority contained in section 8(c) of the Act, stating that the holder of the certificate is competent to capacity and credit to perform a specific Government procurement or sales contract.

(i) "Concern" means any business entity organized for profit (even if its ownership is in the hands of a nonprofit entity) with a place of business located in the United States and which makes a significant contribution to the economy through payment of taxes and/or use of American products, material and/or labor, etc. "Concern" includes but is not limited to an individual, partnership, corporation, joint venture, association, or cooperative. For the purpose of making affiliation findings (see paragraph (a) of this section) any business entity, whether organized for profit or not, and any foreign business entity, i.e., any entity located outside the United States, shall be included.

(j) "Contracting officer" means the person executing a particular contract on behalf of the Government and any other employee who is a properly designated contracting officer: the term includes the authorized representative of a contracting officer acting within the limits of his authority.

(k) "Convalescent or nursing home" means those facilities for the accommodation of convalescents or other persons who are not acutely ill or not in need of hospital care but who may require nursing care and related medical services, which facility is privately owned and operated for the purpose of obtaining profit which shall accrue to the benefit of its owners, stockholders, or members.

(l) "Department store" means a store maintaining 35 or more persons engaged in the retail sale of some items in

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each of the following merchandise lines:

(1) Furniture, home furnishings, appliances, radio and television sets;
(2) a general line of apparel for the family; and
(3) household linens and dry goods provided, however, that sales within any one of these lines need not exceed 80 percent of the concern's total sales and the aggregate of such lines account for at least 50 percent of the concern's total sales.

A concern is "not dominant in its field of operation" if it does not exert a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether a concern exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

A concern is "not dominant in its field of operation" even if it does not manufacture or produce the products required to be furnished by virtue of having or requesting amendments or rescission of a published size standard.

"Size determination" means an SBA ruling, in writing, that a concern is or is not, or was or was not, a small business concern in the meaningful part. An opinion rendered by SBA to a contracting officer on the basis of published or commonly known information and without the benefit of a formal SBA inquiry, is not a "size determination" as that term is used in this part.

"United States" as used in this regulation includes the several States, the territories and possessions of the United States, the District of Columbia, the Trust Territory of the Pacific Islands, and the District of Columbia.

§ 121.3-3 Organization—size functions.

The Assistant Administrator for Advocacy, Planning and Research shall:

(a) Develop and recommend small business size standards;

(b) Establish procedures for the implementation of all size programs;

(c) Establish procedures for the implementation of all size programs;

(d) Perform such other related functions as may be appropriate to administer the SBA size program.

§ 121.3-4 Size determinations.

Original size determinations shall be made by the regional director, or his delegate, serving the region in which the principal office of the concern (not including its affiliates) whose size is in question is located, except that for lease guarantee reinsurance purposes such determinations shall be made by the Associate Administrator for Finance and Investment.

The regional director, or his delegate, or the Associate Administrator for Finance and Investment, promptly shall notify in writing, by certified mail, return receipt requested, the concern in question and other interested persons of the decision. Such determination shall become effective 40 days after written notice is given.

§ 121.3-5 Protest.

§ 121.3-5—Redetermination.

For the purpose of Government procurement contracts, a size determination shall be made only in the event of a protest pursuant to § 121.3-5, a request for a reconsideration pursuant to § 121.3-15, a request for a Certificate of Competent Small Business concern, or a request for a Certificate of Competent Small Business concern.
or his delegatee may have information which causes him to question the size status of a concern for the purpose of the Small Business Subcontracting Program or Source Search Program, or for any other purpose relating to Government procurement, and he concludes that a size determination is necessary; provided that the contracting officer or his delegatee may, whenever he deems such action necessary, determine the size status of a concern for the purpose of the Government Timber Sales Program.

§ 121.3-5 Protest of small business

(a) How to protest: Any bidder or offeror or other interested party may challenge the small business status of any other bidder or offeror on a particular Government procurement or sale. Such challenge shall be made by delivering a protest to the contracting officer responsible for the particular procurement or sale involved. In order to apply to the protest or sale in question, such protest must be filed prior to the close of business on the 5th working day, exclusive of Saturdays, Sundays, and legal holidays, after bid or proposal opening, except that in the case of negotiated procurements, a protest may be filed within 5 days exclusive of Saturdays, Sundays, and legal holidays after receipt from the contracting officer of notification of the identity of the offeror being protested. Such filing must be delivered to the contracting officer, by hand, telegraph, or mail within the 5-day period allotted. Provided, however, that a protest shall be considered timely if made by telephone to the contracting officer within the 5-day period allotted, and the contracting officer thereafter receives a confirming letter within such 5-day period or postmarked no later than 1 day after the date of such telephone protest. Any contracting officer shall promptly forward any such protest to the SBA district office serving the geographical area in which the principal office of the protested concern, not including its affiliates, is located. A protest by a contracting officer shall be timely if it is filed prior to the close of the procurement or sale in question whether filed before or after award.

(b) Notification of protest: Upon receipt of such protest, the SBA district director or his delegate shall immediately notify the contracting officer and the protestant of the date such protest has been received and that the size of the concern being protested is being considered. The contracting officer or his delegate shall also advise the protested bidder or offeror of the receipt of the protest and shall forward to the protested bidder or offeror a copy of the protest and a blank SBA Form 355, Application for Small Business Size Determination, by certified mail, return receipt requested. Such bidder must, within 3 working days after receipt of the copy of the protest and SBA Form 355, file the completed form as directed by SBA, must attach thereto a statement in answer to the allegations of the letter of protest, and evidence to support such position. If such bidder or offeror does not submit the completed SBA Form 355 within thebling period provided above, or within any additional period of time granted by SBA for cause, SBA will rule the protested concern is other than a small business.

(c) Notification of determination. After receipt of a protest and responses thereto, SBA shall determine the small business status of the protested bidder or offeror and, by certified mail, return receipt requested, notify the contracting officer, the protestant, and the protested bidder or offeror of such decision within 10 working days, if possible.

(d) If SBA has determined that a concern is ineligible as a small business for the purpose of a particular procurement, it cannot thereafter become eligible for the purpose of such procurement by taking affirmative acts to constitute itself a small business.

§ 121.3-6 Appeals

(a) Organization. The Size Appeals Board shall review appeals from size determinations made pursuant to §§ 121.3-4 and 121.3-5 and from product classification determinations made by contracting officers for the purpose of Government procurements. It has no jurisdiction to consider an appeal from a size determination or product classification determination made by SBA to classify a concern for the purpose of Government procurements. If it cannot thereafter become eligible for the purpose of a particular procurement, it cannot thereafter become eligible for the purpose of such procurement by taking affirmative acts to constitute itself a small business.

(b) Notice of determination. If an appeal is filed, the SBA district director or his delegatee shall, within 5 days exclusive of Saturdays, Sundays, and legal holidays, after receipt of the copy of the protest and SBA Form 355, file the protest, together with evidence to support such position, with the SBA district office serving the geographical area in which the principal office of the protested concern, not including its affiliates, is located. A protest by a contracting officer shall be timely if it is filed prior to the close of the procurement or sale in question whether filed before or after award.

(c) Notice of determination. If an appeal is filed, the SBA district director or his delegatee shall, within 5 days exclusive of Saturdays, Sundays, and legal holidays, after receipt of the copy of the protest and SBA Form 355, file the protest, together with evidence to support such position, with the SBA district office serving the geographical area in which the principal office of the protested concern, not including its affiliates, is located. A protest by a contracting officer shall be timely if it is filed prior to the close of the procurement or sale in question whether filed before or after award.

(d) Time for appeal. (1) An appeal from a size determination or product classification by a regional director, his delegate, or by the Associate Administrator for Finance and Investment pursuant to §§ 121.3-4 and 121.3-5; and

(2) The Small Business Administration Associate Administrator for the Small Business Administration program involved.

(e) Notice of appeal. Written notice of appeal shall be filed with the Size Appeals Board, Small Business Administration, Washington, D.C. 20416.

(f) Time for appeal. (1) An appeal from a size determination or product classification by a regional director, his delegate, or by the Associate Administrator for Finance and Investment pursuant to §§ 121.3-4 and 121.3-5; and

(2) The Small Business Administration Associate Administrator for the Small Business Administration program involved.

(g) Notice of appeal. Written notice of appeal shall be filed with the Size Appeals Board, Small Business Administration, Washington, D.C. 20416.
of receipt of the appeal by the Size Appeals Board: Provided, however, That an appeal received after such time limit has expired shall be deemed received within the requisite time limit if, in the case of mailed appeals, such appeal is sent by registered or certified mail and the postmark thereon indicates that the appeal would have been received within the requisite time limit but for delays beyond the control of the appellant, or in the case of telegraphed appeals, the telegram date and time line indicates that the appeal would have been received within the requisite time limit but for delays beyond the control of the appellant.

(4) Notice of appeal. No particular form is prescribed for the notice of appeal. However, the appellant shall submit to the Board an original and four legible copies of such notice and, to avoid time-consuming correspondence, the notice should include the following information:

(i) Name and address of concern on which the size determination was made;
(ii) The character of the determination from which appeal is taken and its date;
(iii) If applicable, the IFB or contract number and date, and the name and address of the contracting officer;
(iv) A concise and direct statement of the reasons why the decision of a regional director, or his delegatee, the contracting officer or the Associate Administrator for Finance and Investment is alleged to be erroneous;
(v) Documentary evidence in support of such allegations;
(vi) Action sought by the appellant.

(c) Notice to interested parties. The Size Appeals Board shall promptly acknowledge receipt of the Notice of Appeal and shall send a copy of such Notice of Appeal to the appropriate regional director or his delegatee and to the contracting officer (if applicable) and to the applicant. If the applicant is not the concern whose size status is in question, the Board shall also send a copy of the notice to the concern. The Board shall also inform interested parties that the appeal has been filed. The Board in its discretion may also provide any of such interested parties with copies of applicant's Notice of Appeal, or parts thereof, when the Board determines that this would be in the interest of fairness or would assist it in the performance of its functions.

(d) Statement of interested parties. After an appeal has been filed, any other interested parties may file with the Board a signed statement, together with four legible copies thereof, as to why the appeal should or should not be denied. Such statement shall be accompanied by appropriate evidence. Such statements and supporting evidence shall be mailed or delivered to the Chairman, Size Appeals Board, Small Business Administration, Washington, D.C. 20416, within 5 calendar days of the receipt of appropriate notification of appeal or other action in the proceeding unless an extension is for cause granted by the Chairman of the Size Appeals Board. If the appellant is the concern whose size status is in question to the Board, it will provide to the Board a signed statement and appropriate evidence submitted in connection with the appeal or a reconsideration thereof to such appellant.

(e) Consideration by the Size Appeals Board. (1) The Size Appeals Board shall consider the appeal on the written submission of the parties. The Board may, in its discretion, conduct oral inquiries in the consideration of all relevant information. The Board shall promptly render a decision which shall state the reason for such decision.

(2) Procedures in oral inquiries. In considering size appeals, and in reconsideration size appeals decisions, the Size Appeals Board may hold an oral inquiry to assist it in arriving at facts necessary in deciding the appeal. The following rules shall govern such oral inquiries:

(i) Oral inquiries may be held by the Size Appeals Board upon the request of any party to a size appeal or by the Board itself in its discretion, determine whether an oral inquiry will be of assistance in its determination of a size appeal. The Board shall inform the party making a request that it grants or denies the request. If the Board grants the request for an oral inquiry, it will so notify all other interested parties.

(ii) Oral inquiries by the Board are investigative in nature and not adversary. Such inquiries shall be conducted informally in a manner which will facilitate the Board's factfinding function and insure fairness.

(iii) Whichever the Board permits the appearance of two or more parties before it in an oral inquiry, cross-examination shall not be permitted between or among such parties; however, any party appearing in such oral inquiry may suggest questions for the Board to direct to other parties which may assist the Board in its determination of relevant facts.

(f) Decision of the Size Appeals Board. The decision of the Size Appeals Board shall be predicated on the entire record, and it shall state in writing the basis for its findings and conclusions. The Chairman shall promptly notify, in writing, the appellant and the other interested parties of the Board's decision together with the reasons therefor.

(g) Reconsiderations. (1) Following any decision in a size appeals case, an interested party, within no more than 5 business days following the decision, may petition the Board for reconsideration upon presentation of appropriate justification therefor. The petition for reconsideration to the Board may be in any form, with an original and four copies. The Board will notify interested parties that a petition for reconsideration has been received.

(2) The Board shall consider the petition for reconsideration upon the state and other evidence presented by the petitioners and any other evidence the Board, in its discretion, deems necessary.

(3) Grounds for reconsideration. Grounds for reconsideration shall be:

A material error of fact in the original decision; or
Relevant information not previously considered by the Board or relevant information not previously available to any of the parties involved.

(iii) When a petition for reconsideration is filed by any of the interested parties, such requesting party must demonstrate to the Board that the grounds for reconsideration involve facts or information which were not previously presented to the Board through no fault or omission of such party.

(4) If the Board denies the request for reconsideration, it shall notify all parties. If the request for reconsideration is granted, the Board shall so notify all interested parties, setting forth a reasonable time within which the interested parties may, if appropriate, submit additional information. The Board may, in its discretion, provide interested parties with copies of appropriate information submitted by other parties where it determines that this is necessary in the interest of fairness or to better assist the Board in performing its factfinding functions.

(5) Following its reconsideration of the matter, the Board will promptly render a final decision. Paragraph (f) of this section. The decision of the Board shall constitute the final administrative remedy afforded by this Agency.

§ 121.3–7 Differentials.

(a) Alaska. If an applicant for a size determination is a concern which has 50 percent or more of its annual sales or receipts attributable to business activity in or near Alaska, then, whenever “annual sales or annual receipts” are used in any size definition contained in this part, said dollar limitation is increased by 25 percent of the amount set forth therein, provided interested parties with copies of appropriate information submitted by other parties where it determines that this is necessary in the interest of fairness or to better assist the Board in performing its factfinding functions.

(b) Substantial or persistent unemployment areas; areas of concentrated unemployment or underemployment; certified eligible concerns and redevelopment areas.

(1) Financial assistance programs of the Small Business Administration and financial assistance under the Small Business Investment Act of 1958, as amended. Notwithstanding any other provision of this part, the applicable size standards for the purpose of all financial assistance programs of the Small Business Administration, except the surety bond guarantee assistance program, and for the purpose of financial assistance under the Small Business Investment Act of 1958, as amended, are increased by 25 percent whenever the concern maintains or operates a plant, facility, or other business establishment within an area of substantial unemployment or underemployment or redevelopment area as defined in § 131.3–3 (d) and (v) or (vii) “Certified Eligible Concern” by the Department of Labor and agrees to use the assistance within such area, or, if it does not maintain a plant, facility, or other business establishment within such area, agrees to utilize the assistance for the establishment and/or
operation of a plant, facility, or other business establishment within such and

(2) Government procurement assistance, sales of Government property, and Government subcontracting. Section 121.3—8, if not applicable to size determinations for the purpose of Government procurement assistance, sales of Government property, or Government subcontracting.

§ 121.3—8 Definition of small business for Government procurement.

A small business concern for the purpose of Government procurement is a concern, including any affiliates, which (1) is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts and can further qualify under the criteria set forth in this section; (2) when computing the size status of a bidder or offeror, the number of employees, annual receipts, or other applicable standard set forth in § 121.3—3(b) for the classification for which it is bidding on a contract for a product classified within an industry; and (3) neither has been determined eligible as a small business nor was certified by SBA as a small business.

§ 121.3—3(b) Definition of eligibility as a small business concern.

(a) General. A concern is eligible as a small business concern if, including its affiliates, it is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and has been determined eligible as a small business concern by SBA. If a concern has been determined to be ineligible but subsequently has on the basis of a significant change in ownership, management, or the manner of conducting business, applied for recertification and had its application granted, may represent that it is a small business concern.

(b) Government procurement assistance, sales of Government property, and Government subcontracting. Section 121.3—8, if not applicable to size determinations for the purpose of Government procurement assistance, sales of Government property, or Government subcontracting.

§ 121.3—8 Definition of small business for Government procurement.

A small business concern for the purpose of Government procurement is a concern, including any affiliates, which (1) is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts and can further qualify under the criteria set forth in this section; (2) when computing the size status of a bidder or offeror, the number of employees, annual receipts, or other applicable standard set forth in § 121.3—3(b) for the classification for which it is bidding on a contract for a product classified within an industry; and (3) neither has been determined eligible as a small business nor was certified by SBA as a small business concern. If a concern has been determined to be ineligible but subsequently has on the basis of a significant change in ownership, management, or the manner of conducting business, applied for recertification and had its application granted, may represent that it is a small business concern.

§ 121.3—3(b) Definition of eligibility as a small business concern.

(a) General. A concern is eligible as a small business concern if, including its affiliates, it is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and has been determined eligible as a small business concern by SBA. If a concern has been determined to be ineligible but subsequently has on the basis of a significant change in ownership, management, or the manner of conducting business, applied for recertification and had its application granted, may represent that it is a small business concern.
products of a small business manufacturer or producer, which products are manufactured or produced in the United States; Provided, however, if the goods to be furnished are woolen, worsted, knitwear, duck, and webbing, dealers and converters thereof, such manufacturers or producers which have been manufactured or produced by a small weaver (small knitter for knitwear), and if finishing is required, by a small finisher. If the procurement is for goods, and dealers and converters shall furnish such products which have been finished by a small finisher. (Finishing of thread is defined as all "dyeing, bleaching, spinning, throwing, or twisting operations required by the pertinent specifications but excluding mercerizing, spinning, throwing, or twisting operations.")

(ii) If the procurement is for a refined petroleum product, other than a product classified in Standard Industrial Classification Industries No. 2951, Paving Mixtures and Blocks; No. 2992, Lubricating Oils and Greases; or No. 2999, Products of Petroleum and Coal, Not Elsewhere Classified; paragraph (g) of this section is for application, if more than 50 percent of the value of the commodity in question there can only be one manufacturer of the end item being procured. The manufacturer of the end item being procured is the concern which works transforms organic or organic substances including raw materials and/or miscellaneous parts or components into such end item. Whether a bidder on a particular procurement is the manufacturer or a nonmanufacturer for the purpose of a size determination is not for determination by the contracting officer. The decision shall be made by the appropriate SBA regional director or his delegate, and need not be consistent with the contracting officer's decision as to whether such concern is or is not a manufacturer for the purpose of the Walsh-Healey Act, etc. The Government often purchases items in the form of kits such as, but not limited to, tool kits and survival kits, which are not manufactured items but are kits of small or large manufactured items. Accordingly, a concern which purchases some or all of such items and packages them into kit form is considered to be a nonmanufacturer for size determination purposes. Such a concern can qualify as a small business only if it meets all other qualifications of a small nonmanufacturer set forth in this part and if more than 50 percent of the total value of each item is comprised of kit and its contents is accounted for by items manufactured by small business.

For the purpose of a size determination, a sawmill is considered as the manufacturer of the end item which with its own forces transforms the lumber. Therefore, a small business sawmill can be one manufacturer of the end item being procured. The manufacturer of the end item being procured is the concern which with its own forces transforms organic or organic substances including raw materials and/or miscellaneous parts or components into such end item. Whether a bidder on a particular procurement is the manufacturer or a nonmanufacturer for the purpose of a size determination is not for determination by the contracting officer. The decision shall be made by the appropriate SBA regional director or his delegate, and need not be consistent with the contracting officer's decision as to whether such concern is or is not a manufacturer for the purpose of the Walsh-Healey Act, etc. The Government often purchases items in the form of kits such as, but not limited to, tool kits and survival kits, which are not manufactured items but are kits of small or large manufactured items. Accordingly, a concern which purchases some or all of such items and packages them into kit form is considered to be a nonmanufacturer for size determination purposes. Such a concern can qualify as a small business only if it meets all other qualifications of a small nonmanufacturer set forth in this part and if more than 50 percent of the total value of each item is comprised of kit and its contents is accounted for by items manufactured by small business. 

For the purpose of a size determination, a concern which converts liquid oxygen into gaseous oxygen and, therefore, must furnish gaseous oxygen converted from liquid oxygen manufactured by a small business concern.

(iv) Research, development, and testing. Any concern bidding on a contract for research, development, and/or testing is classified:

(1) As small if it is bidding on a contract for research and/or development which requires delivery of a manufactured product and (i) it qualifies as a small business manufacturer within the meaning of paragraph (b) of this section for the industry in which the product is classified, or (ii) it qualifies as a small business nonmanufacturer within the meaning of paragraph (c) of this section.

(2) As small if it is bidding on a contract for research and/or development which does not require delivery of a manufactured product or on a contract for testing and/or development of employees does not exceed 500 persons.

(e) Services. Any concern bidding on a contract for services (including but not limited to services set forth in Division 600, Services, Classification Manual, not elsewhere defined in this section, is classified as small if its average annual receipts for its preceding 3 fiscal years do not exceed $5 million.

(1) Any concern bidding on a contract for engineering services other than marine engineering service is classified as small if its average annual receipts for its preceding 3 fiscal years do not exceed $5 million.

(2) Any concern bidding on a contract for motion picture production or motion picture services is classified as small if its average annual receipts for its preceding 3 fiscal years do not exceed $5 million.

(3) Any concern bidding on a contract for janitorial and/or custodial services is classified as small if its average annual receipts for its preceding 3 fiscal years do not exceed $3 million. This section applies only to procurements requiring the use of one or more helicopters or fixed-wing aircraft classified as small if its average annual receipts for its preceding 3 fiscal years do not exceed $5 million.

(4) Any concern bidding on a contract for computer maintenance services or truck rental and leasing services or truck rental and leasing services is classified as small if its average annual receipts for its preceding 3 fiscal years do not exceed $3 million. This section applies only to procurements requiring the use of one or more helicopters or fixed-wing aircraft classified as small if its average annual receipts for its preceding 3 fiscal years do not exceed $5 million.

(f) Transportation. Any concern bidding on a contract for passenger or freight transportation, not elsewhere defined in this section, is classified:

(1) As small if its number of employees does not exceed 500 persons.

(2) As small if it is bidding on a contract for air transportation and its number of employees does not exceed 1,500 persons.

(3) As small if it is bidding on a contract for long-distance (local and/or long-distance), and/or warehousing and/or packing and crating and/or freight forwarding, and its annual receipts do not exceed $6 million.

(g) Refined petroleum products. Any concern bidding on a contract for refining services other than a product classified in Standard Industrial Classification Industries No. 2981, Paving Mixtures and Blocks; No. 2993, As-
phalt, Felt and Coatings: No. 2992, Lubricating Oils and Grease; or No. 2999, Products of Petroleum and Coal, Not Elsewhere Classified. It is classified as small if (1) its number of employees does not exceed 1,000 persons; (ii) it does not have more than 30,000 barrels-per-day crude oil or bona fide feed stock capacity from owned or leased facilities or from facilities made available to such concern under an arrangement such as, but not limited to, an exchange agreement (except one on a refined-product-for-refined-product basis), a throughput or other form of processing agreement, with the same effect as though such facilities had been leased; and (iii) the product to be delivered in the performance of the contract will contain at least 90 percent components refined by the bidder utilizing only its own employees and its own facilities or facilities obtained through a bona fide lease.

§ 121.3-9 Definition of small business for sales of Government-owned property.

In the submission of a bid or proposal for the purchase of Government-owned property, a concern which meets the criteria provided in this section and which either has not been determined by SBA to be ineligible or has been determined to be ineligible but subsequently has, on the basis of a significant change in ownership, management or contractual relations, applied for recertification and has been recertified, may represent that it is a small business. In the absence of a written protest or other information which would cause him to question the veracity of the self-certification, the contracting officer shall accept the self-certification at face value for the particular sale involved. If the contracting officer has cause to question the veracity of a self-certification and elects to do so, he shall refer the eligibility issue to SBA by filing a formal protest pursuant to § 121.3-5. If a concern has been determined by SBA to be ineligible as a small business under paragraph (1) or (2) of this section, it shall immediately notify the contracting officer of such adverse determination and shall not thereafter self-certify on a sale subject to the same or a lower employee size standard or on an exchange agreement, with the same effect as though such facilities had been leased, under subparagraph (1)(ii) of this paragraph; and, provided further, that the exchange of products for products to be delivered under a Government contract must be delivered on a refined-product-for-refined-product basis, or a throughput or other form of processing agreement, with the same effect as though such facilities had been leased.

(a) Sales of Government-owned property other than timber. A small business concern for the purpose of the sale of Government-owned property other than timber is a concern that:

(i) Is primarily engaged in the logging or forest products industry;

(ii) Is independently owned and operated;

(iii) Is not dominant in its field of operation; and

(iv) Together with its affiliates, its number of employees does not exceed 500 persons.

(b) Sales of Government-owned timber. (1) In connection with sale of Government-owned timber, a small business concern is a concern that:

(i) Is primarily engaged in the logging or forest products industry;

(ii) Is independently owned and operated;

(iii) Is not dominant in its field of operation; and

(iv) Together with its affiliates, its number of employees does not exceed 500 persons.

In the case of Government sales of timber reserved for or involving preferential treatment of small businesses, when the Government timber being purchased is to be resold, a concern is a small business when:

(1) It is a small business within the meaning of subparagraph (1) of this paragraph, and

(2) It agrees that it will not sell to a concern which is not a small business within the meaning of this paragraph more than 30 percent of such timber or, in the case of timber from certain areas, to the exchange of sawlogs for sawlogs on a refined-product-for-product basis with or without monetary adjustment, and an indirect transfer such as the sale of the assets of (or a controlling interest in) a concern after it has been awarded one or more sales of timber. Under the latter circumstances, if, after being awarded a set-aside sale of timber a small business concern merges with or becomes subject to the control of a larger business, so much of such timber (or sawlogs therefrom) shall be sold to one or more small businesses as is necessary for compliance with the 30 percent (50 percent in Alaska) restriction.

(3) In the case of Government sales reserved for or involving preferential treatment of small businesses, when the Government timber purchased is not to be resold, a concern is a small business when:

(i) It meets the criteria contained in subparagraph (1) of this paragraph, and

(ii) It agrees that in manufacturing lumber or timbers from such sawlogs cut from the Government timber, it will do so only with its own facilities or those of concerns that qualify under subparagraph (1) of this paragraph as a small business. This provision assumes that the successful bidder will remain a small
business until the products have been manufactured. Accordingly, if, after acquiring title, the bidder is purchased by, becomes controlled by, or merged with a large business, so much of the small business shall be sold to one or more small businesses as a small business concern for 30 percent (50 percent in Alaska) set-aside sale of Government timber or sawlogs did so in good faith. Accordingly, such a concern will have to maintain for the log species, grades, and volumes of timber or sawlogs were sold or disposed, and the log species, grades, and volumes involved. Such concern, and any subsequent smaller and smaller business purchaser is to be reimbursed for compliance with the 30 percent (50 percent in Alaska) restriction. Any concern which self-certifies as a small business concern for the purpose of award of contract, is determined by the SBA to be a small business concern, is expected to maintain evidence that it did so in good faith. Accordingly, such a concern will have to maintain for a period of 3 years that the state of each concern to whom the timber or sawlogs were sold or disposed, and the log species, grades, and volumes involved. Such concern, and any subsequent smaller and smaller business purchaser is to be reimbursed for compliance with the 30 percent (50 percent in Alaska) restriction. Any concern which self-certifies as a small business concern, is determined by the SBA to be a small business concern, is expected to maintain evidence that it did so in good faith. Accordingly, such a concern will have to maintain for a period of 3 years that the state of each concern to whom the timber or sawlogs were sold or disposed, and the log species, grades, and volumes involved. Such concern, and any subsequent smaller and smaller business purchaser is to be reimbursed for compliance with the 30 percent (50 percent in Alaska) restriction. Any concern which self-certifies as a small business concern, is determined by the SBA to be a small business concern, is expected to maintain evidence that it did so in good faith. Accordingly, such a concern will have to maintain for a period of 3 years that the state of each concern to whom the timber or sawlogs were sold or disposed, and the log species, grades, and volumes involved. Such concern, and any subsequent smaller and smaller business purchaser is to be reimbursed for compliance with the 30 percent (50 percent in Alaska) restriction.
(1) Transportation and warehousing. Any concern primarily engaged in passenger and freight transportation or warehousing is classified:
   (a) As small if its annual receipts do not exceed $1 million;
   (b) As small if it is primarily engaged in the air transportation industry and its number of employees does not exceed 1,000 persons;
   (c) As small if it is primarily engaged in the railroad transportation industry and its number of employees does not exceed 1,000 persons;
   (d) As small if it is primarily engaged in the inland water transportation industry and its number of employees does not exceed 1,000 persons;
   (e) As small if it is primarily engaged in the highway transportation industry and its number of employees does not exceed 1,000 persons.

(2) Wholesale. (1) Any wholesaling concern is classified:
   (a) As small if it is primarily engaged in an industry or subindustry set forth in Schedule B of this part and its annual receipts do not exceed $2 million;
   (b) As small if it is primarily engaged in an industry or subindustry set forth in Schedule C of this part and its annual receipts do not exceed $5 million.

(2) Any concern primarily engaged in wholesaling, but also engaged in manufacturing, is not a "small business concern" unless it qualifies under both the manufacturing and wholesaling standards.

(3) Mining and mineral services. Any mining or mineral services concern primarily engaged in an industry set forth in Schedule F of this part and its annual receipts do not exceed $2 million.

(4) Agriculture production (crops). Any concern primarily engaged in agriculture production (crops), fish farms and fish hatcheries, etc. Any concern in connection with custom livestock feeding is classified as small if its annual receipts do not exceed $2 million.

(5) Agriculture production (crops), fish farms and fish hatcheries, etc. Any concern primarily engaged in agriculture production (crops), fish farms and fish hatcheries, etc. Any concern primarily engaged in an industry set forth in Major Group 01—Agriculture Production—Crops, of the Census classification Industry No. 0111, and its annual receipts do not exceed $2 million.

(6) In the air transportation industry and its number of employees does not exceed 1,000 persons.

(7) As small if it is primarily engaged in an industry or subindustry set forth in Schedule B of this part and its annual receipts do not exceed $2 million.

(8) As small if it is primarily engaged in an industry or subindustry set forth in Schedule C of this part and its annual receipts do not exceed $5 million.

(9) Provided, however, That a nonmanufacturer is considered as small business for the purpose of Government subcontractors.

(10) As small if in an industry or subindustry not set forth in Schedule C of this part and its annual receipts do not exceed $2 million.

(11) Any concern in connection with subcontracts exceeding $2,500 which relate to Government procurement will be considered a small business concern if, including its affiliates, its number of employees does not exceed 500 persons.

(12) Any concern in connection with subcontracts exceeding $2,500 which relate to Government procurement will be considered a small business concern if, including its affiliates, its number of employees does not exceed 500 persons.

(13) A small business concern for the purpose of lease guarantee is a concern that qualifies as a small business under Section 121.3, "Definition of small business."
<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2621</td>
<td>Pressed and molded pulp</td>
<td>500</td>
</tr>
<tr>
<td>2648</td>
<td>Stationery, tablets and related</td>
<td>500</td>
</tr>
<tr>
<td>2649</td>
<td>Converted paper and paper-based products</td>
<td>500</td>
</tr>
<tr>
<td>2654</td>
<td>Sanitary food containers</td>
<td>500</td>
</tr>
<tr>
<td>2643</td>
<td>Bags, except textile bags</td>
<td>500</td>
</tr>
</tbody>
</table>

**MAJOR GROUP 29—PETROLEUM REFINING AND RELATED PRODUCTS**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
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</thead>
<tbody>
<tr>
<td>2911</td>
<td>Petroleum refining</td>
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</tr>
<tr>
<td>2912</td>
<td>Petroleum refining, except oil</td>
<td>1,000</td>
</tr>
<tr>
<td>2921</td>
<td>Petroleum refining, except oil</td>
<td>1,000</td>
</tr>
<tr>
<td>2952</td>
<td>Asphalt felts and coatings</td>
<td>500</td>
</tr>
<tr>
<td>2992</td>
<td>Asphalts, resins, and related</td>
<td>500</td>
</tr>
</tbody>
</table>

**MAJOR GROUP 30—RUBBER AND MISCELLANEOUS PRODUCTS**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
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</thead>
<tbody>
<tr>
<td>3021</td>
<td>Rubber and plastics footwear</td>
<td>500</td>
</tr>
<tr>
<td>3069</td>
<td>Fabricated rubber products</td>
<td>500</td>
</tr>
<tr>
<td>3068</td>
<td>Synthetic rubber (vulcanized)</td>
<td>500</td>
</tr>
<tr>
<td>3040</td>
<td>Synthetic rubber, except vulcanized</td>
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</table>

**MAJOR GROUP 31—LEATHER AND LEATHER PRODUCTS**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
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</thead>
<tbody>
<tr>
<td>3132</td>
<td>Footwear, except athletic</td>
<td>500</td>
</tr>
<tr>
<td>3144</td>
<td>Women's footwear, except ath-</td>
<td>500</td>
</tr>
<tr>
<td></td>
<td>letic</td>
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</tr>
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</table>

**MAJOR GROUP 32—STONE, GLASS AND CONCRETE PRODUCTS**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
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</thead>
<tbody>
<tr>
<td>3211</td>
<td>Flat glass</td>
<td>500</td>
</tr>
<tr>
<td>3221</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3231</td>
<td>Pressed and blown glass and glazing</td>
<td>500</td>
</tr>
<tr>
<td>3241</td>
<td>Semi-finished glass</td>
<td>500</td>
</tr>
<tr>
<td>3251</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3269</td>
<td>Glass containers</td>
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</tr>
<tr>
<td>3274</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3283</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3293</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3303</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3313</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3323</td>
<td>Glass containers</td>
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<tr>
<td>3333</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3343</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3353</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3363</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3373</td>
<td>Glass containers</td>
<td>500</td>
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<tr>
<td>3383</td>
<td>Glass containers</td>
<td>500</td>
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<tr>
<td>3393</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
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<td>Glass containers</td>
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<tr>
<td>3413</td>
<td>Glass containers</td>
<td>500</td>
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<tr>
<td>3423</td>
<td>Glass containers</td>
<td>500</td>
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<tr>
<td>3433</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3443</td>
<td>Glass containers</td>
<td>500</td>
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<tr>
<td>3453</td>
<td>Glass containers</td>
<td>500</td>
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<tr>
<td>3463</td>
<td>Glass containers</td>
<td>500</td>
</tr>
<tr>
<td>3473</td>
<td>Glass containers</td>
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**MAJOR GROUP 33—METAL PRODUCTS**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
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<tbody>
<tr>
<td>3312</td>
<td>Steel forgings</td>
<td>500</td>
</tr>
<tr>
<td>3322</td>
<td>Forged and cast steel</td>
<td>500</td>
</tr>
<tr>
<td>3332</td>
<td>Selective steels</td>
<td>500</td>
</tr>
<tr>
<td>3342</td>
<td>Steel investment foundries</td>
<td>500</td>
</tr>
<tr>
<td>3352</td>
<td>Steel investment foundries</td>
<td>500</td>
</tr>
<tr>
<td>3362</td>
<td>Steel investment foundries</td>
<td>500</td>
</tr>
<tr>
<td>3372</td>
<td>Steel investment foundries</td>
<td>500</td>
</tr>
<tr>
<td>3382</td>
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<td>500</td>
</tr>
<tr>
<td>3392</td>
<td>Steel investment foundries</td>
<td>500</td>
</tr>
<tr>
<td>3402</td>
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<td>3422</td>
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<td>3482</td>
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<td>500</td>
</tr>
<tr>
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<td>Steel investment foundries</td>
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**MAJOR GROUP 34—ELECTRICITY**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
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<tbody>
<tr>
<td>3411</td>
<td>Electric lighting fixtures</td>
<td>1,000</td>
</tr>
<tr>
<td>3421</td>
<td>Electric lighting fixtures</td>
<td>1,000</td>
</tr>
<tr>
<td>3431</td>
<td>Electric lighting fixtures</td>
<td>1,000</td>
</tr>
<tr>
<td>3441</td>
<td>Electric lighting fixtures</td>
<td>1,000</td>
</tr>
<tr>
<td>3451</td>
<td>Electric lighting fixtures</td>
<td>1,000</td>
</tr>
<tr>
<td>3461</td>
<td>Electric lighting fixtures</td>
<td>1,000</td>
</tr>
<tr>
<td>3471</td>
<td>Electric lighting fixtures</td>
<td>1,000</td>
</tr>
<tr>
<td>3481</td>
<td>Electric lighting fixtures</td>
<td>1,000</td>
</tr>
<tr>
<td>3491</td>
<td>Electric lighting fixtures</td>
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**MAJOR GROUP 35—MACHINERY, Except ELECTRICAL**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
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</thead>
<tbody>
<tr>
<td>3511</td>
<td>Steam, gas, and hydraulic turbines and turbines</td>
<td>1,000</td>
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<tr>
<td>3521</td>
<td>Steam, gas, and hydraulic turbines and turbines</td>
<td>1,000</td>
</tr>
<tr>
<td>3531</td>
<td>Steam, gas, and hydraulic turbines and turbines</td>
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**MAJOR GROUP 36—MACHINERY, Except ELECTRICAL**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
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<tbody>
<tr>
<td>3611</td>
<td>Farm machinery</td>
<td>500</td>
</tr>
<tr>
<td>3621</td>
<td>Farm machinery</td>
<td>500</td>
</tr>
<tr>
<td>3631</td>
<td>Farm machinery</td>
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<td>3641</td>
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<tr>
<td>3651</td>
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<td>500</td>
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<tr>
<td>3661</td>
<td>Farm machinery</td>
<td>500</td>
</tr>
<tr>
<td>3671</td>
<td>Farm machinery</td>
<td>500</td>
</tr>
<tr>
<td>3681</td>
<td>Farm machinery</td>
<td>500</td>
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<tr>
<td>3691</td>
<td>Farm machinery</td>
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**MAJOR GROUP 37—MACHINERY, Except ELECTRICAL**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
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</thead>
<tbody>
<tr>
<td>3711</td>
<td>Farm machinery</td>
<td>500</td>
</tr>
<tr>
<td>3721</td>
<td>Farm machinery</td>
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<tr>
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<tr>
<td>3741</td>
<td>Farm machinery</td>
<td>500</td>
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<td>Farm machinery</td>
<td>500</td>
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<tr>
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<td>Farm machinery</td>
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</tr>
<tr>
<td>3771</td>
<td>Farm machinery</td>
<td>500</td>
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<tr>
<td>3781</td>
<td>Farm machinery</td>
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<tr>
<td>3791</td>
<td>Farm machinery</td>
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**MAJOR GROUP 38—MACHINERY, Except ELECTRICAL**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
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</thead>
<tbody>
<tr>
<td>3811</td>
<td>Farm machinery</td>
<td>500</td>
</tr>
<tr>
<td>3821</td>
<td>Farm machinery</td>
<td>500</td>
</tr>
<tr>
<td>3831</td>
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</tr>
<tr>
<td>3881</td>
<td>Farm machinery</td>
<td>500</td>
</tr>
<tr>
<td>3891</td>
<td>Farm machinery</td>
<td>500</td>
</tr>
</tbody>
</table>
### RULES AND REGULATIONS

#### Census classification code
- Industry or class of products
- Employment size standard (number of employees)

#### MAJOR GROUP 36—ELECTRICAL AND ELECTRONIC MACHINERY, EQUIPMENT AND SUPPLIES

<table>
<thead>
<tr>
<th>Code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3611</td>
<td>Engineering, laboratory, scientiﬁc and research instruments</td>
<td>500</td>
</tr>
<tr>
<td>3612</td>
<td>Automatic controls for regulating residential and commercial environments and appliances</td>
<td>500</td>
</tr>
<tr>
<td>3613</td>
<td>Industrial control systems</td>
<td>500</td>
</tr>
<tr>
<td>3614</td>
<td>Household control equipment, n.e.c.</td>
<td>500</td>
</tr>
<tr>
<td>3621</td>
<td>Household refrigerators and freezers</td>
<td>1,000</td>
</tr>
<tr>
<td>3641</td>
<td>Electric lamps</td>
<td>1,000</td>
</tr>
<tr>
<td>3642</td>
<td>Cash registers</td>
<td>500</td>
</tr>
<tr>
<td>3643</td>
<td>Radio and television transmitters and receivers, except for certain communication types</td>
<td>750</td>
</tr>
<tr>
<td>3671</td>
<td>Radios and television receiving tubes, except cathode ray tubes</td>
<td>1,000</td>
</tr>
<tr>
<td>3672</td>
<td>Cathode-ray television picture tubes</td>
<td>750</td>
</tr>
<tr>
<td>3673</td>
<td>Transmitting, industrial and medical instruments</td>
<td>500</td>
</tr>
<tr>
<td>3674</td>
<td>Scientific instruments and apparatus</td>
<td>500</td>
</tr>
<tr>
<td>3675</td>
<td>Radio and television transmitting and detection equipment and apparatus</td>
<td>750</td>
</tr>
<tr>
<td>3676</td>
<td>Radio and television receiving tubes, except cathode ray tubes</td>
<td>750</td>
</tr>
<tr>
<td>3677</td>
<td>Electron tubes, transformers and other inductors</td>
<td>500</td>
</tr>
<tr>
<td>3678</td>
<td>Cathode-ray electron apparatus</td>
<td>500</td>
</tr>
<tr>
<td>3679</td>
<td>Electrical apparatus and apparatus for industrial control systems</td>
<td>500</td>
</tr>
<tr>
<td>3680</td>
<td>Electrical machinery, equipment and supplies, n.e.c.</td>
<td>500</td>
</tr>
</tbody>
</table>

#### MAJOR GROUP 22—TRANSPORTATION EQUIPMENT

<table>
<thead>
<tr>
<th>Code</th>
<th>Industry or class of products</th>
<th>Employment size standard (number of employees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2211</td>
<td>Engineering, laboratory, scientiﬁc and research instruments</td>
<td>500</td>
</tr>
<tr>
<td>2221</td>
<td>Automatic controls for regulating residential and commercial environments and appliances</td>
<td>500</td>
</tr>
<tr>
<td>2222</td>
<td>Industrial control systems</td>
<td>500</td>
</tr>
<tr>
<td>2223</td>
<td>Household control equipment, n.e.c.</td>
<td>500</td>
</tr>
<tr>
<td>2224</td>
<td>Household refrigerators and freezers</td>
<td>1,000</td>
</tr>
<tr>
<td>2241</td>
<td>Electric lamps</td>
<td>1,000</td>
</tr>
<tr>
<td>2242</td>
<td>Cash registers</td>
<td>500</td>
</tr>
<tr>
<td>2243</td>
<td>Radio and television transmitters and receivers, except for certain communication types</td>
<td>750</td>
</tr>
<tr>
<td>2271</td>
<td>Radios and television receiving tubes, except cathode ray tubes</td>
<td>1,000</td>
</tr>
<tr>
<td>2272</td>
<td>Cathode-ray television picture tubes</td>
<td>750</td>
</tr>
<tr>
<td>2273</td>
<td>Transmitting, industrial and medical instruments</td>
<td>500</td>
</tr>
<tr>
<td>2274</td>
<td>Scientific instruments and apparatus</td>
<td>500</td>
</tr>
<tr>
<td>2275</td>
<td>Radio and television transmitting and detection equipment and apparatus</td>
<td>750</td>
</tr>
<tr>
<td>2276</td>
<td>Radio and television receiving tubes, except cathode ray tubes</td>
<td>750</td>
</tr>
<tr>
<td>2277</td>
<td>Electron tubes, transformers and other inductors</td>
<td>500</td>
</tr>
<tr>
<td>2278</td>
<td>Cathode-ray electron apparatus</td>
<td>500</td>
</tr>
<tr>
<td>2279</td>
<td>Electrical apparatus and apparatus for industrial control systems</td>
<td>500</td>
</tr>
<tr>
<td>2280</td>
<td>Electrical machinery, equipment and supplies, n.e.c.</td>
<td>500</td>
</tr>
</tbody>
</table>
### RULES AND REGULATIONS

#### MAJOR GROUP 33—PRIMARY METAL INDUSTRIES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>3311</td>
<td>Primary smelting and refining of copper</td>
<td>1,000</td>
</tr>
<tr>
<td>3312</td>
<td>Aluminum rolling and drawing</td>
<td>750</td>
</tr>
<tr>
<td>3313</td>
<td>Aluminum foil</td>
<td>750</td>
</tr>
<tr>
<td>3314</td>
<td>Aluminum extruded products</td>
<td>750</td>
</tr>
</tbody>
</table>

#### MAJOR GROUP 36—ELECTRICAL AND ELECTRONIC MACHINERY, EQUIPMENT, AND SUPPLIES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>3612</td>
<td>Electric locomotives</td>
<td>1,000</td>
</tr>
<tr>
<td>3613</td>
<td>Electric street cars</td>
<td>1,000</td>
</tr>
<tr>
<td>3614</td>
<td>Electric service operators and apparatus</td>
<td>1,000</td>
</tr>
<tr>
<td>3615</td>
<td>Electric lighting and illumination equipment</td>
<td>1,000</td>
</tr>
</tbody>
</table>

#### MAJOR GROUP 37—TRANSPORTATION EQUIPMENT

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>3711</td>
<td>Motor vehicles and passenger coaches</td>
<td>1,000</td>
</tr>
<tr>
<td>3712</td>
<td>Aircraft</td>
<td>1,500</td>
</tr>
<tr>
<td>3713</td>
<td>Aircraft engines and engines for aircraft parts</td>
<td>1,000</td>
</tr>
<tr>
<td>3714</td>
<td>Airplanes and auxiliary equipment</td>
<td>1,000</td>
</tr>
</tbody>
</table>

#### SUPPLEMENTARY TABLE

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>3715</td>
<td>Guided missile and space vehicle propulsion units</td>
<td>1,000</td>
</tr>
<tr>
<td>3716</td>
<td>Guided missile and space vehicle propulsion units</td>
<td>1,000</td>
</tr>
<tr>
<td>3717</td>
<td>Radiated equipment</td>
<td>1,000</td>
</tr>
</tbody>
</table>

### SCHEDULE D—ANNUAL RECEIPTS SIZE STANDARDS FOR CONCERNS PRIMARILY ENGAGED IN RETAILING

The following size standards are to be used when determining the size status of retailing concerns for the purpose of SBA loans, displaced business loans, economic opportunity loans, and as alternate standards for the purpose of SBA loans, displaced business loans, economic opportunity loans. A concern is engaged in retailing where it primarily deals in the sale of goods for household or personal consumption. The size standard is based on the maximum annual receipts for the calendar year of the concern or its predecessor. 

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>D111</td>
<td>Department stores</td>
<td>10</td>
</tr>
<tr>
<td>D112</td>
<td>Grocery stores</td>
<td>10</td>
</tr>
</tbody>
</table>

### MAJOR GROUP 51—INDUSTRIES DIRECTLY ENGAGED IN WHOLESALE TRADE

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>5111</td>
<td>Motor vehicle dealers (new and used)</td>
<td>10</td>
</tr>
<tr>
<td>5121</td>
<td>Blue book dealers</td>
<td>10</td>
</tr>
</tbody>
</table>

### SCHEDULE E—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN MANUFACTURING

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>E211</td>
<td>Furniture</td>
<td>15</td>
</tr>
<tr>
<td>E221</td>
<td>Textile mills</td>
<td>10</td>
</tr>
<tr>
<td>E231</td>
<td>Leather and furs</td>
<td>10</td>
</tr>
</tbody>
</table>

### SCHEDULE F—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN CONSTRUCTION

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>F211</td>
<td>Construction contractors</td>
<td>15</td>
</tr>
<tr>
<td>F221</td>
<td>Roofers, siding and painting contractors</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE G—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN TRANSPORTATION AND WHOLESALE TRADE

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>G211</td>
<td>Steam and electric power lines</td>
<td>15</td>
</tr>
<tr>
<td>G221</td>
<td>Electrical and electronic equipment</td>
<td>10</td>
</tr>
</tbody>
</table>

### SCHEDULE H—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN TRANSPORTATION AND PROFESSIONAL SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>H211</td>
<td>Accountants and bookkeepers</td>
<td>15</td>
</tr>
<tr>
<td>H221</td>
<td>Lawyers and counselors</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE I—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN PROFESSIONAL SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>I211</td>
<td>Physicians and surgeons</td>
<td>15</td>
</tr>
<tr>
<td>I221</td>
<td>Dentists</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE J—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN EDUCATION

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>J211</td>
<td>Public schools</td>
<td>15</td>
</tr>
<tr>
<td>J221</td>
<td>Private schools</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE K—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN PERSONAL AND OTHER SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>K211</td>
<td>Personal service industries</td>
<td>15</td>
</tr>
<tr>
<td>K221</td>
<td>Other personal services</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE L—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN BUSINESS SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>L211</td>
<td>Accounting and bookkeeping services</td>
<td>15</td>
</tr>
<tr>
<td>L221</td>
<td>Legal services</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE M—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN INFORMATION SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>M211</td>
<td>Information providing services</td>
<td>15</td>
</tr>
<tr>
<td>M221</td>
<td>Information processing services</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE N—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN RECREATIONAL AND PERSONAL SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>N211</td>
<td>Recreation and travel services</td>
<td>15</td>
</tr>
<tr>
<td>N221</td>
<td>Personal services</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE O—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN DOMESTIC SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>O211</td>
<td>Home economic enterprises</td>
<td>15</td>
</tr>
<tr>
<td>O221</td>
<td>Personal services</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE P—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN EDUCATIONAL SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>P211</td>
<td>Educational services</td>
<td>15</td>
</tr>
<tr>
<td>P221</td>
<td>Other educational services</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE Q—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN PERSONAL AND OTHER SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q211</td>
<td>Personal service industries</td>
<td>15</td>
</tr>
<tr>
<td>Q221</td>
<td>Other personal services</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE R—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN BUSINESS SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>R211</td>
<td>Accounting and bookkeeping services</td>
<td>15</td>
</tr>
<tr>
<td>R221</td>
<td>Legal services</td>
<td>5</td>
</tr>
</tbody>
</table>

### SCHEDULE S—ANNUAL RECEIPTS SIZE STANDARDS FOR INDUSTRIES DIRECTLY ENGAGED IN INFORMATION SERVICES

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
<th>Employees</th>
</tr>
</thead>
<tbody>
<tr>
<td>S211</td>
<td>Information providing services</td>
<td>15</td>
</tr>
<tr>
<td>S221</td>
<td>Information processing services</td>
<td>5</td>
</tr>
</tbody>
</table>
Recent changes to the Federal Aviation Administration (FAA) regulations have been made to provide compliance times in terms of number of flights or hours of service. The changes were made to address a fatigue problem caused by flight cycles. The amendments have been effective December 30, 1974.

Title 14—Aeronautics and Space— CHAPTER I—FEDERAL AVIATION ADMINISTRATION

Amendment 39-646 33 FR 12303, AD 68-18-3 requires inspection of the wing center section upper forward skin panels for cracks and repair as necessary, on Boeing model 707/720 series airplanes.

The skin cracks have been shown to be a fatigue problem caused by flight cycles. Therefore, the AD is being amended to provide compliance times in terms of number of flights, as well as hours of time-in-service. Further, the transfer of administrative responsibility for the AD to the Northwest Region of the FAA as a result of agency organizational changes is recognized in the amendment.

Since this amendment imposes no additional burden on any person, notice and public procedure hereon are unnecessary and the amendment may be made effective in less than thirty days.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (31 FR 13667) § 39.13 of Part 39 of the Federal Aviation regulations, Amendment 39-646 33 FR 12303, AD 68-18-3 is amended as follows:

The reference to “Chief, Aircraft Enginering Division, FAA Western Region” is hereby changed to “Chief, Engineering and Manufacturing Branch, FAA Northwest Region.” The following new paragraphs (m) and (n) are added:

(m) Where the following hours of time-in-service appear herein, an operator may use the following tabulation of equivalencies to flights as an alternative to determine inspection requirements:

<table>
<thead>
<tr>
<th>Hours of Service</th>
<th>Equivalency to Flights</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 hours or 300 flights</td>
<td>1000 hours or 600 flights</td>
</tr>
<tr>
<td>1000 hours or 600 flights</td>
<td>2000 hours or 1200 flights</td>
</tr>
<tr>
<td>2000 hours or 1200 flights</td>
<td>4000 hours or 2400 flights</td>
</tr>
<tr>
<td>4000 hours or 2400 flights</td>
<td>8000 hours or 4800 flights</td>
</tr>
<tr>
<td>8000 hours or 4800 flights</td>
<td>16000 hours or 9600 flights</td>
</tr>
<tr>
<td>16000 hours or 9600 flights</td>
<td>32000 hours or 19200 flights</td>
</tr>
</tbody>
</table>

(n) For the purpose of complying with this AD, subject to acceptance by the assigned FAA maintenance inspector, the number of flights may be determined by dividing each airplane’s hours’ time in service by the operator’s fleet average time from takeoff to landing for the airplane type.

This amendment becomes effective December 30, 1974.
PART 39—AIRWORTHINESS DIRECTIVES
Certain AirResearch Engines

There have been failures of the high speed pinion (HSP) gear bearing assembly and decoupling of the propeller speed pinion (HSP) gear bearing as a result of oil starvation caused by loosening of the HSP gear bearing carriage attachment bolts and/or failure of the oil transfer tube support bracket. Since this condition is likely to exist or develop in other engines of the same type design, an airworthiness directive is being issued to require a modification of the HSP gear bearing carriage bolts and recurring inspection of the oil transfer tube bracket on certain AirResearch Model TPE331-1, -2, -3, -5 and -6 series engines.

Since a situation exists that requires immediate adoption of this regulation, it is found that notice and public procedure hereon are impracticable and good cause exists for making this amendment effective in less than 30 days.

In consideration of the foregoing, and pursuant to the authority delegated to me by the Administrator (31 FR 13697), § 39.13 of Part 39 of the Federal Aviation regulations is amended by adding the following new airworthiness directive.

AirResearch Manufacturing Company of Arizona—Applies to certain Model TPE381 series engines:

Compliance required as indicated.

To detect, correct and prevent loosening of the high speed pinion (HSP) gear bearing carriage bolts and to detect fatigue failure of the HSP gear oil transfer tube, accomplish the following:


and subsequent, Within the next 100 hours time in service, unless accomplished within the last 100 hours time in service prior to the effective date of this AD, and thereafter, at intervals not to exceed 200 hours time in service, inspect the oil transfer tube, P/N 3101187—1, for the instructions contained in paragraph 2.C. of the above referenced service bulletin. If the oil transfer tube bracket is cracked or separated, either:

(a) Replace with a serviceable P/N 3101187—1;

(b)Disassemble the installation of a tube, P/N 3101187—2, clamp, P/N 3101484—1, and washer, P/N AN900C146L, using the existing clamp bolt, per the instructions of paragraph 2.E. of the above referenced service bulletin.

(c)Equivalent procedures may be approved by the Chief, Aircraft Engineering Division, FAA Western Region, upon submission of adequate substantiation data.

(4) Aircraft may be flown to a base for performance of maintenance required by paragraph (1) and the inspection required by paragraph (2) of this AD per FAR’s 21.187 and 21.199.

This amendment becomes effective December 30, 1974.


PART 121—CERTIFICATION AND OPERATIONS: DOMESTIC, FLAG, AND SUPPLEMENTAL AIR CARRIERS AND COMMERCIAL OPERATORS OF LARGE AIRCRAFT

Ground Proximity Warning Systems

The purpose of this amendment to Part 121 of the Federal Aviation Regulations is to require installation of an approved ground proximity warning system on each large turbine-powered airplane.

The regulations presented in response to Notice 74–32, a number of air carrier accidents involving large turbine-powered airplanes operated under Part 121 by December 1, 1975. Accordingly, § 121.360, as adopted, prohibits the operation of a large turbine-powered airplane under Part 121 after December 1, 1975, unless it is equipped with a ground proximity warning system that meets the requirements of that section.

Several commentators asserted that flight crewmembers should have adequate warning of ground proximity through the flight procedures provided for safe and adequate terrain clearance as long as those procedures are followed. Following those comments received and on further investigation, the FAA believes that flight crewmembers should have adequate warning of ground proximity through the use of present instrumentation, including altitudes, airspeed, and appropriate in-flight procedures.

The FAA believes that new § 121.360 must be capable of providing warnings during non-precision approaches. A number of comments were received with respect to the kind of warnings to be given. One commentator suggested that a visual warning should not be required, since it could distract the pilot from taking corrective action. However, notwithstanding those instruments and procedures, as stated in Notice 74–32, a number of air carrier accidents involving large turbine-powered airplanes have been caused by inadvertent contact with the ground, and might have been avoided if a ground proximity warning system had been installed to give warnings with no required input from the flight crew.

Several commentators pointed out that the warning system should operate during non-precision approaches. The FAA believes that flight crewmembers can be capable of providing warnings during non-precision approaches.

A number of comments were received with respect to the kind of warnings to be given. One commentator suggested that a visual warning should not be required, since it could distract the pilot from taking corrective action. However, notwithstanding those instruments and procedures, as stated in Notice 74–32, a number of air carrier accidents involving large turbine-powered airplanes have been caused by inadvertent contact with the ground, and might have been avoided if a ground proximity warning system had been installed to give warnings with no required input from the flight crew.
hazard exists, since the cessation of the warning might lead to a mistaken belief that the hazard no longer exists. The FAA does not agree that the continuous operation of either the visual or the aural warning will distract the pilot from taking corrective action.

With respect to comments concerning the type certificate, the equipment that would be required under the proposed rule, it should be noted that the equipment must be capable of providing not only a warning based on the rate of descent of the aircraft but also a warning based on the computed height of the aircraft above the terrain directly beneath the aircraft, but also a warning based on the computed height of the aircraft above the terrain along the aircraft's projected flight path. The rule, as adopted, has been clarified so that it clearly states this requirement and the other requirements for approval discussed in the preamble to Notice 74-32.

One commentator contended that turbopropeller-powered airplanes should not be required to have the proposed warning system because they do not have "sink rates" as high as those of turbojet airplanes; they are more responsive to the application of power, and they are less subject to an insidious loss of altitude after takeoff. In addition, the commentator contended that the proposed warning system would cause engineering and installation problems for older aircraft. The FAA does not agree that turbopropeller-powered airplanes should be excepted from this requirement, since a review of air carrier accidents involving inadvertent contact with the ground does not support such an exception.

One commentator questioned whether the rule as proposed would require a ground proximity warning system separate from other aircraft systems. It was not the intent of the FAA to preclude the incorporation of such a warning system with other aircraft systems when compatibility exists.

Certain commentators pointed out that the requirement in proposed § 121.360(a), that the ground proximity warning system provide a warning at any height less than 3,000 feet above the ground, is not appropriated in the light of the capability of radio altimeters presently in use in large turbine-powered airplanes. The FAA agrees, and § 121.360(a), as adopted, requires only that the system provide a warning at any height less than 2,500 feet.

A number of commentators urged the FAA to expedite the development of standards for ground proximity warning systems. As stated in Notice 74-32, the FAA has initiated a study to develop either a Technical Standard Order or an amendment to Part 25 establishing specific standards. The FAA expects to issue those standards in the very near future. However, pending the development of such standards, the FAA in its discretion may continue to approve the installation of ground proximity warning systems through the issuance of supplemental type certificates after compliance has been shown with the general equipment requirements of Part 25.

The phrase "impending terrain hazard" in proposed § 121.360(a) has been changed to "imminent inadvertent contact with the ground," so as to more clearly describe the hazard for which the system must provide a warning.

Proposed § 121.360(a) would have prohibited the operation of a large turbine-powered airplane under Part 121 6 months after the effective date of the amendment unless it had been equipped with a system that automatically provides a discrete aural warning when the airplane descends below a predetermined height between 1,000 and 500 feet above the ground. In view of the shortening of the period for compliance with § 121.360(a) to require the installation of ground proximity warning systems by December 1, 1975, proposed § 121.360(c) has not been adopted.

In lieu of proposed § 121.360(d), a reference to new § 121.360 has been added to § 121.303(d)(2). This will prohibit the takeoff of any large turbine-powered airplane unless the ground proximity warning system required by § 121.360 is in operable condition. However, § 121.627(c) will allow the continuation of a flight beyond a terminal point with the equipment inoperative if the minimum equipment list and procedures for the continuation of flight are included in the certificate holder's manual.

(See § 313(a), 601, 603, and 604 of the Federal Aviation Act of 1958; 49 U.S.C. 1354(a), 1421, 1423, and 1424. Sec. 6(c) of the Department of Transportation Act; 49 U.S.C. 1668(e)).

In consideration of the foregoing, and for the reasons stated in Notice No. 74-32, Part 121 of the Federal Aviation Regulations is amended, effective January 23, 1975, as follows:

§ 121.303 [Amended]

1. By amending paragraph (d) (2) of § 121.303 by deleting the phrase "and 121.359" and substituting therefor the phrase ", 121.359, and 121.360."

2. By adding a new § 121.360 immediately after § 121.359 to read as follows:

§ 121.360 Ground proximity warning systems.

(a) After December 1, 1975, no person may operate a large turbine-powered airplane unless it is equipped with an approved ground proximity warning system that is designed, constructed, and installed so as to provide a warning of imminent inadvertent contact with the ground.

(b) The ground proximity warning system required by paragraph (a) of this section must:

(1) Operate at any height less than 2,500 feet above the ground;

(2) Provide both visual and aural warnings that shall operate simultaneously and are distinct from each warning provided by any other aircraft warning device;

(3) Initiate automatically without any crewmember action; and
Economic Regulations (14 CFR Part 298) effective January 23, 1975, to read as follows:

1. Amend §298.50(c) to read as follows:

§298.50 Filing for registration by air taxi operators.

(c) Registration and reregistration shall be accomplished by filing with the Board's Bureau of Operating Rights:

(1) CAB Form 298-A, "Registration, Reregistration and Amendments Under Part 293 of the Economic Regulations of the Civil Aeronautics Board," executed in duplicate. This form shall be certified by a responsible official and shall include the following information:

(i) The name of the carrier and its mailing address;

(ii) The carrier's principal place of business, if different from its mailing address, and its area code and telephone number;

(iii) The carrier's FAA certificate number, if any, and the address and telephone number of the carrier's local FAA office;

(iv) Whether the carrier proposes to perform (or, for reregistration, whether the carrier is currently performing) scheduled passenger or cargo, on-demand passenger or cargo, and/or mail service;

(v) A list of the aircraft which the carrier proposes to operate (or, for reregistration, the aircraft which the carrier is currently operating) in air taxi operations, and the aircraft type, FAA registration number and passenger capacity of each such aircraft;

(vi) For initial registration, the proposed date of commencement of air taxi operations;

(vii) For reregistration, whether the carrier has carried passengers in air transportation between any point in the United States and any point outside thereof in the past 12 months.

(2) A certificate of insurance which is currently effective (or, in case of initial registration, is to become effective), as defined in §298.41(b);

(3) A $15 registration or reregistration fee, except in the case of mail, which shall be in the form of a check, draft, or postal money order, payable to the Civil Aeronautics Board.

2. Amend §298.52 to read as follows:

§298.52 Notification to the Board of change in operations.

Each air taxi operator (whether or not he has on file with the Board a currently effective registration under §298.50) shall notify the Board's Bureau of Operating Rights, Washington, D.C. 20428, on CAB Form 298-A, of any change in his name or address, or of any change in the type of operations, type of aircraft, passenger, cargo, mail, scheduled, etc., or of his temporary or permanent cessation of operations. Such notification shall be mailed, or otherwise delivered, as soon as received by the Board no later than 30 days after the reported event has occurred.

Title 15—Commerce and Foreign Trade

CHAPTER VIII—BUREAU OF ECONOMIC ANALYSIS, DEPARTMENT OF COMMERCE

Name Change From Office of Business Economics To Bureau of Economic Analysis Pursuant to Department of Commerce Organization Order 38-44, effective January 1, 1972, which established the Social and Economic Statistics Administration and changed the name of the Office of Business Economics to the Bureau of Economic Analysis (37 FR 3461), Title 15 of the Code of Federal Regulations is amended as follows:

The title of Chapter VIII of Title 15 of the Code of Federal Regulations is revised to read as set forth above. All references to the "Office of Business Economics" in Chapter VIII are correspondingly changed.

In accordance with Administrative Procedure 5 U.S.C. 553, notice and hearing on the amendment, and postponement of the effective date thereof is unnecessary since this amendment is entirely administrative in nature. Therefore, this amendment will become effective on December 24, 1974.

Dated: December 17, 1974.

GEORGE JASIK,
Director, Bureau of Economic Analysis.

[FR Doc.74-30005 Filed 12-33-74; 7:45 am]

Title 23—Highways

CHAPTER I—FEDERAL HIGHWAY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

SUBCHAPTER H—RIGHT-OF-WAY AND ENVIRONMENT

PART 770—AIR QUALITY GUIDELINES FOR USE IN FEDERAL-AID HIGHWAY PROGRAMS

Air Quality Guidelines

By notice in the Federal Register of September 5, 1973 (38 FR 23369), the Federal Highway Administration (FHWA) published a notice of proposed rulemaking containing air quality guidelines. These guidelines were required to implement section 136(b) of the Federal Aid Highway Act of 1970 (23 U.S.C. 109(j)), which requires that guidelines be promulgated to assure that highways constructed pursuant to Title 23, U.S.C., are consistent with any approved plan for the implementation of any ambient air quality standard for any air quality control region designated pursuant to the Clean Air Act, as amended (42 U.S.C. 1857 et seq.).

Because it was necessary to have guidelines for the assessment of highway plans, interim regulations were promulgated on November 16, 1973 (38 FR 31677) as Part 770 of Title 23 CFR. Since that time FHWA has considered all comments received. These are set forth and discussed in the final environmental impact statement prepared for the issuance of these guidelines which was transmitted to the Council on Environmental Quality on September 17, 1974.

In consideration of the foregoing, Part 770 of Title 23 of the Code of Federal Regulations is amended to read as follows:

Subpart E—Air Quality Guidelines

Sec. 770.200 Purpose.

The policy and procedures covering air quality guidelines for use in planning, locating, and constructing highway improvements pursuant to 23 U.S.C. 109(j) are consistent with any approved plan for the implementation of any ambient air quality standard for any air quality control region designated pursuant to the Clean Air Act of 1970.

770.201 Definitions.

(a) Action, The construction or reconstruction, including associated activities, of a highway section.

(b) Air quality control region. An Interstate or intrastate area designated by the Environmental Protection Agency pursuant to 42 U.S.C. 1857. (Section 107 of the Clean Air Act of 1970.)

(c) Air pollution control agency. The State, local, or multistate agency as defined by 42 U.S.C. 1857. (Section 302(b) of the Clean Air Act of 1970.)

(d) Environmental impact statement (EIS). A statement prepared in response to 42 U.S.C. 4332. (Section 102(2)(c) of the National Environmental Policy Act of 1969.)

(e) Air pollution control agency. The agency with the primary responsibility for initiating and carrying forward the action for highway sections financed with Federal-aid highway funds, the highway agency will normally be the appropriate State, county, or city highway agency. For highways financed with other funds, such as forest highways, park roads, etc., the highway agency will be the appropriate Federal or State agency with the primary responsibility for initiating and carrying forward the action.

(f) Highway section. A highway development proposal between logical termini (population centers, major traffic generators, major crossroads, etc.) as normally included in a location study or yearly highway improvement program.

(g) Indirect source review agency. The agency designated in an applicable State implementation plan to meet the requirements of 40 CFR 51.11 (38 FR 15834, June 18, 1973).

(h) National Ambient Air Quality Standards. The National Ambient Air...
The procedures described in § 770.206 shall apply to the consideration of construction specifications as related to air quality.

§ 770.204 Urban Transportation Plans and Programs.

(a) To assure that land use and transportation plans and programs are consistent with the approved State implementation plan.

(b) The highway agency shall request the pollution control agency to determine the consistency of the current transportation plan and program with the approved State implementation plan prior to transportation plan approval by the policy board; and

(c) The final EIS may be adopted by the Regional Federal Highway Administrator for adoption if the indirect source review agency has found as a part of the procedures established pursuant to 40 CFR 51.18 that the highway section will result in a violation of any ambient air quality standard. For the purposes of this directive, an approved SIP is the implementation plan, or most recent revision thereof, which has been approved or promulgated by the Environmental Protection Agency under section 110 of the Clean Air Act of 1970.

§ 770.206 Highways Sections.

(a) The following procedures shall apply to highway sections for which both the draft and the final environmental impact statement are submitted to FHWA or for which a negative declaration is considered by FHWA after the effective date of this directive:

(1) The studies and coordination activities related to the construction or reconstruction of a highway section shall include an appropriate consideration of air quality. The level of this consideration and/or the air quality analysis is to be determined on the basis of the nature and location of the highway section, anticipated traffic volume, existing air quality problems, sensitivity of nearby receptors to air pollution and meteorological conditions. It is anticipated that lower volume facilities in areas without critical air quality problems can be satisfactorily analyzed using simplified analysis techniques and that some reaquirements will not be required. High volume facilities in areas with critical air quality problems will usually require on-site data gathering and a high level of analysis.

(2) For highway sections where a negative declaration rather than an EIS is to be prepared, the negative declaration shall briefly outline the air quality considerations and, where applicable, a brief summary of consultation with the indirect source review agency.

(3) Where required by 40 CFR 51.18, the preferred alternative shall be submitted to the indirect source review agency for review.
In making his determination, the Regional Federal Highway Administrator shall consider the following:

(i) The adequacy and the conclusions of the air quality analysis;

(ii) The comments received from the air pollution control agency resulting from the requirements of §770.204(a)(2) and §770.205(a)(3) (where issues raised by the air pollution control agency have not been resolved by the highway agency or the FHWA Division Engineer prior to submission of the proposed final EIS to the FHWA, the Regional Administrator shall not make a positive determination on consistency without first consulting with the EPA Regional Administrator); and

(iii) Comments received from other agencies as part of the EIS procedure and the disposition of these comments.

The Regional Federal Highway Administrator shall furnish the results of any consultation with the EPA Regional Administrator on the final EIS to the FHWA, the FHWA Division Engineer shall constitute the FHWA determination on consistency in the transmitted information for those final environmental impact statements which require review by FHWA Headquarters.

The following procedures shall apply to highway sections for which the draft environmental impact statement was submitted to the FHWA prior to the effective date of this directive and for which the final environmental impact statement is submitted to FHWA after the effective date of this directive:

(1) Prior to the processing of the final EIS, the highway agency, in consultation with the FHWA Division Engineer, shall review available material on the development of the highway section, including the draft EIS, and shall make a written determination on the adequacy of the consideration of air quality for the highway section.

(2) If the determination concludes that the consideration of air quality is adequate, the final EIS may be processed following established EIS processing procedures.

(3) If the determination concludes that additional information and/or analysis are necessary, a revised draft or supplemental EIS may be prepared following the procedures established in the Federal-Aid Highway Program Manual, "Environmental Impact and Related Statements."

(4) Comments received shall be incorporated and addressed in the final EIS as required in Volume 7, Chapter 7, Section 2 of the Federal-Aid Highway Program Manual, "Environmental Impact and Related Statements."

(5) Where required by 40 CFR §51.18 the preferred alternative shall be submitted to the indirect source review agency for review. The proposed final EIS shall not be submitted to the FHWA Regional Administrator for adoption if the indirect source review agency has found that the proposed action is not of such magnitude as to make the processing in this form necessary. The revised or supplemental EIS shall be processed in accordance with procedures contained in Volume 7, Chapter 7, Section 2 of the Federal-Aid Highway Program Manual, "Environmental Impact and Related Statements."

(6) If the information on the development of the highway section, including the draft EIS, and the FHWA determination that the highway section is considered to be consistent with the approved State implementation plan.

The following procedures shall apply to highway sections for which the final environmental impact statement is submitted to the FHWA after the effective date of this directive:

(i) The highway agency shall review the information available on the development of the highway section, including the final EIS, and shall prepare a report for the FHWA on the consistency of the proposed action with the approved State implementation plan.

(ii) The FHWA Division Engineer shall make a written determination on the consistency of the proposed action with the approved State implementation plan.

(iii) The FHWA Division Engineer shall prepare a report for the FHWA on the consistency of the proposed action with the approved State implementation plan.

(iv) If the information on the development of the highway section, including the draft EIS, and the FHWA determination that the highway section is considered to be consistent with the approved State implementation plan.

The following procedures shall apply to highway sections for which the final environmental impact statement is submitted to the FHWA after the effective date of this directive:

(i) The highway agency shall review the information available on the development of the highway section, including the draft EIS, and shall make a written determination on the consistency of the proposed action with the approved State implementation plan.

(ii) The FHWA Division Engineer shall prepare a report for the FHWA on the consistency of the proposed action with the approved State implementation plan.

(iii) The FHWA Division Engineer shall prepare a report for the FHWA on the consistency of the proposed action with the approved State implementation plan.

(iv) The FHWA Division Engineer shall prepare a report for the FHWA on the consistency of the proposed action with the approved State implementation plan.

(v) Where required by 40 CFR §51.18 the preferred alternative shall be submitted to the indirect source review agency for review. The proposed final EIS shall not be submitted to the FHWA Regional Administrator for adoption if the indirect source review agency has found that the proposed action is not of such magnitude as to make the processing in this form necessary. The revised or supplemental EIS shall be processed in accordance with procedures contained in Volume 7, Chapter 7, Section 2 of the Federal-Aid Highway Program Manual, "Environmental Impact and Related Statements."

(6) If the information on the development of the highway section, including the draft EIS, and the FHWA determination that the highway section is considered to be consistent with the approved State implementation plan.

(7) Adoption of the final EIS by the FHWA shall constitute the FHWA determination that the highway section is considered to be consistent with the approved State implementation plan.

The following procedures shall apply to highway sections for which the final environmental impact statement is submitted to the FHWA after the effective date of this directive, for which a substantial amount of the grade and drain work remains to be advertised for bids, and for which a decision on the consistency of the highway section with the approved State implementation plan has not been made by the Regional Federal Highway Administrator.

(1) The highway agency shall review the information available on the development of the highway section, including the final EIS, and shall make a written determination on the consistency of the proposed action with the approved State implementation plan.

(ii) If the information on the development of the highway section, including the draft EIS, and the FHWA determination that the highway section is considered to be consistent with the approved State implementation plan.

(c) The following procedures shall apply to highway sections for which the final environmental impact statement is submitted to the FHWA after the effective date of this directive, for which a substantial amount of the grade and drain work remains to be advertised for bids, and for which a decision on the consistency of the highway section with the approved State implementation plan has not been made by the Regional Federal Highway Administrator.

(1) Prior to the processing of the final EIS, the highway agency, in consultation with the FHWA Division Engineer, shall review available material on the development of the highway section, including the draft EIS, and shall make a written determination on the consistency of the proposed action with the approved State implementation plan.

(ii) The FHWA Division Engineer shall prepare a report for the FHWA on the consistency of the proposed action with the approved State implementation plan.

(iii) The FHWA Division Engineer shall prepare a report for the FHWA on the consistency of the proposed action with the approved State implementation plan.

(iv) The FHWA Division Engineer shall prepare a report for the FHWA on the consistency of the proposed action with the approved State implementation plan.

(v) Where required by 40 CFR §51.18 the preferred alternative shall be submitted to the indirect source review agency for review. The proposed final EIS shall not be submitted to the FHWA Regional Administrator for adoption if the indirect source review agency has found that the proposed action is not of such magnitude as to make the processing in this form necessary. The revised or supplemental EIS shall be processed in accordance with procedures contained in Volume 7, Chapter 7, Section 2 of the Federal-Aid Highway Program Manual, "Environmental Impact and Related Statements."

(6) If the information on the development of the highway section, including the draft EIS, and the FHWA determination that the highway section is considered to be consistent with the approved State implementation plan.

(7) Adoption of the final EIS by the FHWA shall constitute the FHWA determination that the highway section is considered to be consistent with the approved State implementation plan.

For the purpose of reviewing the air quality information and consistency determination presented in the report.

(b) The highway agency shall establish procedures in order that any changes in the State implementation plan will be reviewed to determine if revisions to the construction specifications will be necessary.
RULING 1—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY

[T.D. 7353]

PART I—INCOME TAX: TAXABLE YEARS BEGINNING AFTER DECEMBER 31, 1973

Rates and Earnings Base of Certain Religious Orders and Religious Professionals

By a notice of proposed rule making appearing in the Federal Register for July 3, 1973 (38 FR 17777), amendments to the Income Tax Regulations (26 CFR Part 1) were proposed in order to conform such regulations to the provisions of sections 115(b) (2), 118(a), 122(b), and (c), and 502(b) of the Social Security Amendments of 1967 (81 Stat. 839, 841, 843, 844, 934), section 203(b) (1) of the Act of March 17, 1971 (Pub. L. 92-5, 85 Stat. 10), sections 203(b) (1) and 204(a) (1) and (b) (1) of the Act of July 1, 1972 (Pub. L. 92-336, 86 Stat. 418, 450, 451, 453, 454, and section 235 (a) (1) and (b) (1) of the Social Security Amendments of 1972 (86 Stat. 1362, 1363), relating to the rates and earnings base of the self-employment tax and to self-employment coverage of retired partners, certain employees of States and political subdivisions, and ministers, members of religious orders, and Christian Science practitioners. After consideration of all relevant comments received from interested persons regarding the rules proposed, certain changes were made. The proposed amendments of the regulation thereunder were revised, including an amendment to the section 1.1401—1, as set forth in paragraph 2 below, is amended by revising paragraph (b) (2).

Several of the above statutory amendments revised the rates and earnings base of the tax on self-employment income. For taxable years beginning after 1974, the taxable earnings base may be increased by the Secretary of the Department of Health, Education, and Welfare under section 230 of the Social Security Act if he provides a cost-of-living increase in benefits under section 215 of that Act.

Under prior law, the term "trade or business", for self-employment tax purposes, did not include the performance of services by a minister, a member of a religious order, or other Christian Science practitioner in his capacity as such unless such individual (other than a member of a religious order under a vow of poverty) elected to have his self-employment income subject to the social security program extended to him in respect of such services. Under present law such service constitutes a trade or business

(except in the case of a member of a religious order under a vow of poverty) unless the individual is granted an exemption from the tax on self-employment income in respect of such service. To qualify for the exemption an individual must be conscientiously opposed to, or because of religious convictions, be opposed to, the acceptance (with respect to service performed by him in his capacity as a minister, member, or Christian Science practitioner) of any insurance payments in the event of death, disability, old age, or retirement or makes payments toward the cost of, or provides services for, medical care (including the benefits of any insurance established by the Social Security Act). Based on the legislative history of section 115(b) (2) of the Social Security Amendments of 1967, the regulations require that this conscientious opposition be based on religious grounds.

Applications for exemption must be made by the later of (1) the due date of the return (including any extension thereof) for the taxable year for which the clergyman has at least $400 of net earnings from self-employment, or (2) the due date of the return (including any extension thereof) for the second taxable year ending after 1967. For this purpose, if a clergyman's last original return filed before the expiration of the application period shows no liability for tax on self-employment income, that return will be treated as an application for exemption, provided that, before February 18, 1975, he files a Form 4561, the form specified for use as an application for exemption.

Under prior law, the term "trade or business", for self-employment tax purposes, did not include the performance of the functions of a public office or service rendered by an individual as an employee of a State or a political subdivision. The amendment placed a minor limitation on the scope of these exclusions thereby providing coverage to certain individuals in service for a State or a political subdivision thereof in a position compensated solely on a fee basis. In general, the rules of the proposed regulations on this subject are finally without substantive change, except that section 1.1402(c) (2) (a) (2), describing certain covered officials, has been revoked and is the subject of a new notice of proposed rule-making.

Retirement payments made by a partnership to a retired partner are excluded from net earnings from self-employment (except as guaranteed to/from a self-insurance plan). Generally speaking, the treatment accorded such payments is similar to that accorded retirement income under the Federal Insurance Contributions Act. A credit or refund is provided, under certain circumstances, in respect of the hospital insurance tax in the case of a railroad employee or employee representative subject to tax under the Railroad Retirement Act who is also subject to tax under the Federal Insurance Contributions Act. If such an employee or employee representative has net earnings from self-employment, his taxable railroad compensation is taken into account in computing self-employment income. The purpose of these changes was to prevent the imposition of a double tax burden with respect to self-insurance plans and certain forms of compensation (such as pension plans) which are exempt from the hospital insurance tax.

On July 3, 1973, a notice of proposed rule making with respect to the Income Tax Regulations (26 CFR Part 1) under sections 1401 and 1402 of the Internal Revenue Code of 1954 to conform such regulations to sections 115(b) (2), 118(a), 122(b), and (c), and 502(b) of the Social Security Amendments of 1967 (81 Stat. 839, 841, 843, 844, 934), section 203(b) (1) of the Act of March 17, 1971 (Pub. L. 92-5, 85 Stat. 10), sections 203(b) (1) and 204(a) (1) and (b) (1) of the Act of July 1, 1972 (Pub. L. 92-336, 87 Stat. 418, 420, 421), and section 135 (a) (1) and (b) (1) of the Social Security Amendments of 1972 (86 Stat. 1362, 1363) was published in the Federal Register (38 FR 17777). After consideration of all relevant matters presented by interested persons regarding the proposed rules, the amendment of the Income Tax Regulations under section 1401 and 1402 is hereby adopted, subject to the following changes (including changes conforming such regulations to the provisions of section 203(b) (1) of the Act of July 9, 1973 (Pub. L. 93-66, 87 Stat. 153), section 5 (b) (1) and (f) of the Act of December 31, 1973 (Pub. L. 93-233, 87 Stat. 854), and section 6(b) (1) of the Act of December 31, 1973 (Pub. L. 93-233, 87 Stat. 855).

Paragraph 1. Section 1.1401 is amended as set forth in paragraph 1 below.

Paragraph 2. Section 1.1401—1, as set forth in paragraph 2 below, is amended by revising paragraph (b) (2).

Paragraph 3. Section 1.1402 (b), as set forth in paragraph 8 below, is amended by revising subparagraph (H) and the historical note.

Paragraph 4. Section 1.1402 (b) (1) and (2) (ii) (ii) (i), as set forth in paragraph 9 below, is amended by revising paragraphs (b) (1) and (ii) and the examples in paragraphs (b) (2) (i) (i) (ii) and (e).

Paragraph 5. Section 1.1402(c) (2), as set forth in paragraph 11 below, is amended by revising paragraph (c).

Paragraph 6. Section 1.1402(c) (2), as set forth in paragraph 12 below, is amended by revising paragraph (f) (1).

[This Treasury decision is issued under the authority contained in section 7806 of the Internal Revenue Code of 1954 (68A Stat. 917, 26 U.S.C. 7806).]

Seal

Donald C. Alexander, Commissioner of Internal Revenue.

Approved: December 16, 1974.

Frederic W. Hickman, Assistant Secretary of the Treasury.
§ 1.1401 Statutory provisions: rate of tax on self-employment income.

Sec. 1401. Rate of tax—(a) Old-age, survivors, and disability insurance.

(1) For any taxable year beginning after December 31, 1970, and before January 1, 1973, the tax shall be equal to 0.9 percent of the amount of the self-employment income for such taxable year;

(b) Hospital insurance. * * *

(2) In the case of any taxable year beginning after December 31, 1972, and before January 1, 1973, the tax shall be equal to 1.0 percent of the amount of the self-employment income for such taxable year;

(c) Hospital insurance. * * *

(3) In the case of any taxable year beginning after December 31, 1973, and before January 1, 1978, the tax shall be equal to 1.35 percent of the amount of the self-employment income for such taxable year;

(4) In the case of any taxable year beginning after December 31, 1977, and before January 1, 1980, the tax shall be equal to 1.50 percent of the amount of the self-employment income for such taxable year;

(5) In the case of any taxable year beginning after December 31, 1980, and before January 1, 1986, the tax shall be equal to 1.8 percent of the amount of the self-employment income for such taxable year;

(6) In the case of any taxable year beginning after December 31, 1985, and before January 1, 1986, the tax shall be equal to 2.1 percent of the amount of the self-employment income for such taxable year;

Sec. 1402. Definitions of terms used in this act—(a) Net earnings from self-employment.

(1) Subject to the special rules set forth in §§ 1.1402(a)-1 to 1.1402(a)-7, inclusive, and to the exclusions set forth in §§ 1.1402(c)-2 to 1.1402(c)-7, inclusive, the term “net earnings from self-employment” means—

(b) Aggregate net earnings. Where an individual is engaged in more than one trade or business within the meaning of section 1402(c) and § 1.1402(c)-1, his net earnings from self-employment comprise the aggregate of the net earnings from each trade or business and losses (computed subject to the special rules provided in §§ 1.1402(a)-1 to 1.1402(a)-17 inclusive) of all such trades or businesses carried on by him. Thus, a loss sustained in one trade or business carried on by an individual will operate to offset the income derived by him from another trade or business.

(d) Partnerships. The net earnings from self-employment of an individual include, in addition to the earnings from a trade or business carried on by him, his distributive share of the income or loss, described in section 702(a)(9), from any trade or business carried on by each partnership of which he is a member. An individual’s distributive share of such income or loss of a partnership shall be determined as provided in section 704, subject to the special rules set forth in section 1402(a) and in §§ 1.1402(a)-1 to 1.1402(a)-17, inclusive, and to the exclusions provided in section 1402(c) and §§ 1.1402(c)-2 to 1.1402(c)-7, inclusive.

For purposes of computing the taxable income of a partnership, see section 703.

PAR. 2. Section 1.1401-1 is amended by revising subparagraph (2) of paragraph (b), to read as follows:

§ 1.1401-1 Tax on self-employment income.

(b) The rates of tax on self-employment income are as follows:

(1) For hospital insurance:

<table>
<thead>
<tr>
<th>Taxable Year</th>
<th>Rate of Tax</th>
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<td>January 1, 1965 to December 31, 1965</td>
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</tr>
<tr>
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</tr>
<tr>
<td>January 1, 1967 to December 31, 1967</td>
<td>0.60</td>
</tr>
<tr>
<td>January 1, 1968 to December 31, 1968</td>
<td>0.80</td>
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<tr>
<td>January 1, 1969 to December 31, 1969</td>
<td>1.00</td>
</tr>
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(2) For insurance:

<table>
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<th>Rate of Tax</th>
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</thead>
<tbody>
<tr>
<td>January 1, 1970 to December 31, 1970</td>
<td>0.90</td>
</tr>
<tr>
<td>January 1, 1971 to December 31, 1971</td>
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<td>1.10</td>
</tr>
<tr>
<td>January 1, 1973 to December 31, 1973</td>
<td>1.20</td>
</tr>
<tr>
<td>January 1, 1974 to December 31, 1974</td>
<td>1.30</td>
</tr>
</tbody>
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(3) For hospital insurance:

<table>
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<th>Rate of Tax</th>
</tr>
</thead>
<tbody>
<tr>
<td>January 1, 1975 to December 31, 1975</td>
<td>1.40</td>
</tr>
<tr>
<td>January 1, 1976 to December 31, 1976</td>
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</tr>
<tr>
<td>January 1, 1977 to December 31, 1977</td>
<td>1.60</td>
</tr>
<tr>
<td>January 1, 1978 to December 31, 1978</td>
<td>1.70</td>
</tr>
<tr>
<td>January 1, 1979 to December 31, 1979</td>
<td>1.80</td>
</tr>
<tr>
<td>January 1, 1980 to December 31, 1980</td>
<td>1.90</td>
</tr>
<tr>
<td>January 1, 1981 to December 31, 1981</td>
<td>2.00</td>
</tr>
</tbody>
</table>

§ 1.1402(a) Statutory provisions: definitions; net earnings from self-employment.

Sec. 1402(a) Statutory provisions: definitions; net earnings from self-employment.

(1) Subject to the special rules set forth in §§ 1.1402(a)-1 to 1.1402(a)-7, inclusive, and to the exclusions set forth in §§ 1.1402(c)-2 to 1.1402(c)-7, inclusive, the term “net earnings from self-employment” means—

(a) Aggregate net earnings. Where an individual is engaged in more than one trade or business within the meaning of section 1402(c) and § 1.1402(c)-1, his net earnings from self-employment comprise the aggregate of the net earnings from each trade or business and losses (computed subject to the special rules provided in §§ 1.1402(a)-1 to 1.1402(a)-17 inclusive) of all such trades or businesses carried on by him. Thus, a loss sustained in one trade or business carried on by an individual will operate to offset the income derived by him from another trade or business.

(d) Partnerships. The net earnings from self-employment of an individual include, in addition to the earnings from a trade or business carried on by him, his distributive share of the income or loss, described in section 702(a)(9), from any trade or business carried on by each partnership of which he is a member. An individual’s distributive share of such income or loss of a partnership shall be determined as provided in section 704, subject to the special rules set forth in section 1402(a) and in §§ 1.1402(a)-1 to 1.1402(a)-17, inclusive, and to the exclusions provided in section 1402(c) and §§ 1.1402(c)-2 to 1.1402(c)-7, inclusive.

For purposes of computing the taxable income of a partnership, see section 703.
§ 1.1402(a)-17 Retirement payments to retired partners.

(a) In general. There shall be excluded, in computing net earnings from self-employment for taxable years ended on or after December 31, 1967, certain payments made on a periodic basis by a partnership, pursuant to a written plan of the partnership, to a retired partner; provided that, if the payments made on a periodic basis by a partnership, pursuant to a written plan of the partnership, to a retired partner are made in order to provide retirement income, such payments shall be included in computing net earnings from self-employment for taxable years ending on or after December 31, 1967, if, for purposes of this paragraph (a), the requirements prescribed in paragraph (c) of this section are met.

(b) Retirement plan of partnership. (1) To meet the requirements of section 1402(a)(10), the written plan of the partnership must set forth the terms and conditions of the program or system established by the partnership for the purpose of making payments to retired partners on account of their retirement. For purposes of this paragraph (b), the payments made pursuant to a written plan of the partnership, to a retired partner, are payments made on a periodic basis by a partnership, pursuant to a written plan of the partnership, to a retired partner except with respect to retirement payments. As of the close of the taxable year of both D and the partnership is referred to in subdivision (i) of this subparagraph, either all payments on account of retirement received by a retired partner during the taxable year of the partnership ending within which such payments are made are included or none of the payments are excluded. Subdivision (ii) of this subparagraph has application only to obligations which arose and exists from a transaction unrelated to the partnership or to a trade or business carried on by the partnership. The effect of the conditions set forth in paragraphs (a), (b), (c), and (d) of this section is that the exclusions apply only if the payments are made pursuant to a plan which meets the requirements prescribed in paragraph (c) of this section, and, in addition, the payments made pursuant to such a plan shall be included in computing the net earnings from self-employment for taxable years ending on or after December 31, 1967, if, for purposes of this paragraph (a), the requirements prescribed in paragraph (c) of this section are met.

(c) Conditions relating to exclusion—(1) In general. A payment made pursuant to a written plan of a partnership which meets the requirements of paragraph (b) of this section shall be excluded, in computing net earnings from self-employment, only if—

(i) The retired partner to whom the payment is made rendered no service with respect to any trade or business carried on by the partnership (or its successors) during the taxable year of the partnership (or its successors), which ends within or with the taxable year of the retired partner and in which the payment was received by him;

(ii) No obligation (whether certain in amount or contingent on a subsequent event) exists (as of the close of the partnership's taxable year referred to in subdivision (i) of this subparagraph) from the other partners to the retired partner; or payment is made to the retired partner except with respect to retirement payments made under the plan or rights such as benefits payable on account of sickness, accident, hospitalization, medical expenses, or death; and

(iii) The retiring partner's share (if any) of the capital of the partnership has been paid to him in full before the close of the partnership's taxable year referred to in subdivision (i) of this subparagraph.

By application of the conditions set forth in this subparagraph, either all payments on account of retirement received by a retired partner during the taxable year of the partnership ending within which such payments are made are included or none of the payments are excluded. Subdivision (ii) of this subparagraph has application only to obligations which arose and exist from a transaction unrelated to the partnership or to a trade or business carried on by the partnership. The effect of the conditions set forth in paragraphs (a), (b), (c), and (d) of this section is that the exclusions apply only if the payments are made pursuant to a plan which meets the requirements prescribed in paragraph (c) of this section, and, in addition, the payments made pursuant to such a plan shall be included in computing the net earnings from self-employment for taxable years ending on or after December 31, 1967, if, for purposes of this paragraph (a), the requirements prescribed in paragraph (c) of this section are met.

(d) Examples—The application of subparagraph (1) of this paragraph may be illustrated by the following examples. Each example assumes that the partner or partners to whom payments are made meets the requirements of paragraph (b) of this section.

Example (1). A, who files his income tax return on a calendar year basis, is a partner in the ABC partnership. The taxable year of the partnership is the period July 1 to June 30, inclusive. A retired from the partnership on January 1, 1973, and receives monthly payments on account of his retirement. As of June 30, 1973, no obligation existed from the other partners to A (except with respect to retirement payments under the plan) and A's share of the capital of the partnership had been paid to him in full. The monthly retirement payments received by A from the partnership in his taxable year ending on December 31, 1973, were excluded from net earnings from self-employment since A rendered service to the partnership during a period after A's retirement from the partnership's taxable year (July 1, 1972, through June 30, 1972) which ended within A's taxable year ending on June 30, 1973.

Example (2). D, a partner in the DEF partnership, retired from the partnership as of the close of December 31, 1972. The taxable year of both D and the partnership is a calendar year. During the partnership's taxable year ending December 31, 1973, D rendered no service with respect to any trade or business carried on by the partnership. On or before December 31, 1973, all obligations (whether certain in amount or contingent on a subsequent event) from the other partners to D have been liquidated, and D's share of the capital of the partnership has been paid to him. Retirement payments received by D pursuant to the partnership's plan in this taxable year ending December 31, 1973, are excluded in determining the net earnings from self-employment (if any) for that taxable year.

Example (3). Assume the same facts as in example (2) except that as of the close of December 31, 1973, D has a right to a fixed amount (irrespective of payments under the plan) which is to be paid at least until the date that those payments cease. Retirement payments received by D pursuant to the partnership's plan in this taxable year ending December 31, 1973, are excluded in determining his net earnings from self-employment (if any) for that taxable year.
RULES AND REGULATIONS

States but who is a resident of the Commonwealth of Puerto Rico, the Virgin Islands, Guam, or American Samoa shall not, for purposes of this chapter, be considered to be a nonresident alien individual.


PAR. 9. Paragraphs (b) and (c) of § 1.1402(b)–1 are amended to read as follows:

§ 1.1402(b)–1 Self-employment income.

(b) Maximum self-employment income—(1) General rule. Subject to the special rules described in subparagraph (2) of this paragraph, the maximum self-employment income of an individual for a taxable year (whether a period of 12 months or less) is:

(i) For any taxable year beginning in a calendar year after 1974, an amount equal to the contribution and benefit base (as determined under section 230 of the Social Security Act) which is effective for such calendar year; and

(ii) For any taxable year—

Ending before 1965

Ending after 1965

Beginning before 1971 and before 1973

Beginning after 1971 and before 1973

Beginning after 1972 and before 1974

Beginning after 1973 and before 1974

$1,000

$6,000

$9,000

$13,200

$10,000

$7,900

$13,200

(2) Special rules. (i) If an individual is paid wages as defined in subparagraph (3) of this paragraph as a maximum self-employment income for such taxable year is computed as provided in subdivision (ii) or (iii) of this subparagraph.

(ii) If an individual is paid wages as defined in subparagraph (3) or (ii) of this paragraph in a taxable year, the maximum self-employment income for such taxable year is the excess of the amounts indicated in subparagraph (1) of this paragraph over the amount of wages, as defined in paragraph (b)(3)(i) or (ii) of this paragraph, paid to him during the taxable year.

For example, M, a calendar-year taxpayer, has $15,000 of net earnings from self-employment for 1974 and during the taxable year is paid $1,000 of wages as defined in section 3121(a) (see subparagraph (3)(i) of this paragraph) and $6,000 of compensation subject to tax under section 3301 (see subparagraph (3)(ii) of this paragraph). Then M's maximum self-employment income for 1974 is $7,900 ($13,200 — $5,300). If M also has wages, as defined in paragraph (b)(3) of this paragraph, paid to him during the taxable year, the result occurs only if such maximum self-employment income exceeds the amount of such wages.

(iii) Compensation, as defined in section 3231(e), which is subject to the tax imposed under section 3211 (a) or (b) or may have self-employment income of $100 or more for the taxable year, is not subject to the tax imposed under section 3211.

(c) Minimum net earnings from self-employment. Self-employment income does not include the net earnings from self-employment of an individual for any taxable year if the amount of such earnings for the taxable year is less than $400. Thus, an individual having only $300 of net earnings from self-employment for the taxable year would not have any self-employment income. However, an individual having net earnings from self-employment of $400 or more for the taxable year may, by application of paragraph (b)(2) of this section, have less than $400 of self-employment income for purposes of the tax imposed under section 1401 (a) and the tax imposed under section 1401 (b) and of less than $400 for purposes of the tax imposed under section 1401 (c) and (d) and of less than $400 for purposes of the tax imposed under section 1401 (e) and for the tax imposed under section 1401 (f). The computation of the maximum self-employment income for purposes of the tax imposed under section 1401 (a) is illustrated by the following example:

Example. M, a calendar-year taxpayer, has $15,000 of net earnings from self-employment for 1974 and during the taxable year is paid $1,000 of wages as defined in section 3121(a) (see subparagraph (3)(i) of this paragraph) and $6,000 of compensation subject to tax under section 3301 (see subparagraph (3)(ii) of this paragraph). If M also has wages, as defined in paragraph (b)(3) of this paragraph, paid to him during the taxable year, the result occurs only if such maximum self-employment income exceeds the amount of such wages. The computation of the maximum self-employment income in this case may be illustrated by the following example:

Example. For 1974 M, a calendar-year taxpayer, has $15,000 of net earnings from self-employment for 1974 and during the taxable year is paid $1,000 of wages as defined in section 3121(a) (see subparagraph (3)(i) of this paragraph) and $6,000 of compensation subject to tax under section 3301 (see subparagraph (3)(ii) of this paragraph). If M also has wages, as defined in paragraph (b)(3) of this paragraph, paid to him during the taxable year, the result occurs only if such maximum self-employment income exceeds the amount of such wages.
purposes of the tax imposed under section 1401(b).

For provisions relating to when wages as defined in paragraph (b) and (d) of this section are treated as paid, see paragraphs (c) and (d) of this section.

PAR. 10. Section 1.1402(c) is amended by revising paragraphs (1) and (2) of section 1402(c), by revising the historical note, and by adding material following the title of this section. These amended and added provisions read as follows:

§ 1.1402 (e) Statutory provisions; definitions; trade or business.

Sec. 1402. Definitions. * * *

(c) Trade or business. * * *

(1) The performance of the functions of a public office, other than the functions of a public office of a State or a political subdivision thereof with respect to fees received in a position and material of the Executive, Legislative, and Judicial departments of the Government of the United States; the functions performed in a position compensated solely on a fee basis and in which such functions are not covered under an agreement entered into by the President, the Vice President, the Secretary of State, a member of Congress, a State representative, a county commissioner, a judge, a justice of the peace, a county or city attorney, a marshall, a sheriff, a constable, a registrar of deeds, or a notary public performs the functions of a public office.

PAR. 12. Section 1.1402(c)-3 is amended by revising paragraph (a) and by adding a new paragraph (f) immediately after paragraph (e). These amended and added provisions read as follows:

§ 1.1402 (c)-3 Employees.

(a) General rule. Generally, the performance of service by an individual as an employee, as defined in the Federal Insurance Contributions Act (chapter 21 of the Internal Revenue Code) does not constitute a trade or business within the meaning of section 1402(c) and § 1.1402(c)-1. However, in five cases set forth in paragraphs (b) to (f), inclusive, of this section, the performance of service by an individual is considered to constitute a trade or business within the meaning of section 1402(c) and § 1.1402(c)-1.

(As to when an individual is an employee, see section 3121 (d) and (o) and the regulations thereunder in Part 31 of this chapter (Employment Tax Regulations).)

(f) State and local government employees compensated on fee basis—(1) In general. (1) Section 1402(c) (2) (E) and this paragraph are applicable only with respect to fees received by an individual after 1967 for service performed by him as an employee of a State or a political subdivision thereof in a position compensated solely on a fee basis with respect to fees received in any period in which such service is not covered under an agreement entered into by such State and the Secretary of Health, Education, and Welfare pursuant to section 218 of the Social Security Act; (2) if an individual performs service in a position as an individual as an employee, other than—

(A) Service described in section 3121(b) (14) (B) performed by an individual who has attained the age of 18; (B) Service described in section 3121(b) (16); (C) Service described in section 3121(b) (11), (12), or (15) performed in the United States (as defined in section 3121(e) (2)), and (D) Service described in paragraph (4) of this subsection, and (E) Service performed by an individual as an employee of a State or a political subdivision thereof in a position compensated solely on a fee basis with respect to fees received in any period in which such service is not covered under an agreement entered into by such State and the Secretary of Health, Education, and Welfare pursuant to section 218 of the Social Security Act; (3) if a new paragraph (f) immediately after paragraph (e) is added to section 1.1402(c)-3 to read as follows:

§ 1.1402 (c)-3A Ministers, members of religious orders; and Christian Science practitioners; application for exemption from self-employment tax.

(a) In general. (1) Subject to the limitations set forth in subparagraphs (2) and (3) of this paragraph, any individual who is (i) a duly ordained, commissioned, or licensed minister of a church or a member of a religious order (other than a member of a religious order who has taken a vow of poverty as a member of such order) or (ii) a Christian Science practitioner may request an exemption from the tax on self-employment income (see §§ 1.1401 and 1.1401-1) with respect to services performed by him in his capacity as a minister or member, or as a Christian Science practitioner, as the case may be. Such a request will be made on application for exemption on Form 4561 in the manner provided in paragraph (b) of this section and within the time specified
in § 1.1402(e)–3A. For provisions relating to the taxable year or years for which an exemption from the tax on self-employment income with respect to services performed by a minister, member, or Christian Science practitioner in his capacity as such may not be granted to a minister, member, or Christian Science practitioner with the provisions of section 1402(e) as in effect prior to amendment by section 115(b) (2) of the Social Security Amendments of 1967 (61 Stat. 659) to have been filed a valid waiver certificate on Form 4361 (or any extension thereof), the Federal old-age, survivors, and disability insurance system established by title II of the Social Security Act extended to services performed by him in the exercise of his ministry or in the exercise of duties required by the order of which he is a member, or in the exercise of his profession as a Christian Science practitioner. For provisions relating to waiver certificates on Form 4361, see §§ 1.1402(e) (1)–1 through 1.1402(e) (6)–1.

(b) Application for exemption. An application for exemption on Form 4361 will be treated as an application for exemption from self-employment income with respect to services performed by him in his capacity as a minister, member, or Christian Science practitioner if the application shows no liability for tax on self-employment income, such return or waiver certificate on Form 4361 or any extension thereof, including any extension thereof, is filed within the time prescribed in § 1.1402(e)–3A. If the last original Federal income tax return of an individual to whom paragraph (a) of this section applies which was filed after 1967, or before the expiration of such time limitation for filing an application for exemption, provided that before February 18, 1975 such individual also files a properly executed Form 4361.

(c) Application for exemption. The filing of an application for exemption on Form 4361 by a minister, a member of a religious order, or a Christian Science practitioner does not constitute an exemption from the tax on self-employment income with respect to services performed by him in his capacity as a minister, member, or practitioner. The exemption is granted only if the application is approved by an appropriate revenue officer. See § 1.1402(d)–4A relating to the period for which an exemption is effective.

§ 1.1402(e)–3A Time limitation for filing application for exemption.

(a) General rule. (1) Any individual referred to in paragraph (a) of § 1.1402(e)–3A who desires an exemption from the tax on self-employment income with respect to services performed by him in his capacity as a minister or member of a religious order or as a Christian Science practitioner must file the application for exemption (Form 4361) prescribed by § 1.1402(e)–2A on or before the due date of his income tax return (see section 6072), including any extension thereof (see section 6081), for his second taxable year ending after 1967, or

(ii) The due date of the income tax return, including any extension thereof, for his second taxable year beginning after 1953 for which he has net earnings from self-employment of $400 or more, any part of which—

(a) In the case of a duly ordained, commissioned, or licensed minister of a religious order of a denomination of remuneration for service performed in the exercise of his ministry,

(b) In the case of a member of a religious order who has not taken a vow to perpetual poverty as member of such order, consists of remuneration for service performed in the exercise of duties required by such order, or

(c) In the case of a Christian Science practitioner consists of remuneration for service performed in the exercise of his profession as a Christian Science practitioner.

See paragraph (c) of this section for provisions relating to the computation of net earnings from self-employment.

(2) If a minister, a member of a religious order, or a Christian Science practitioner derives gross income in a taxable year both from service performed in such capacity and from the conduct of another trade or business, and the total gross income from services performed in such capacity, no part of the net earnings from self-employment (computed as prescribed in paragraph (c) of this section) for the taxable year shall be considered as derived from services performed in such capacity.

(3) The application of the rules set forth in subparagraphs (1) and (2) of this paragraph may be illustrated by the following examples:

Example (1). M, who makes his income tax returns on a calendar year basis, was ordained as a minister in January 1966. During each of two or more taxable years ending before 1968 M has net earnings from self-employment in excess of $400 some part of which is from service performed in the exercise of his ministry. M has not filed an effective waiver certificate on Form 4361 (see paragraph (a) (3) of § 1.1402(e)–2A). If M derives an exemption from the tax on self-employment income with respect to service performed in the exercise of his ministry, he must file an application for exemption on or before the due date of his income tax return for 1969 (his second taxable year ending after 1967), or any extension thereof.

Example (2). M, who makes his income tax returns on a calendar year basis, was ordained as a minister in January 1966. M has net earnings from self-employment in excess of $350 for the taxable year 1968 and has net earnings in excess of $400 from service performed in the exercise of his ministry. M has not filed an effective waiver certificate on Form 4361 (see paragraph (e) (3) of § 1.1402(e)–2A). If M derives an exemption from the tax on self-employment income with respect to service performed in the exercise of his ministry, he must file an application for exemption on or before the due date of his income tax return for 1969 (his second taxable year ending after 1967), or any extension thereof.
Example (3). Assume the same facts as in example (2) except that M has net earnings in each of the years 1967 and 1968 (but less than $400 in 1968). The application for exemption must be filed on or before the due date of his income tax return for 1969, or any extension thereof.

Example (4). M was ordained as a minister in January 1973. During each of the taxable years 1973 and 1974, M, who makes his income tax returns on a calendar year basis, derives net earnings of $400 from his activities as a minister. He has no other net earnings for the taxable year 1974, $200 of which is derived from service performed by him in the exercise of his ministry, and $100 of which is derived from the tax on self-employment income with respect to service performed in the exercise of his ministry, he must file an application for exemption on or before the due date of his income tax return for 1975, or any extension thereof.

Example (5). M, who was ordained a minister in January 1973, is employed as a companyighthousekeeper for the XYZ Corporation in the exercise of his ministry. M makes his income tax returns on a calendar year basis. During each of the taxable years 1973 and 1974, M receives $4,000 for service performed in the exercise of his ministry. If M desires an exemption for taxable years ending after 1967, he must file an application for exemption on or before the due date of his income tax return for 1974, or any extension thereof. The expenses incurred by him in connection with his ministry, or by a member of a religious order in the exercise of duties required by such order, or the performance of service by an individual in the exercise of his profession as a Christian Science practitioner, does not constitute a trade or business for purposes of the tax on self-employment income.

(2) Taxable years ending after 1967. For purposes of this section and § 1.1402(e)–4A net earnings from self-employment for taxable years ending after 1967 shall be determined without regard to section 1402(c) (4) and (5). See § 1.1402(e)–3(e) (2) and § 1.1402(c)–5 relating to ministers and members of religious orders, and paragraphs (a) (5) (ii) and (b) (1) of § 1.1402(c)–6 relating to Christian Science practitioners.

§ 1.1402(e)–4A Period for which exemption is effective.

(a) In general. If an application for exemption on Form 4361

(1) Is filed by a minister, a member of a religious order, or a Christian Science practitioner eligible to file such an application (see particularly paragraph (a) (2) and (3) of § 1.1402(e)–2A), and

(2) Is approved (see paragraph (c) of § 1.1402(e)–2A),

the exemption from the tax on self-employment income shall be effective for the first taxable year ending after 1967 for which such minister, member, or practitioner has net earnings from self-employment of $400 or more of which $14,000 is derived from contracts or subcontracts subject to such renegotiation agreements in conformance with the standards in effect with respect to such renegotiable contracts and subcontracts.

Significant changes in the proposed amendments are reflected in the within regulations adopted by the Board. The second phase of the proposed program has been eliminated and conformance with cost accounting standards has been limited only to that portion of a contractor's renegotiable business which is derived from contracts or subcontracts subject to such standards. The remaining portion of the contractor's renegotiable business will be reported in accordance with the contractor's usual method of accounting, except that, under certain circumstances, extended application of cost accounting standards is permissible. New regulations, as adopted, read as set forth below.


Rex M. Mattingly,
Acting Chairman.

Section 1459.1 is amended as follows:

1. Paragraphs (b) (1) through (7) inclusive are deleted in their entirety and the following inserted in lieu thereof.

2. Paragraph (b) (8) is redesignated as (b) (9) and a new paragraph (b) (8) is added as follows.

§ 1459.1 Statutory provisions and general regulations.

(b) Profits, cost allocation and allowance; general—(1) Accounting methods. In connection with renegotiation on an over-all fiscal year basis, except as otherwise provided in these regulations, income received or accrued and costs paid or incurred will be considered as having been received or accrued or paid or incurred in the fiscal year to which such items are to be attributed in accordance with the method of accounting for federal income tax purposes.

The Renegotiation Board hereby adopts the proposed amendments to Parts 1459 and 1470 of its regulations which were published on October 9, 1974 (39 FR 36352-36354), certain significant changes having been made therein.
employed by the contractor in determining net income for Federal income tax purposes or in accordance with such other method of accounting as the contractor and the Board may agree upon pursuant to the provisions of paragraph (b)(2) of this section: Provided, That, the method of accounting to be employed is not in conflict with the contractor's obligations under paragraph (b)(2) of this section, except in respect to allocations made pursuant to such paragraph (b)(2), nothing in the preceding sentence shall affect the authority of the Board under section 103 (c) and (d) of the Act, in the opinion of the Board, properly reflect such income or costs, and the contractor and the Board are unable to agree upon a method which does properly reflect such income or costs.

(2) Cost accounting standards. The Board was designated a "relevant Federal agency" by Cost Accounting Standards Board regulation, § 331.2, 4 CFR 331.2, issued under Pub. L. 91-379 (84 Stat. 796, approved August 15, 1970), 50 U.S.C. App. 2168. Accordingly, the Board extends recognition to cost accounting standards promulgated by the Cost Accounting Standards Board, and in filing financial statements with the Renegotiation Board, contractors are required to comply with such standards as provided herein.

(i) Fiscal years beginning after December 31, 1974. For fiscal years beginning after December 31, 1974, contractors with any renegotiable contracts or subject to cost accounting standards are required to file financial statements with the Renegotiation Board in conformance with these standards for that portion of their renegotiable business subject to such accounting standards, with the remaining portion of their renegotiable business to be reported in such financial statements in accordance with the provisions of paragraphs (b)(1) of this section, except as provided in paragraphs (b)(2) (ii) (a), (b) and (c) of this section.

(ii) Extended application of cost accounting standards for fiscal years beginning after December 31, 1974. Contractors subject to cost accounting standards for a portion of their renegotiable business who file financial statements with the Renegotiation Board as provided in subsection paragraph (b)(2) (i) of this section, may extend the applicability of such cost accounting standards in the following manner:

(a) In addition to that portion of the renegotiable business that is subject to one or more cost accounting standards and required to be reported for renegotiation purposes in accordance with such standards, contractors may report all other renegotiable business within the same profit center defined in § 351.30 (b) of the Cost Accounting Standards Board regulations, 4 CFR 351.30, in accordance with such cost accounting standards.

(b) In addition to that portion of the renegotiable business subject to one or more cost accounting standards and required to be reported for renegotiation purposes in accordance with such standards, or any renegotiable business required to be reported pursuant to this section, contractors, with Board approval, may report any other renegotiable business in accordance with such standards.

(3) Differing accounting methods. (i) The Board will permit a contractor to adopt for renegotiation purposes a method of accounting other than that used by the contractor for Federal income tax purposes, provided that:

(a) The method of accounting to be adopted is not in conflict with the contractor's obligations under 50 U.S.C. App. 2168 or paragraph (b) (2) (ii) (a) or (ii) (b) of this section shall conform with all other requirements of this part of the regulations, including the requirement that no item will be allowed as a cost of renegotiable business to the extent that such item has, in a previous renegotiation under the act, been allowed as a cost of renegotiable business (see RBR § 1459.1 (c) (8)); and the requirement that any reporting practice followed pursuant to paragraphs (b)(2) (ii) (a) or (b) must be followed in subsequently filed statements for the same fiscal year, provided in paragraph (b)(2) (ii) (a) or (b) of this section, contractors, with Board approval, may report any other renegotiable business in accordance with such standards.

(ii) Under this section, a contractor may adopt a different method of accounting for the purpose of determining performance and allocation of income and cost that could result in material distortion in accounting on an interim basis that may include contracts for construction of major facilities or major units (such as a vessel or group of vessels) when the profits can best be determined upon completion.

(iv) If a contractor employs, for the purposes of a renegotiation proceeding relating to the year under review, a method of accounting different from that which was employed for the purposes of a renegotiation proceeding relating to the preceding fiscal year, whether pursuant to this section or otherwise, it will be required to employ such different method of accounting for the purposes of all subsequent renegotiation proceedings, and the amounts received or accrued and costs paid or incurred which have been recognized in prior renegotiation proceedings will not be recognized in the proceedings relating to the year under review.

(4) Allocation of costs. In general, except as provided in paragraph (b)(3) of this section, the costs paid or incurred with respect to renegotiable business in the fiscal year under review will be the costs allocated to such business and such costs may be covered by the established cost accounting method if that method reflects recognized accounting principles and practices. In the opinion of the Board there is no adequate or effective cost accounting method in use, or if the method employed does not properly reflect any such costs the Board may permit such allocation, if the Board determines that such allocation is in the public interest.
(5) Tax deductions. When an item of cost is allocable in whole or in part to renegotiable business, the Board will estimate the amount allocable as a deduction or exclusion under chapter 1 of the Internal Revenue Code, and such estimated amount will be allowed as a cost of renegotiable business in the fiscal year under review to the extent that it is allowable to such business and such year in accordance with the principles set forth in this paragraph (b). No such item of cost will be allowed in an amount less than the amount on which it is based for the determination of taxable income under the Internal Revenue Code, and all items of cost will be allocated to the fiscal year in which they are allowable in the determination of taxable income under said Code, except as otherwise provided in this paragraph (b). When it is clear that a contractor's deductions and exclusions under the Internal Revenue Code result in allocable costs of renegotiable business which are in the aggregate either high or low on a comparative basis, this circumstance will be considered in arriving at the estimate of the "reasonableness of costs" of the contractor and the determination of the amount of any profit adjustment to be required of the contractor. In estimating amounts allocable as deductions or exclusions under chapter 1 of the Internal Revenue Code, due consideration will be given to any pertinent action by the Internal Revenue Service. Published rulings and revenue procedures concerning matters of general application will be adhered to in making such estimates. However, the allowance of items as costs is not required merely because they have been specifically include in the applicable regulations. The Board will exercise independent judgment on whether and to what extent and for what year items are allowable as deductions or exclusions under the Internal Revenue Code. Such judgment will be based upon an estimate of what the courts would do if the deductibility or excludability of the items were the subject of litigation.

(6) Effect of cost principles promulgated by other agencies. Agreements for the allowance or disallowance of costs entered into by a contractor with another agency of the Government, either by specific contractual provision or by acceptance (expressed or implied) of Government regulations or policies, are not controlling in determining allowable costs for renegotiation purposes. Thus, a cost properly disallowed in accordance with the cost accounting standards promulgated by the Cost Accounting Standards Board, To the extent one or more such standards are applicable to a fiscal year, under the provisions of 50 U.S.C. App. 2165 and §1450.1(b) (2) of this chapter, the Standard Form of Contractor's Report shall be prepared in accordance therewith. Upon request there shall be filed with the Board copies of disputed statements, if any, and other explanatory documents and information filed with the Cost Accounting Standards Board and procurement agencies.

Title 33—Navigation and Navigable Waters
CHAPTER I—COAST GUARD
DEPARTMENT OF TRANSPORTATION
[CGD 74 295]
PART 117—DRAWBRIDGE OPERATION REGULATIONS
GIWW, Mile 57.6 Through Mile 59.8, West of Harvey Lock, Houma, La.

This amendment changes the regulations for the drawbridges located across the GIWW at mile 57.6 through mile 59.8, west of Harvey Lock, Houma, Louisiana to allow closed periods during the morning and evening rush hour vehicular traffic. This amendment is required while extensive repairs are completed on the drawbridge located at mile 57.7. Marine interests have agreed to this temporary restriction. The Coast Guard has found that good cause exists for granting this change without notice of proposed rule making on the basis that it would be contrary to the public interest to delay this work.

Accordingly, Part 117 of Title 33 of the Code of Federal Regulations is amended by adding a new §117.241 immediately after §117.240 to read as follows:

§117.241 GIWW, Houma, Louisiana, bridges.
(a) The drawbridges located at mile 57.6 through mile 59.8, west of Harvey Lock, Houma, Louisiana are not open for the passage of vessels from 7:30 to 8:30 a.m. and 4:30 to 5:30 p.m., Monday through Friday, except holidays.
(b) These regulations shall be revoked as of January 31, 1975.
RULING AND REGULATIONS

§ 1-5.902 Authorization to contractors.

1. Paragraphs (a) and (b) of § 9-5.5206-5 are revised as follows:

§ 9-5.5206-5 Steel filing cabinets.

(a) Procurement of steel filing cabinets, by either AEC or cost-type contractors, is subject to AEC utilization requirements.

(b) Direct AEC procurements of steel filing cabinets are subject to the requirements of FPMR 101-25.302. These requirements do not apply to grantees or contractors authorized to use GSA supply sources. However, such filing cabinets shall not be procured by AEC cost-type contractors unless approved by the Manager of the cognizant Field Office, on the basis that AEC utilization requirements have been met and the actions prescribed by FPMR 101-25.302-2 have been taken. A copy of the Field Office approval order shall be retained in the appropriate purchasing office files.

Effective date: This amendment is effective December 24, 1974.

Dated at Germantown, Maryland this 18th day of December, 1974.

For the Atomic Energy Commission.

JOSEPH L. SMITH,
Director, Division of Contracts.

[FR Doc.74-30069 Filed 12-23-74; 8:45 am]
CHAPTER 101—FEDERAL PROPERTY MANAGEMENT REGULATIONS
SUBCHAPTER E—SUPPLY AND PROCUREMENT
[FPMR Amdt. E-156]
PART 101—25—GENERAL
Subpart 101—25.3—Use Standards

CHAPTER 101—FEDERAL PROPERTY MANAGEMENT REGULATIONS
SUBCHAPTER E—SUPPLY AND PROCUREMENT
[FPMR Amdt. E-156]
PART 101—25—GENERAL
Subpart 101—25.3—Use Standards

USE OF UNLEADED GASOLINE IN 1975 MODEL YEAR GOVERNMENT-OPERATED MOTOR VEHICLES

This regulation provides revised policy requiring that only unleaded gasoline be used in all 1975 or later model year Government-operated motor vehicles designed to operate on such fuel.

Section 101-25.303 is revised to read as follows:


Pursuant to the regulations of the Environmental Protection Agency (EPA), codified in 40 CFR Part 60, unleaded (0.05 gm./gal.) gasoline shall be used in 1975 or later model year Government-operated motor vehicles designed to operate on such fuel (passenger carrying vehicles and trucks up to and including 6000 lbs. GVWR) within the 50 States. For 1974 or earlier model year Government-operated motor vehicles within the 50 States, unleaded or low-lead content (0.5 gm./gal.) gasoline shall be used unless it is clearly impractical or unfeasible to do so.

(a) Government-operated motor vehicles used overseas shall be fueled in accordance with this § 101-25.303 unless (1) such use would be in conflict with country-to-country or multinational logistics agreements or (2) such gasoline is not available locally.

(b) The cost of gasoline shall not be used as a factor in determining the feasibility of using unleaded or low-lead content gasoline in 1974 or earlier model year Government-operated motor vehicles; however, manufacturers' recommendations for octane requirements and minimum lead content shall be generally followed.

Effective date. This regulation is effective December 24, 1974.

Dated: December 12, 1974.

ARTHUR F. SAMPAIO,
Administrator of General Services.

Title 47—Telecommunication
CHAPTER I—FEDERAL COMMUNICATIONS COMMISSION
[FCO 74—1281]
PART 73—RADIO BROADCAST SERVICES
Two-Tone Attention Signal System
Correction

In FR Doc. 74—28060 appearing at page 43301 in the issue for Thursday, December 12, 1974 make the following change:

In the center column, in § 73.906(a), the third line should read “frequencies of 583 and 960 hertz and shall”.

PART 76—CABLE TELEVISION SERVICES
Cable Television Systems, Development of Services
Correction

In FR Doc. 74—28062 appearing at page 43310 in the issue for Thursday, December 12, 1974 make the following change:

In the third column, in § 76.305(c), the third line from the bottom should read “(a) (7) shall be retained for the period”. 
DEPARTMENT OF AGRICULTURE
Agricultural Stabilization and Conservation Service

[7 CFR Part 726 ]

BURLEY TOBACCO
Determinations on Marketing Quotas for the 1975-76 Marketing Year

Pursuant to the Agricultural Adjustment Act of 1933, as amended, (7 U.S.C. 1281 et seq., hereinafter referred to as the "Act"), the Secretary is preparing to determine and announce the amount of the national marketing quota, the national reserve and the national factor for burley tobacco for the 1975-76 marketing year.

Section 319(b) of the Act provides that the national marketing quota for the 1975-76 marketing year shall be determined and announced not later than February 1, 1975. Burley tobacco farmers approved marketing quotas on a poundage basis for the 1974-75, 1975-76, and 1976-77 marketing years (39 FR 23985).

Section 319(c) provides that the national marketing quota shall be the amount produced in the United States which the Secretary estimates will be utilized in the United States and will be exported during such marketing year, adjusted upward or downward in such amount as the Secretary, in his discretion, determines is desirable for the purpose of maintaining an adequate supply or for effecting an orderly reduction of supplies to the reserve supply level. Any such downward adjustment shall not exceed five percent of the estimated utilization in the United States during the calendar year in which the marketing year begins. The total supply for the 1974-75 marketing year is 1,848 million pounds, composed of carryover of 1,071 million pounds and estimated production of 772 million pounds.

The Act (7 U.S.C. 1301(b)) defines "total supply" as the carry-over at the beginning of the marketing year (October 1) plus the estimated production in the United States during the calendar year in which the marketing year begins. The total supply for the 1974-75 marketing year is 1,848 million pounds, composed of carryover of 1,071 million pounds and estimated production of 772 million pounds.

The Act (7 U.S.C. 1301(b)) defines "reserve supply level" as normal supply plus 5 percent. "Normal supply" is defined as a normal year's domestic consumption and exports plus 175 percent of a normal year's domestic consumption and 65 percent of a normal year's exports as an allowance for a normal carry-over. A "normal year's domestic consumption" is defined as the yearly average quantity produced in the United States and consumed in the United States during the ten marketing years immediately preceding the marketing year in which such consumption is determined, adjusted for current trends in such consumption. A "normal year's exports" is defined as the yearly average quantity produced in the United States which was exported from the United States during the ten marketing years immediately preceding the marketing year in which such exports are determined in the United States and estimated to be 1,635 million pounds, calculated from a normal year's domestic consumption of 538 million pounds and a normal year's exports of 85 million pounds.

The amount of burley tobacco produced in the United States and estimated to have been utilized in the United States during the 1973-74 marketing year was 533 million pounds, and the amount exported was 87 million pounds, farm-sales basis. The amount of the national marketing quota for the 1974-75 marketing year is 608 million pounds based upon estimated utilization in the United States of 565 million and estimated exports of 75 million pounds, with a downward adjustment of 32 million pounds (39 FR 4565). For the 1973-74 marketing year, utilization in the United States is estimated to be about 555 million pounds and imports estimated to be about 95 million pounds.

The total supply for the 1974-75 marketing year is 58 million pounds less than the proposed reserve supply level, but the amount of the downward adjustment, if any, desirable for maintaining an adequate supply is still being considered.

Section 319(e) provides, in part, that the farm marketing quota shall be determined for the immediately preceding year for any farms for which burley tobacco marketing quotas will be determined: Provided, That such national factor shall not be less than 95 per cent.

Section 319(h) provides that effective with the marketing year beginning October 1, 1976, no marketing quota, other than a new farm marketing quota, shall be established for a farm on which no burley tobacco was planted or considered planted in any of the five years immediately preceding the year for which farm marketing quotas are being established.

The subjects and issues involved in the proposed determinations with respect to burley tobacco for the 1975-76 marketing year are:

1. The amount of the national marketing quota.
2. The amount of the reserve supply level.
3. The amount of the national reserve.
4. Whether the Secretary should implement the provision in section 319(h) authorizing adjustment of farm marketing quotas of any grades to insure traditional market patterns.

The national factor is not considered an issue in these determinations because it results from a mathematical computation under section 319(e).

Consideration will be given to data, views and recommendations pertaining to the proposed determinations, rules and regulations covered by this notice which are submitted in writing to the Director, Tobacco and Peanut Division, Agricultural Stabilization and Conservation Service, United States Department of Agriculture, Washington, D.C. 20250. All written submissions will be made available for public inspection from 8:15 a.m. to 4:30 p.m., Monday through Friday, in room 6741-South Building, 14th and Independence Avenue SW, Washington, D.C. All submissions must, in order to be sure of consideration, be postmarked not later than January 14, 1975.
with the other fiduciary responsibility provisions of the Act.

Interested persons are invited to submit comments to "Comments—Section 2552.1," Office of Employee Benefits Security, Labor-Management Services Administration, P.O. Box 176, Washington, D.C. 20044. All comments received before January 24, 1975, will be considered before final action is taken on this proposal. The proposal may be changed in light of the comments received.

Accordingly, it is proposed to amend Chapter XXV of Title 29 of the Code of Federal Regulations, by adding a new Part 2552 to read as follows:

PART 2552—CONTROL AND MANAGEMENT OF FUNDS

Sec. 2552.1 Exemption from trust requirements for unfunded welfare benefit plans.

(a) Under the authority of section 403(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1135), any employee welfare benefit plan, under which benefits are paid or to be paid directly to plan participants and beneficiaries only from the general assets of the person establishing or maintaining the plan is to be considered an unfunded welfare benefit plan. A plan is not an unfunded welfare benefit plan if plan participants and beneficiaries make contributions to the plan through withholding or otherwise, or if there is a separately maintained bank account or other evidence of the existence of a fund or trust account or separately maintained bank account or other evidence of the existence of a fund or trust account or administratively or separately maintained assets out of which plan benefits are to be provided. All funded employee benefit plans, welfare or pension, would still be subject to the requirements of section 403(a).

(b) The exemption set forth in paragraph (a) above does not exempt an unfunded welfare benefit plan from any other provisions of Parts 1 and 2 of Title I (participation and vesting), Part 3 of Title I (funding), or Title IV (plan termination insurance).

The proposed regulation would exempt any unfunded welfare benefit plan from the requirements of section 403(a) of the Act. For the purposes of this regulation, any welfare benefit plan under which benefits are paid or to be paid directly to plan participants and beneficiaries only from the general assets of the person establishing or maintaining the plan is to be considered an unfunded welfare benefit plan. A plan is not an unfunded welfare benefit plan if plan participants and beneficiaries make contributions to the plan through withholding or otherwise, or if there is a separately maintained bank account or other evidence of the existence of a fund or trust account or administratively or separately maintained assets out of which plan benefits are to be provided. All funded employee benefit plans, welfare or pension, would still be subject to the requirements of section 403(a).

Unfunded welfare benefit plans do not have assets. In such plans, benefits are paid directly from the general assets of the person establishing or maintaining the plan. There is no need for or use of a trust account or funds out of which plan benefits are to be provided. All funded employee benefit plans, welfare or pension, would still be subject to the requirements of section 403(a).

Unfunded welfare benefit plans do not have assets. In such plans, benefits are paid directly from the general assets of the person establishing or maintaining the plan. Therefore, the underlying rationale for the Act’s requirement that a trust be utilized—to prevent commingling of plan assets with assets belonging to the person managing the plan assets—is not applicable to such unfunded welfare benefit plans. It should be noted that the exemption proposed by this regulation for unfunded welfare benefit plans applies only to the requirement that the assets of employee benefit plans generally be held in trust by one or more trustees. A plan exempted therefrom under the provisions of other regulations issued under the Act. Furthermore, any person who is a fiduciary with respect to an unfunded welfare benefit plan must still comply
Interested persons wishing to appear at any one of the listed hearings must file a written notice of intention to appear, together with two copies, postmarked no later than January 15, 1975. Such requests should be addressed to Mrs. Jeannie Perrone, Attn: Docket OSH-38, Occupational Safety and Health Administration, Room 200, 1725 M Street, NW, Washington, D.C. 20210. The notice must state the name and address of the person wishing to appear, the capacity in which he will appear, and the approximate amount of time required for his presentation. The notice must also include or be accompanied by, a statement of the position to be taken in regard to the specific issues to be raised, and the evidence to be adduced in support to this position. For persons wishing to appear at the hearings but unable to attend, written statements postmarked no later than January 20, 1975 may be submitted to the above address. The written statements should be submitted in triplicate.

The hearing shall be conducted in accordance with the rules of procedure in 29 CFR Part 111. The oral proceedings shall be reported verbatim. The use of prepared statements by witnesses is encouraged. An original and two copies of all documents should be submitted at the time of the presentation.

The presiding administrative law judge shall have all the powers necessary or appropriate to conduct a fair and full informal hearing, including the powers:

(a) To regulate the course of the proceeding;

(b) To dispose of procedural requests, objections, and comparable matters;

(c) To confine the presentations to pertinent issues;

(d) To regulate the conduct of those present at the hearing by appropriate means;

(e) In his discretion, to permit cross-examination of any witness; and

(f) In his discretion, to keep the record open for a reasonable, stated time to receive written recommendations, supporting reasons, and additional data, views, and arguments from any person who has participated in the oral proceeding.

Following the close of the hearings, the presiding administrative law judge shall certify the entire record of the hearings to the Assistant Secretary of Labor for Occupational Safety and Health.

Upon consideration of the record of the hearing, and any written data, views, or arguments received in response to the notice of proposed rulemaking, a determination may be made to adopt the proposal with or without changes or to withdraw the proposal.

Signed at Washington, D.C. this 26th day of December, 1974.

JOHN STENBERG, Assistant Secretary of Labor.

[FR Doc. 74-30108 Filed 12-29-74; 8:45 am]

DEPARTMENT OF TRANSPORTATION

Urban Mass Transportation Administration

URBAN TRANSPORTATION PLANNING

Extension of Comment Period

This notice extends the period for comments on the notice published October 9, 1974 (39 FR 39650) proposing urban area boundary regulations, and the notices published November 8, 1974 (39 FR 39660, 39665), proposing urban transportation planning regulations and transportation improvement program regulations.

A number of requests for extensions of time were submitted including one from the American Public Transit Association (APTA). Among other matters, APTA felt the need for additional time to consider the impact on the proposed procedures of the recently enacted National Mass Transportation Assistance Act of 1974 (Pub. L. 93-503). The Maryland Department of Transportation also requested an extension in view of the substantial implication to existing State laws and procedures. A number of other States and organizations informally requested an extension for reasons similar to those formally expressed by APTA and the Maryland Department of Transportation.

Accordingly, UMTA and FHWA grant these requests and extend the comment period until January 15, 1975. If further analysis of the National Mass Transportation Assistance Act of 1974 indicates that substantive amendments should be made to these proposed regulations, they will be published at a later time; however, at this time it is not anticipated that these proposed regulations will require any major amendment necessitating republication for formal comment.

Dated: December 18, 1974.

NORBERT T. TIEMANN, Federal Highway Administrator.

FRANK C. HERRINGER, Urban Mass Transportation Administrator.

[FR Doc. 74-39880 Filed 12-29-74; 8:45 am]

ACTION

[48 CFR Part 1213]

ACTION COOPERATIVE VOLUNTEER PROGRAM

Terms and Conditions of Volunteer Service

The ACTION Cooperative Volunteer Program (ACV) is authorized under section 122(a), Part C, Title I, of the Domestic Volunteer Act of 1973, Pub. L. 93-113. It provides full-time volunteer service opportunities for individuals on projects involving a broad range of human, social, and environmental needs. Full-time service involves the enrollment of individuals in the program for a period of at least one year. In keeping with 402(12) of Pub. L. 92-113, volunteer sponsors enter into an agreement with ACTION to reimburse ACTION for the direct costs of volunteer support, i.e., allowances, stipend and other direct benefits. This feature distinguishes ACV from other Title I full-time volunteer programs such as VISTA and the Program for Local Service.

Section 122(b) requires that the assignment of volunteers under Part C, Title I of Pub. L. 93-113 be on such terms and conditions as the Director of ACTION shall determine. Also, section 122(c) provides that the Director may provide to persons serving as full-time volunteers in a program of at least one year’s donation such allowances and stipends as he determines are necessary. The kinds and amount of such allowances and stipends may not exceed those authorized to be provided to VISTA volunteers (Part A, Title I, Pub. L. 92-113).

Notice is hereby given that the Director of ACTION proposes to amend Chapter XII of Title 45, Code of Federal Regulations to add a new Part 1213. This amendment will provide regulations concerning two areas: (1) the terms and conditions for volunteer service in ACV, and (2) the amount of allowances and stipends that ACV volunteers receive.

Inquiries may be addressed and comments and views concerning the proposed new part may be submitted to ACTION, 800 Connecticut Avenue NW, Washington, D.C. 20525, Attention: Associate Director for Domestic and Operations. All comments received on or before January 21, 1975 will be considered.

All comments in response to this proposal will be available for public inspection during normal business hours at the foregoing address.

It is therefore proposed to add a new Part 1213 to Chapter XII of Title 45 of the Code of Federal Regulations as follows:

PART 1213—ACTION COOPERATIVE VOLUNTEER PROGRAM

Subpart A—General

Sec. 1213.1-1 Introduction.

Subpart B—Description of Volunteer Service

1213.2-1 Enrollment and duration of service.

1213.2-2 Provisional volunteers.

1213.2-3 Extension of service and reenrollment.

1213.2-4 Living conditions.

1213.2-5 Role of volunteer.
PROPOSED RULES

Subpart C—ACTION Provided Volunteer Support

§ 1213.3-1 Financial support.

(a) Food and lodging. Each ACV volunteer receives from ACTION a food and lodging allowance approximately commensurate with the actual standard of living of the residents of the community in which he is assigned. The amount of this allowance is determined by the Regional Office after consultation with the sponsor.

(b) Provisional volunteers. Provisional volunteers do not receive any allowances nor do they accrue stipends. During the period they are provisional volunteers their food and lodging is provided by ACTION and they receive a nominal amount of money for living expenses.

§ 1213.3-2 Transportation.

ACTION will be responsible for providing the volunteer with needed transportation for the following purposes:

(a) To, and when appropriate, from volunteer/sponsor staging;

(b) To the pre-service processing site, whether it is the Regional Office or any other designated facility;

(c) To the project site following completion of pre-service processing, and at the beginning of the volunteer’s term of service;

(d) For the return trip from the project site to the volunteer’s home of record following completion of service;

(e) Whenever necessary to enable the volunteer to travel outside the geographic

Subpart C—ACTION Provided Volunteer Support
area to which he has been assigned when he does so at the request of the Government; (f) When approved in cases of emergency.

For the purpose of (d) of this section, the term “home of record” shall be either:

(1) The legal residence of the volunteer, parent, or legal guardian if the volunteer had been residing with the parent or legal guardian immediately prior to entering ACTION service, if the volunteer was a full-time student whose permanent residence was with the parent or legal guardian.

(2) The residence established by the volunteer while attending college immediately prior to entering ACTION.

(3) The residence established by the volunteer while employed immediately prior to entering ACTION.

(4) The legal residence established by the volunteer for purposes of voting and/or payment of state tax.

Each volunteer must specify a home of record at the time he is enrolled. Subsequent modification of the home of record may be authorized in certain circumstances at the discretion of the Regional Director.

§ 1213.3—3 Health support.

ACTION provides ACV volunteers with a health benefits program at no cost to the volunteers.

Coverage includes most medical and surgical costs, hospitalization, prescription drugs, and emergency dental care.

ACTION reserves the right to alter the extent of the program or the method of providing health care for volunteers. In certain emergency situations, the Regional Office must clear actual travel expenses incurred, but not in excess of those authorized in standard government travel regulations.

§ 1213.3—7 Federal service.

Section 415 (c) of the Act provides that an ACV volunteer subsequently enter Federal service, his period of volunteer service counts as a like period of Federal service for certain purposes, including job security and retirement benefits.

§ 1213.3—8 Legal support.

(a) The Regional Director may at his discretion reimburse travel of volunteers or trainees for or replace lost, damaged, or stolen property; cash representing certain allowances; and equipment and supplies if, (1) reimbursement is essential to the volunteer's capacity to serve effectively in his particular assignment for the duration of his service, and (2) the loss, damage, or theft did not result from the volunteer's negligence.

(b) Lost or stolen cash may be reimbursed only if it represents the volunteer's food and lodging or living allowance or other payments essential to the volunteer's service. Lost or stolen cash representing payment of stipend or vacation allowances will not be reimbursed.

(c) No reimbursement will be made for luxury items, such as photographic or phonograph equipment or jewelry.

Subpart D—Sponsor Provided Volunteer Support

§ 1213.4—1 Training.

(a) The sponsor is fully responsible for designing and implementing a program of in-service training which will completely equip the volunteer to perform the tasks to which he has been assigned.

(b) In-service training will be conducted by the sponsor in accordance with plans agreed upon during the program development process, and submitted to ACTION as part of the agreement. Those plans must be tailored to the volunteer's needs for additional skills and information in the performance of assigned tasks.

§ 1213.4—2 Supervision.

The sponsor has the sole responsibility for providing appropriate supervision, leadership, and direction to the volunteers in conformance with the plan prepared in cooperation with ACTION and submitted with the project proposal. The plan is to be executed in such a manner that the volunteers can attain project goals within the proposed time frame.

§ 1213.4—3 Job-related transportation.

The sponsor is responsible for determining the job-related transportation needs of the volunteer. The volunteers are expected to use public transportation in connection with their work whenever it is available and adequate. When it is not, the sponsor shall provide suitable private transportation, including obtaining and maintaining motor vehicle licenses for the job-related use of the volunteers as appropriate. Whether the sponsor purchases vehicles or obtains them through a leasing arrangement, he is responsible for monitoring the use of those vehicles and restricting the use of transportation provided to volunteers to work on the project. The volunteer and the sponsor are jointly responsible for ensuring that no persons other than volunteers or authorized personnel concerning vehicle registration, operator licensing, and financial responsibility on any private vehicles used by the volunteer, either as part of his work assignment or for personal convenience.

§ 1213.4—4 Supplies and equipment and office facilities.

The sponsor is responsible for providing most job-related support involving facilities, equipment, and consumable supplies needed by the volunteer, including telephone and secretarial support.

Subpart E—Administrative Hold, Grievances, Removal, Resignation, Suspension and Termination

§ 1213.5—1 Administrative hold.

(a) Volunteers will be placed in Administrative Hold Status under the following circumstances:

(1) No placement after training.

(2) Pending transfer to a new project.

(3) Leave taken for personal reasons in excess of the seven days for vacation leave, seven days for emergency leave, seven days for extension beyond three months, and fourteen days for reenrollment.

(4) Absence from project site without authority of the sponsoring organization.

(5) During termination action.

(6) Arrest and placement in jail without bail depending on nature of charge.

(7) Removal from site at request of sponsoring organization, pending decision on transfer to new assignment.

(b) Exceptions to these guidelines must be authorized by the Regional Director. Volunteers may be placed in Administrative Hold status for up to 30 days. In exceptional circumstances, the
Regional Director may extend this period of time as appropriate. The Regional Director may modify any and all allowances, including stipend, when a volunteer is placed in Administrative Hold status.

§ 1213.5—2 Volunteer grievances.

(a) At times, a volunteer will consider that he has been adversely affected in some matter arising out of his work situation or the terms and conditions of his service. The Volunteer Grievance Procedure, Part 1211, furnished to each volunteer, applies to certain of these matters. This procedure is applicable to situations in which the volunteer believes there has been a deviation from, misinterpretation or misapplication of laws, regulations, policies or procedures governing his service.

(b) The Grievance Procedure establishes a formal and informal mechanism to resolve such problems. The Informational Mechanism aims to resolve disputes at the level of the sponsor and the state program officer. The formal part of the Grievance Procedure provides a hearing in certain cases and includes appeals to ACTION's national office in Washington.

(c) The procedure that the sponsor employs at the informal stage of the ACTION Grievance Procedure will also be used for any disputes between the sponsor and a volunteer not involving a law or regulation or an ACTION policy and procedure.

§ 1213.5—3 Resignation.

A volunteer may resign at any time, by notifying the sponsoring organization and the Regional Office. When practicable, thirty days advance notice should be given to insure that the departure will be only minimally disruptive to the project. In case of resignation, all outstanding advances, including unearned vacation and sick leave, are deducted from the volunteer's stipend. The volunteer receives his final stipend check three to five weeks after regional submission of the termination papers to ACTION/Washington.

§ 1213.5—4 Sponsor request for removal of volunteer.

The sponsoring organization may request ACTION to remove a volunteer whose performance in its view is unsatisfactory at any time. Before resorting to a formal request for removal the sponsor should contact the appropriate ACTION official to seek help in trying to resolve any problem with a volunteer. The sponsor may then prepare a written request for removal and submit it to the Regional Office. ACTION may, depending on the circumstances, follow one of three courses of action: (a) suspend the volunteer, (b) terminate him, or (c) transfer him to another project.

§ 1213.5—5 Suspension and termination.

(a) Causes. ACTION may suspend or terminate a volunteer for any of the following reasons:

(1) Conviction of any criminal offense under Federal, state, or local statute or ordinance;
(2) Violation of any provision of the Domestic Volunteer Service Act of 1973, or any ACTION policy, regulation or instruction;
(3) Failure, refusal or inability to perform prescribed project duties as outlined in the project proposal and directed by the sponsoring organization to which the volunteer is assigned;
(4) Involvement in activities which substantially interfere with the volunteer's performance of his/her duties on the project;
(5) Intentional false statement, omission, fraud, or deception in obtaining selection as a volunteer;
(6) Any conduct on the part of the volunteer which substantially diminishes his/her effectiveness as a volunteer;
(7) Inability to perform the project duties because of serious illness, medical disability, or pregnancy, as determined by the attending physician, in accordance with ACTION policy;
(8) Lack of a viable job for which the volunteer is qualified if the initial job assignment ends or is terminated prior to completion of a period of service;
(9) Unsatisfactory job performance.

Procedures for the suspension and termination of volunteers are contained in Part 1212.

(b) Suspension. Volunteers may be suspended for up to thirty days to enable ACTION to determine whether termination proceedings should be started against the volunteer. Suspension is not warranted if sufficient evidence exists to start termination proceedings.

(c) Termination of or refusal to reemploy volunteer. If the Memorandum of Agreement between ACTION and a sponsoring organization is terminated or not renewed, a volunteer who is removed from the project and whose removal was not caused by conduct which would otherwise be grounds for termination is entitled to the following administrative considerations:

(1) Reassignment to another project where possible.
(2) If reassignment is not possible at the time of project close-out, and if the volunteer wishes to resume service (provided that his/her job performance has been satisfactory), he/she may, at the discretion of the Regional Director, receive special consideration for reemployment as soon as an appropriate slot is open.

If a volunteer wishes, he/she may terminate without prejudice in the event that a Memorandum of Agreement between ACTION and the sponsor is terminated.

(d) Deselection of a provisional volunteer. The Regional Director may deselected a provisional volunteer on the grounds listed in paragraph (a) of this section or for a failure to meet training or selection standards during pre-service orientation. Procedures for such deselection are contained in Part 1212.
national origin, sex, age, or political affiliation.

§ 1213.6-6 Religious activities.

Volunteers will not give religious instruction, conduct worship services, or engage in any other religious activity as part of their duties. Volunteers who serve in an institution that gives religious instruction or engages in other religious activities will not be used as replacements for regular personnel of the institution. For example, volunteers assigned to serve in a program conducted under the auspices of a church-related school may not be used as substitutes for regular teachers in the school. They may, however, work in new programs which are carried on in addition to the school's regular programs and which are conducted in conformance with the above restrictions.

§ 1213.6-7 Evaluation.

(a) On a quarterly basis and two months prior to the termination of a volunteer's year of service, and at any other time which circumstances may dictate, ACTION may inspect that portion of a project with which the volunteer is involved. The purpose of the inspection will be to independently observe and judge the extent to which the volunteer's work has contributed to the objectives of the program described in the project proposal.

(b) The sponsor is expected to cooperate fully with ACTION representatives, and ACTION will in turn review results of the evaluation with the sponsor.

§ 1213.6-3 Limitation on labor and anti-labor activities.

Volunteers may not engage in any activities, services, or duties which assist any labor or anti-labor organizing activity, or related activity.

§ 1213.6-9 Loans and debts.

(a) ACVs have the same legal and financial responsibilities as do all other persons. Volunteers are encouraged to pay all debts promptly to avoid creating a situation which would impair the volunteer's ability to function. In cases of continued financial irresponsibility by a volunteer to the extent of embarrassment or adverse reflection upon the sponsor organization's project or ACTION, administrative or disciplinary action may be taken by the Regional Office, up to and including termination, where appropriate.

(b) Volunteers are not authorized to obtain extension of credit by representing themselves as a Federal Government employee.

Subpart G—Miscellaneous

§ 1213.7-1 Student loan deferrals.

(a) The Higher Education Act of 1965, as amended, exempts full-time domestic volunteers in the Department of National Defense Education Act loans for a period of service not to exceed three years. Volunteers wishing to defer repayment of NDEA loans must obtain the necessary forms from their universities. Regional Offices are authorized to certify these forms, but if the university or volunteer should submit the form to Headquarters for certification, it will be sent to the appropriate Regional Office for completion.

(b) If the volunteer is still in service at the time of ACTION's certification, his anticipated termination date will be furnished to the lender.

(c) Repayment of other college loans may be deferred under the Federal Employees Compensation Act or ACTION policy. Volunteers whose death results from personal injury or illness sustained in the performance of this project may be eligible for reimbursement of funeral expenses. Monthly benefits for eligible dependents of deceased volunteers may be available under the Federal Employees Compensation Act. In certain other unusual circumstances, payment of certain funeral expenses for volunteers not meeting the above requirements may be authorized.

§ 1213.7-3 Firearms.

ACTION volunteers may not normally possess, use, or carry firearms. If a volunteer wishes to keep firearms for hunting, approval must be obtained from the sponsor, State Program Director and the ACTION Regional Director in the region where the volunteer is assigned. The volunteer must request approval for the possession and utilization of firearms either from his sponsor and his State Program Director. If he receives their approval, his request may then be considered by his ACTION Regional Director. If approval is granted by the ACTION Regional Director, the volunteer must adhere to all state and local regulations relating to the possession and use of firearms.

Issued in Washington, D.C. on December 19, 1974.

JOHN L. GANLEY,
Deputy Director, ACTION.

[FR Doc. 74-29919 Filed 12-23-74; 8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[40 CFR Part 52]

WEST VIRGINIA IMPLEMENTATION PLAN

Miscellaneous Amendments

On May 31, 1972 (37 FR 10842), the Administrator of the Environmental Protection Agency published his initial approvals and disapprovals of state implementation plans submitted pursuant to section 110 of the Clean Air Act, as amended in 1970. At that time, the Administrator approved the state implementation plan submitted by the State of West Virginia (40 CFR 52.253).

On November 8, 1974, the State of West Virginia submitted to the Administrator proposed revisions to the state implementation plan for the attainment and maintenance of air quality standards. The proposed changes include:

1. An amendment to Regulation II, "To Prevent and Control Particulate Air Pollution from Combustion and Direct Heat Exchangers." The amendment would allow sulfur oxides to be added to a combustion unit exit gas stream for the purpose of improving fuel burning units.

2. Amendments to Regulation VII, "To Prevent and Control Particulate Air Pollution from Manufacturing Process Operations." The essential change would allow the primary aluminum reduction potlines which are equipped with fluidized bed reactors or other similar gas cleaning devices to be exempt from the present governing process weight operation, provided that at least 99 percent of the gaseous fluoride is removed from the exit gas stream, and that the particulate load not be greater than 0.01 grams per standard cubic foot (gr./scf). Other changes are merely updates of the present regulation.

3. Amendments to Regulation XIII, "Permits for Construction, Modification or Relocation of Stationary Sources of Air Pollutants, and Procedures for Registration and Evaluation." The amendments would require permits for certain indirect sources and would closely parallel those requirements provided in the Administrator's existing regulations. This particular proposal was previously submitted by the State of West Virginia.

Accordingly, the Administrator announced receipt of the submission and provided for a public comment period (39 FR 39584).

4. Amendments to the state implementation plan's control strategies for particulate matter. The essential change would allow compliance schedules for particulate sources to extend beyond June 30, 1975, but no later than June 30, 1977, provided that ambient air quality standards are met by June 30, 1975.

On October 24, 1974 and December 6, 1974, the State of West Virginia submitted a proposal for the approval of the West Virginia State Plan. On December 1, 1974, the Administrator announced receipt of the submission and provided for a public comment period (39 FR 39584)

4. Proposed changes to the SIP—

This notice is to advise the public of the receipt of these proposed amendments, and to request public comments on them. Only those comments received before January 23, 1975, will be considered.

The Administrator's decision to approve or disapprove these proposed revisions will be based on whether or not they meet the requirements of section 110 of the Clean Air Act and EPA regulations in 40 CFR part 51.

Copies of the proposed revisions are available for public inspection during normal business hours at the Offices of EPA, Region III, Curtis Building, Sixth and Walnut Streets, Philadelphia, Pennsylvania 19106; at the Office of the West Virginia Air Pollution Control Commission, 1558 Washington Street, East, Charleston, West Virginia 25311; and at the Freedom of Information Center, EPA, 401 M Street SW, Washington, D.C. 20460. All comments should be addressed to the Director, Air and Hazardous Materials Division, EPA, Region III, Curtis Building, Sixth and Walnut Streets, Philadelphia, Pennsylvania, 19106.

[Docket No. 16976-5]

Table of Assignments; Order Extending the Freedom of Information Center, Charleston, West Virginia 25311; and at the Office of the West Virginia Air Pollution Control Commission, 1558 Washington Street, East, Charleston, West Virginia 25311; and at the Freedom of Information Center, EPA, 401 M Street SW, Washington, D.C. 20460. All comments should be addressed to the Director, Air and Hazardous Materials Division, EPA, Region III, Curtis Building, Sixth and Walnut Streets, Philadelphia, Pennsylvania, 19106.

[Docket No. 20223; RM-2205, 2239, 2350]

FM BROADCAST STATIONS

Table of Assignments; Order Extending Time for Filing Comments and Reply Comments

In the matter of amendment of § 73.605(b), table of assignments, television broadcast stations. (Alliance, Hay Springs, and Scottsbluff, Nebraska).

1. On May 23, 1974, the Commission adopted a Notice of Proposed Rule Making in the above-entitled proceeding. Publication was given in the Federal Register on May 28, 1974, 39 F.R. 19230. The date for filing comments has expired and the present date for filing reply comments is presently December 16, 1974.

2. On October 24, 1974, Counsel for Wyneco Communications, Inc. (Wyneco), licensee of Station KSTF-TV (Wyneco), licensee of Station KSDTV, Scottsbluff, Nebraska, requested authorization to inspect certain Annual Financial Reports for Station KDUH-TV, Hay Springs, its parent Station KOTA-TV, Rapid City, South Dakota, and its sister satellite Station KHSDTV, Lead, South Dakota on the grounds that it was otherwise available and was essential in order that Wyneco can undertake a meaningful evaluation of the contentions in Duhamel's comments with respect to the viability of KDUH-TV in their reply comments. Wyneco's request has not yet been acted on by the Commission. On November 11, 1974, 39 F.R. 40170. The dates for filing comments and reply comments are December 19, 1974, and January 7, 1975, respectively.

3. On December 11, 1974, East Coast Broadcasting Corporation, by its counsel requested that the time for filing comments and reply comments be extended to January 27 and February 14, 1975, respectively. Counsel states that the time for filing comments and reply comments is extended to and including January 27 and February 14, 1975, respectively.

4. This action is taken pursuant to authority found in sections 4(j), 5(d) (1), and 303(r) of the Communications Act of 1934, as amended, and Section 0.281 of the Commission's rules.


Released: December 18, 1974.

[FR Doc.74-30079 Filed 12-23-74; 8:45 am]

TELEVISION BROADCAST STATIONS

Table of Assignments; Order Extending Time for Filing Reply Comments

In the matter of amendment of § 73.605(b), table of assignments, television broadcast stations. (Alliance, Hay Springs, and Scottsbluff, Nebraska).

1. On May 23, 1974, the Commission adopted a Notice of Proposed Rule Making in the above-entitled proceeding. Publication was given in the Federal Register on May 28, 1974, 39 F.R. 19230. The date for filing comments has expired and the present date for filing reply comments is presently December 16, 1974.

2. On October 24, 1974, Counsel for Wyneco Communications, Inc. (Wyneco), licensee of Station KSTF-TV (Wyneco), licensee of Station KSDTV, Scottsbluff, Nebraska, requested authorization to inspect certain Annual Financial Reports for Station KDUH-TV, Hay Springs, its parent Station KOTA-TV, Rapid City, South Dakota, and its sister satellite Station KHSDTV, Lead, South Dakota on the grounds that it was otherwise available and was essential in order that Wyneco can undertake a meaningful evaluation of the contentions in Duhamel's comments with respect to the viability of KDUH-TV in their reply comments. Wyneco's request has not yet been acted on by the Commission. On November 11, 1974, 39 F.R. 40170. The dates for filing comments and reply comments are December 19, 1974, and January 7, 1975, respectively.

3. On December 11, 1974, East Coast Broadcasting Corporation, by its counsel requested that the time for filing comments and reply comments be extended to January 27 and February 14, 1975, respectively. Counsel states that the time for filing comments and reply comments is extended to and including January 27 and February 14, 1975, respectively.

4. This action is taken pursuant to authority found in sections 4(j), 5(d) (1), and 303(r) of the Communications Act of 1934, as amended, and Section 0.281 of the Commission's rules.


Released: December 18, 1974.

[FR Doc.74-30079 Filed 12-23-74; 8:45 am]

RENEGOTIATION BOARD

[ 32 CFR Part 1452 ]

PRIME CONTRACTS AND SUBCONTRACTS

Definition of Subcontracts To Perform Work or Furnish Materials

The Renegotiation Board proposes to amend its regulation interpreting the...
definition of the term "subcontract" contained in section 103(g)(1) of the Renegotiation Act of 1951, 50 U.S.C. App. 1213(g)(1).

Certain prime contracts and "related subcontracts" are made subject to renegotiation by 50 U.S.C. App. 1216, and the regulations promulgated thereunder. The term "subcontract" is defined to include any purchase order or agreement to perform work or furnish materials "required for the performance of" a renegotiable prime contract or subcontract. The present regulation, 32 CFR 1452.4(b), interprets such statutory definition.

Paragraph (b)(1) of the present regulation, 32 CFR 1452.4, describes various transactions within the statutory definition of a subcontract. The proposed amendment of paragraph (b)(1) makes the regulation fully consistent with the scope of the statutory definition of a subcontract. The five illustrations of subcontracts in the present regulation have been retained and a new illustration of a subcontract to perform work or furnish materials for office supplies has been added. The definition of materials used in processing other materials has been eliminated from the proposed regulation because such definition merely explains the illustrations of subcontracts and does not form a necessary part of the definition of such subcontracts.

Paragraph (b)(2) of the present regulation, 32 CFR 1452.4, has been eliminated entirely from the proposed regulation. Paragraph (b)(3) of the present regulation, 32 CFR 1452.4, has been modified to exclude from the definition of a subcontract only purchase orders or agreements for "office supplies." The Board believes that the proposed amendments conform fully with the legislative intent that all arrangements to perform work or furnish materials required for the performance of a renegotiable prime contract or subcontract be subject to renegotiation. Many subcontracts for the sale of items excluded from renegotiation under paragraphs (b)(2) and (3) of the present regulation but not so excluded under the proposed regulation may be eligible for one of the exemptions found in section 106 of the Renegotiation Act of 1951, as amended, 50 U.S.C. App. 1216, and the regulations promulgated thereunder.

The Board proposes to issue the proposed amendments not earlier than February 13, 1975. Interested persons are hereby notified that any changes, to be considered, must be presented in writing, to the Renegotiation Board, 2000 M Street NW, Washington, D.C. 20446, not later than February 7, 1975.

Written material or suggestions submitted will be available for public inspection during regular business hours in the library at the principal office of the Board, 2000 M Street NW, Washington, D.C.


Rex M. Mattingly, Acting Chairman.

PART 1452—PRIME CONTRACTS AND SUBCONTRACTS WITHIN THE SCOPE OF THE ACT

Section 1452.4 Subcontracts to perform work or furnish materials is amended by deleting paragraph (b) in its entirety and inserting in lieu thereof the following:

§ 1452.4 Subcontracts to perform work or furnish materials.

(b) Interpretation of statutory provision.—(1) In general. Except as provided in subsections 103(g) (2) and (3) of the act, the term "subcontract" means any purchase order or agreement to perform all or any part of the work or to make or furnish any materials required for the performance of a renegotiable prime contract or subcontract. For example, without limiting the foregoing, the term "subcontract" includes any purchase order or agreement for any of the following: (i) The sale or processing of an end product which is to be delivered under a renegotiable prime contract or subcontract to perform work or furnish materials required for the performance of a renegotiable prime contract or subcontract to perform work or furnish materials under a renegotiable prime contract or subcontract for work or services; or (ii) the performance of work or services required for the performance of a renegotiable prime contract or subcontract for work or services; or (iii) the performance of work or services required for the performance of a renegotiable prime contract or subcontract included in paragraphs (b)(1), (ii), (iii), (iv), or (v) of this section.

(2) Office supplies. Subcontracts to furnish office supplies are specifically excluded from the statutory definition of a subcontract. Therefore, subcontracts for office supplies, even though such office supplies are ultimately sold to a Department, are not subject to renegotiation. The term "office supplies" includes paper, ink, typewriter ribbons, binders, covers, blotter pads, paper clips, staples, and other items of a consumable character, as well as related items of a relatively short life and minor cost, such as pens, penholders, pencils, blotter pads, and calendars; the term "office supplies" does not include office furniture, machinery and equipment, such as desks, chairs, lamps, rugs, wastebaskets, filing cases, typewriters, and calculating, recording, reproducing, and dictating machines.
DEPARTMENT OF THE TREASURY  
Office of the Secretary  
PRESIDENT'S LABOR MANAGEMENT COMMITTEE  

Continuation of Closed Meeting  
Notice is hereby given that the closed meeting of the President's Labor Management Committee, which took place on February 20, 1974, as to why his Certificate of Registration (DEA Registration No. AR0148406) should not be revoked or suspended.

Dated: December 20, 1974.  
[SEAL]  
WARREN F. BRECHT,  
Assistant Secretary for Administration.

[FR Doc. 74-30112 Filed 12-23-74; 8:45 am]  

DEPARTMENT OF JUSTICE  
Drug Enforcement Administration  
[Docket No. 74-3]  
ALEXANDER ROBBINS, M.D.  
Suspension of Certificate of Registration  

On February 5, 1974, the Drug Enforcement Administration issued an Order to Show Cause to Alexander Robbins, M.D., 1100 Drexel Avenue, Miami Beach, Florida 33139, as to why his Certificate of Registration (DEA Registration No. AR0148406) should not be revoked or suspended for the reason that, on October 26, 1973, in the United States District Court for the Southern District of Florida, he was found guilty of the unlawful dispensing of controlled substances listed in Schedule III, a drug related felony violation of the Controlled Substances Act of 1970.

Thereafter, by letters of February 27, 1974 and March 11, 1974, the respondent requested a hearing in the matter, and on April 5, 1974, a hearing was held before John F. Cook, Administrative Law Judge, in Miami, Florida. Following the hearing, Proposed Findings of Fact and Conclusions of Law were submitted to Judge Cook by counsel for the Government and the Respondent.

On August 30, 1974, Judge Cook filed recommended findings of fact and conclusions of law and his recommended decision with the Drug Enforcement Administration. In his exhaustive opinion, Judge Cook found that the judgment of conviction at the District Court level is final and, therefore, due to the seriousness of the charge underlying Dr. Robbins' conviction, the Administrator, in exercise of his discretion, finds that a suspension of respondent's registration for a period of two years from the date of this opinion is appropriate.

In reaching this conclusion, the Administrator finds that the provisions of section 304 are discretionary in nature upon a finding by the Administrator that the registrant (1) has materially falsified an application for registration, submitted pursuant to the Controlled Substances Act; (2) has been convicted of a felony violation of state or federal law relative to controlled substances; or (3) has had his state license or registration suspended, revoked, or denied by the jurisdiction in which he conducts his registered activity.

Since the Administration Law Judge found that Dr. Robbins has been convicted of a felony violation of federal law relative to controlled substances, specifically 21 U.S.C. section 844(a)(1), the only other issue during this administrative proceeding was: whether (assuming that the Respondent has been convicted of a felony) should the Attorney General suspend or revoke his registration.

In his evaluation of the evidence, the Administrative Law Judge found that the evidence did not "show behavior which would warrant the extreme step of revocation of registration." Also, the Administrative Law Judge noted a lack of evidence of any other criminal violations by respondent, and no "other evidence that respondent is totally unfit to be registered.

Accordingly, the Administrative Law Judge chose to recommend suspension of respondent's registration for a period of nine months. The Administrator finds that, in reference to this particular respondent, and only in light of the nature of the facts and circumstances in this particular case, that suspension is the appropriate sanction to be applied.


Therefore, in accordance with the provisions of § 1316.66, Title 21, Code of Federal Regulations, and in view of the foregoing, it is the Administrator's opinion that Alexander Robbins, M.D. was convicted of a felony violation of the Controlled Substances Act, to wit, the unlawful dispensing of controlled substances.

Therefore, under the authority vested in the Attorney General by section 304 of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 824), and redelegated to the Administrator of the Drug Enforcement Administration, by the Administrator, Title 28, Code of Federal Regulations, the Administrator hereby orders that the Certificate of Registration of Alexander Robbins, M.D. (DEA Registration No. AR0148406), be, and hereby is suspended.
for a period of two years from the date of this order.

Dated: December 18, 1974.

JOHN R. BARTELS, Jr.,
Administrator.

IMPORTER OF CONTROLLED SUBSTANCE
Notice of Application

By Notice dated October 21, 1974, and published in the Federal Register on October 25, 1974; (39 FR 38005) Cord
in accordance with 21 CFR 1311.42, the
been received, and pursuant to section
303 of the Comprehensive Drug Abuse
Prevention and Control Act of 1970, and
303 of the Comprehensive Drug Abuse

Dated: December 18, 1974.

JOHN R. BARTELS, Jr.,
Administrator.

IMPORTATION OF CONTROLLED SUBSTANCES
Notice of Application

Pursuant to section 1008 of the Controlled Substance Import and Export Act (21 U.S.C. 958(h)), the Attorney General shall, prior to issuing a registration under this section to a bulk manufacturer or II, and prior to issuing a regulation of a controlled substance in schedules I or II, and prior to issuing a registration as an Importer of Amobarbital.

Dated: December 18, 1974.

JOHN R. BARTELS, Jr.,
Administrator.

CHESAPEAKE AND OHIO CANAL NATIONAL HISTORICAL PARK COMMISSION
Notice of Meeting

On September 16, 1974, a notice was
published in the Federal Register on September 20, 1974; (39 FR 35188-9) Fliter Corporation Ltd, Carretera 132, Km 28.3, P.O. Box 4108, Ponce, Puerto Rico 00731, made application to the Drug Enforcement Administration to be registered as Importers of Amobarbital, a basic class controlled substance listed in schedule II.

Dated: December 18, 1974.

JOHN R. BARTELS, Jr.,
Administrator.

DEPARTMENT OF THE INTERIOR
Fish and Wildlife Service

AnceL Johnson
Issuance of Permit Marine Mammals

On September 16, 1974, a notice was published in the Federal Register (39 FR 32346-47) that an application had been filed with the Fish and Wildlife Service by Ancel Johnson, Marine Mammal Substation, Naval Support Activity, Seattle, Washington, for a permit to engage in sea otter research.

Notice is hereby given that on December 13, 1974, as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407), the Fish and Wildlife Service issued a permit to Ancel Johnson, subject to certain conditions set forth therein. The permit is available for public inspection during normal business hours at the Fish and Wildlife Service's office in Suite 600, 1612 K Street NW, Washington, D.C.


C. R. BAYLEN,
Chief, Division of Law Enforce­
ment, Fish and Wildlife Serv.

National Park Service

Dated: December 18, 1974.
NOTICES

DEPARTMENT OF AGRICULTURE
Forest Service
TIMBER MANAGEMENT PLAN REVISIONS FOR THE ARAPAHO NATIONAL FOREST
Draft Environmental Statement, Notice of Availability

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969, the Forest Service, Department of Agriculture, has prepared a draft environmental statement for the Timber Management Plan Revisions for the Arapaho National Forest. The Forest Service report number is USDA-FS-R2-DES (Adm) FY-75-04.

The environmental statement concerns a proposal to revise the Timber Management Plan for the Arapaho National Forest and to apply timber management activities at a level compatible with other resources and uses that could be affected by timber harvest.

This draft environmental statement was transmitted to CEQ on December 18, 1974.

Copies are available for inspection during regular working hours at the following locations:

USDA, Forest Service, Bo. Agriculture Bldg., Room 3230, 12th St. and Independence Ave. SW., Washington, D.C. 20250.

USDA, Forest Service, 11177 West 8th Avenue, P.O. Box 25127, Denver, Colorado 80225.


A limited number of single copies are available upon request to W. J. Lucas, Regional Forester, USDA Forest Service, 11177 West 8th Avenue, P.O. Box 25127, Denver, Colorado 80225.

Copies of the environmental statement have been sent to various Federal, State, and local agencies as outlined in the CEQ Guidelines.

Comments are invited from the public, and from State and local agencies which are authorized to develop and enforce environmental standards, and from Federal agencies having jurisdiction by law or special expertise with respect to any environmental impact involved for which comments have not been requested specifically.

Comments concerning the proposed action and requests for additional information should be addressed to W. J. Lucas, Regional Forester, USDA Forest Service, 11177 West 8th Avenue, P.O. Box 25127, Denver, Colorado 80225. Comments must be received by February 16, 1975, in order to be considered in the preparation of the final environmental statement.

CLAYTON B. PIERCE, Director, Multiple Use and Environmental Quality Coordination.


FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
NOTICES

December 24, 1974.

DEPARTMENT OF COMMERCE
Domestic and International Business Administration

NEW YORK UNIVERSITY MEDICAL CENTER, ET AL.

Notice of 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(e) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Public Law 99-651; 89 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, Special Import Programs Division, Office of Import Programs, Washington, D.C. 20230, within 20 calendar days after the date on which this notice of application is published in the Federal Register.

Amended regulations issued under cited Act, as published in the February 24, 1972 issue of the Federal Register, prescribe the requirements applicable to comments.

A copy of each application is on file and may be examined during ordinary Commerce Department business hours at the Special Import Programs Division, Department of Commerce, Washington, D.C. 20230.

Docket Number: 75-00214-01-11000.

Applicant: University of Wisconsin, Purchasing Agent, Madison, Wisconsin 53706. Article: EMI Acoustic Scanner System. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used for the diagnosis and treatment of various congenital brain disorders through computerized transaxial tomographs. The article will also be used to train diagnostic radiology physicians. Application received by Commissioner of Customs: November 19, 1974.

Docket Number: 75-00213-65-46070.

Applicant: Yale University, Purchasing Department, New Haven, Connecticut 06511. Article: JEOL Ltd., Japan. Intended use of article: The article is intended to be used to carry out sophisticated and detailed studies of metallic, nonmetallic, and biological materials. Specific projects will include:

1. Fracture behavior of metallic strength alloys.
2. Surface integrity studies of high strength alloys.
4. Friction and wear behavior of cast irons.
6. Effect of topography and heterogeneity on wetting of solids by liquids.
7. Calculated tissue research.
8. Fracture behavior of metallic strength alloys.

The article will also be used for educational purposes in graduate and undergraduate level courses, including non-technical people in health services.

Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00213-01-11000.

Applicant: New York University, Purchasing Department, 400 East 72nd Street, New York, N.Y. 10021. Article: Scanning Electron Microscope, Model JSM-U-3. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used for the investigation of cerebral diseases such as tumors, cysts and hemorrhages which are otherwise undiagnosable. Application received by Commissioner of Customs: November 19, 1974.
Applicant: University of California at San Diego, California 90024. Article: Ultramicrotome, Model LKB 8800A. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used for studies of biological tissues and products as a result of experimental programs designed to investigate disease processes in man and animals. The experiments to be conducted include both normal and abnormal development of synapses in the young developing nervous system. Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00219-33-46500.

Applicant: Yale University, Purchasing Dept., 20 Ashmun Street, New Haven, Conn. Article: Ultramicrotome, Model LKB 8800A. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used for studies of biological tissues and products as a result of experimental programs designed to investigate disease processes in man and animals. The experiments to be conducted include both normal and abnormal development of synapses in the young developing nervous system. Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00220-33-46500.

Applicant: County of Los Angeles, John Wesley Hospital, 2825 S. Hope Street, Los Angeles, California 90067. Article: Ultramicrotome, Model LKB 8800A. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used for section materials for high resolution electron and light microscope examination of kidney tubules, testis, and kidney tubules and urinary bladders of several species of amphibians and several species of fish. Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00230-33-46500.

Applicant: University of Iowa, Purchasing Department, Jefferson Building, Iowa City, Iowa 52242. Article: Electron Microscope, Model JEM 100C with Side Entry Goniometer & Scanning Device. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used primarily for studies of materials involved in electron microscopic studies of biological platelets, platelet aggregates, and other tissue of varying density. Aggregates will vary in size and compactness from one specimen to another. Other samples to be examined include formed elements of several types ( spleen, lung, alimentary system, skin), with thiorbi or with areas of necrosis and/or inflammation or neoplasm. Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00216-33-46040.

Applicant: Delaware Valley Neurosurgical Association—Episcopal Hospital, C-111 Episcopal Hospital, Front Street and Lehigh Avenue, Philadelphia, Pa. 19125. Article: Electron Microscope System. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article will be used to study the brain by computerized transaxial tomography (CTT). Examples of planned projects are: the study of traumatic and/or spontaneous intracranial hemorrhage, management of cerebral edema, the effect of immunotherapy on the growth of brain tumors, dementia, ischamia, and senile versus CTT and ultrasound versus CTT. The article will also be used to train neurologists, neurosurgeons and radiologists resident, medical students and physicians in the use of CTT. Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00227-33-90000.

Applicant: University of Michigan, 1405 East Ann Street, Ann Arbor, Michigan 48104. Article: EM Scanner System with Magnetic Tape Storage System. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used for scanner evaluation of patients with signs or symptoms of intracranial disease to define more precisely the modern aspects of neuroradiology. The use of the microscope in combination with the computer and the scanner will allow a more effective use of the microscope in combination with the modern aspects of neuroradiology.

Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00234-33-46040.

Applicant: Philadelphia College of Osteopathic Medicine, 300 North 22nd Street, Philadelphia, Pa. 19131. Article: Electron Microscope, Model JEM 100C. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used for research in the following areas:

(1) Study of the female reproductive tract in the fertilization process and sperm physiology, an investigation concerning the effect of the oviductal constituents of various hormones on the capacitation of spermatozoa.

(2) The structural organization of skeletal and cardiac muscle in normal and pathological material from man and animals.

(3) Experiments in the important area of genetic activity and genetic replication that occur in normal and neoplastic tissues.
use in the course Botany 725B, "Electron Microscopy." Students will be taught (1) basic procedures for preparing plant material for examination by transmission electron microscope, and (4) photo-electron optics and related alignment procedures for standard transmission electron microscopy, (3) examination and evaluation of specimen image in the electron microscope, and (4) photographic recording and duplication. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00229-33-46500. Applicant: Veterans Administration Hospital, Laboratory Service, 1400 V.F.W. Parkway, West Roxbury, Mass. 02132. Article: Ultramicrotome, Model LKB 8300, Matreca, use of the electron microscope to determine whether contractile proteins are found in the fetal palate and whether these proteins are responsible for palatal shelf elevation during development. Application received by Commissioner of Customs: November 22, 1974.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Equipment: The article is intended to be used in an investigation carried out both on humans and on animals in the attempt to learn more about the density of tissues, to evaluate the density of tissues as they refer to the various types of pathology effecting the tissue involved, in this case the brain of a patient, and to attempt to correlate the findings with known diagnostic studies previously used and subsequently found operative information. The article will be used to screen large numbers of patients, the mentally retarded, atrophic degenerative disease of the conventional carotid angiography and pneumoencephalography. This poses in lecture courses within the hospital and within the medical school complex in demonstrating its usefulness and in obtaining the information and instructing others in its efficiency and diagnostic facilities. Application received by Commissioner of Customs: October 19, 1974. Advice submitted by the Department of Health, Education, and Welfare: on: November 21, 1974.

Docket Number: 75-00230-33-46904. Applicant: The Pennsylvania State University, College of Medicine, Department of Microbiology, 500 University Drive, Hershey, Pa. 17033. Article: Electron Microscope, Model EM 201, Philips, use of the electron microscope for examination of normal and diseased tissues, in order to achieve more accurate diagnoses of diseases. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00058-33-90000. Applicant: University of California, Los Angeles, Center for the Health Sciences, Los Angeles, California 90024. Article: EMI Scanner and Magnetic Tape System. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used and subsequently found operative information. The article will be used to screen large numbers of patients, the mentally retarded, atrophic degenerative disease of the conventional carotid angiography and pneumoencephalography. This poses in lecture courses within the hospital and within the medical school complex in demonstrating its usefulness and in obtaining the information and instructing others in its efficiency and diagnostic facilities. Application received by Commissioner of Customs: August 16, 1974. Advice submitted by the Department of Health, Education, and Welfare: on: November 21, 1974.

Docket Number: 75-00021-75-69459. Applicant: University of California, Los Alamos Scientific Laboratory, P.O. Box 980, Los Alamos, New Mexico 87544. Article: Pump: Electric Drive, Manufacturer: Philpot Electronic Instruments, N.V., The Netherlands. Intended use of article: the ultrastructural approach in some phase of their research. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00232-33-46500. Applicant: Children's Hospital Research Foundation, Elland and Bethesda Avenues, Cincinnati, Ohio 45229. Article: Ultramicrotome, Model OM U3, Manufacturer: C. Reichert Optische Werke, Austria. Intended use of article: The article is intended to be used to cut sections of mouse palate one-millionth of an inch thin. The section is then to be viewed and photographed with an electron microscope to determine whether contractile proteins are found in the fetal palate and whether these proteins are responsible for palatal shelf elevation during development. Application received by Commissioner of Customs: August 16, 1974. Advice submitted by the Department of Health, Education, and Welfare: on: November 5, 1974.

Docket Number: 75-00079-33-90000. Applicant: Allegheny General Hospital, 330 East North Avenue, Pittsburgh, Pa. 15212. ARTICLE: EMI Scanner and Magnetic Tape System. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used and subsequently found operative information. The article will be used to screen large numbers of patients, the mentally retarded, atrophic degenerative disease of the conventional carotid angiography and pneumoencephalography. This poses in lecture courses within the hospital and within the medical school complex in demonstrating its usefulness and in obtaining the information and instructing others in its efficiency and diagnostic facilities. Application received by Commissioner of Customs: October 19, 1974. Advice submitted by the Department of Health, Education, and Welfare: on: November 21, 1974.

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The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to any of the foreign instruments to which the following applications relate, for such purposes as these articles are intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

RICHARD M. SEPPA, Acting Director, Special Import Programs Division.

MOREHOUSE COLLEGE

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 907) and the regulations issued thereunder as amended (37 FR 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Decision:MOREHOUSE COLLEGE, 223 Chestnut Street SW., Atlanta, Ga. 30314. Article: Electron Microscope, Model EM 95-2. Manufacturer: Carl Zeiss, West Germany. Intended use of article: The article is intended to be used for study of the unsolved problem of the linearity of all axial structures during the regeneration of the tadpole tail and the notochord is especially puzzling in this regard. The article will also be used in the course Biology 487, 488. Techniques in Electron Microscopy to develop more flexible use of the electron microscope by a large number of students.

Comments: No comments have been received with respect to this application. A letter was received from Adam David Company dated December 30, 1973, and is being treated as an offer to supply additional information under Section 701.9 of the regulations.

Decision: Application denied. An instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

In reply to Question 8 the applicant alleges the foreign article provides the following pertinent characteristics which are not possessed by the most closely comparable domestic instrument or apparatus, which the applicant assumes to be the EMU-4C, supplied by the Adam David Company:

1. The design concept of the EM 95-2 differs considerably from the domestically manufactured instrument. The EMU-4C was designed as an extremely versatile instrument for high resolution work with biological and non-biological applications. A much greater number of controls, push buttons and read-out meters were built into this microscope, thus requiring a much higher degree of sophistication in its operation. By comparison, the EMU-4C was designed for biological applications, overall ease of foolproof operation and safer performance for students with little, or even without, previous experience;

2. Extra low magnifications, down to 30x, without change of pole piece. By switch action alone an entire grid can be imaged and focused at 140X without distortion;

3. A semi-automatic "beam finder" enabling rapid beam location even when the condenser aperture and the gun are completely disaligned;

4. All apertures can be removed for cleaning purposes without disassembling or removing parts of the microscope column;

5. Thin metal film objective apertures (three per objective on each).

6. It is possible to obtain stereo tilt, plus or minus 6°, by using the normal specimen holder, thus obviating the necessity of a tilting stage;

7. Phosphomages for 60 and 75 sheet films or glass plates 7 cm. x 7 cm. are available, permitting the uninterrupted taking of micrographs over prolonged periods of time;

8. A fully automatic photographic system. The operation of a single lever activates a spot-reading timing system; there is five-digital sequential numbering of negatives; negatives are transported automatically with double exposure excluded; provision for manual override is included and an "empty magazine" indicator is present;

9. Ultrarapid negative extraction system in which the specimen holder and the handling rod are one unit. Thus, accidental separation and loss of the specimen holder during transfer operation is impossible;

10. The 10x binocular viewing microscope has high-eyepoint eyepieces;

11. Automatic vacuum system with safeguards against water and electrical power failure;

12. Low number of controls at the column and console of the EM 95-2;

13. Highly stable column alignment. The Department of Health, Education, and Welfare (HEW) advises in its memorandum dated October 24, 1974 that the description of research and teaching does not establish a pertinent specification within the meaning of subsection 701.2(n), for the article that upholds duty-free entry. HEW advises that the work intended by the applicant requires an instrument with high resolution capability, such as the EMU-4C, which, according to HEW, possesses the technical capabilities necessary to carry it out. With respect to the specific capabilities listed by the applicant in reply to Question 8 of the application, HEW advises as follows: a. Items (1) and (2) are not pertinent specifications for the purposes intended within the meaning of subsection 701.2(n) of the regulations; b. Items (3), (4), (5), (12) and (13) are convenient which are not necessary for accomplishing the applicant's purposes, and, therefore, are not pertinent specifications within the meaning of subsection 701.2(n) of the regulations; and c. Items (6) (7) (8) (9) and (11) are matched by similar features provided by the EMU-4C.

For these reasons, we find that the Model EMU-4C is of equivalent scientific value to the foreign article for such purposes as this article is intended to be used.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

RICHARD M. SEPPA, Acting Director, Special Import Programs Division.

NATIONAL ACCELERATOR LABORATORY

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to Section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 907) and the regulations issued thereunder as amended (37 FR 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.


Article: 11.105, Importation of Duty-Free Educational and Scientific Materials) applicant for proposal for fabricating the foreign article to 200 Bev energy. A much greater number of scientific exploratory experiments with protons accelerated by the article to 200 Bev energy.

Comments: No comments have been received with respect to this application. Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

In reply to Question 8 the applicant alleges the foreign article provides the following pertinent characteristics which are not possessed by the most closely comparable domestic instrument or apparatus, which the applicant assumes to be the EMU-4C, supplied by the Adam David Company:

1. The design concept of the EM 95-2 differs considerably from the domestically manufactured instrument. The EMU-4C was designed as an extremely versatile instrument for high resolution work with biological and non-biological applications. A much greater number of controls, push buttons and read-out meters were built into this microscope, thus requiring a much higher degree of sophistication in its operation. By comparison, the EMU-4C was designed for biological applications, overall ease of foolproof operation and safer performance for students with little, or even without, previous experience;

2. Extra low magnifications, down to 30x, without change of pole piece. By switch action alone an entire grid can be imaged and focused at 140X without distortion;

3. A semi-automatic "beam finder" enabling rapid beam location even when the condenser aperture and the gun are completely disaligned;

4. All apertures can be removed for cleaning purposes without disassembling or removing parts of the microscope column;

5. Thin metal film objective apertures (three per objective on each).

6. It is possible to obtain stereo tilt, plus or minus 6°, by using the normal specimen holder, thus obviating the necessity of a tilting stage;

7. Phosphomages for 60 and 75 sheet films or glass plates 7 cm. x 7 cm. are available, permitting the uninterrupted taking of micrographs over prolonged periods of time;

8. A fully automatic photographic system. The operation of a single lever activates a spot-reading timing system; there is five-digital sequential numbering of negatives; negatives are transported automatically with double exposure excluded; provision for manual override is included and an "empty magazine" indicator is present;

9. Ultrarapid negative extraction system in which the specimen holder and the handling rod are one unit. Thus, accidental separation and loss of the specimen holder during transfer operation is impossible;

10. The 10x binocular viewing microscope has high-eyepoint eyepieces;

11. Automatic vacuum system with safeguards against water and electrical power failure;

12. Low number of controls at the column and console of the EM 95-2;

13. Highly stable column alignment. The Department of Health, Education, and Welfare (HEW) advises in its memorandum dated October 24, 1974 that the description of research and teaching does not establish a pertinent specification within the meaning of subsection 701.2(n), for the article that upholds duty-free entry. HEW advises that the work intended by the applicant requires an instrument with high resolution capability, such as the EMU-4C, which, according to HEW, possesses the technical capabilities necessary to carry it out. With respect to the specific capabilities listed by the applicant in reply to Question 8 of the application, HEW advises as follows: a. Items (1) and (2) are not pertinent specifications for the purposes intended within the meaning of subsection 701.2(n) of the regulations; b. Items (3), (4), (5), (12) and (13) are convenient which are not necessary for accomplishing the applicant's purposes, and, therefore, are not pertinent specifications within the meaning of subsection 701.2(n) of the regulations; and c. Items (6) (7) (8) (9) and (11) are matched by similar features provided by the EMU-4C.

For these reasons, we find that the Model EMU-4C is of equivalent scientific value to the foreign article for such purposes as this article is intended to be used.
advised that it knows of no additional domestic manufacturers of magnets considered comparable to the foreign article. In response to Question 8(b) of the present submission, the applicant claims inter alia that delivery of the article by July 1, 1971 is necessary for the accomplishment of the research purposes and that the domestic manufacturers who were willing and able to produce the article (those which offered proposals, i.e., National Electric Coil, Westinghouse Electric Corporation and Airco Temescal) could not meet the specified delivery date because of prior contractual obligations with the applicant which absorbed their current production capacity. In this connection, it is noted that § 701.11(c) of the Department's regulations specifies that duty-free entry of the article shall be considered justified, without regard to whether there is being manufactured in the United States an instrument, apparatus, or accessory of equivalent scientific value for the purposes intended, if the delay in obtaining such domestic article will seriously impair the accomplishment of the applicant's intended purposes.

NBS evaluated the present application and advised in its memorandum dated February 19, 1974, that delivery by July 1, 1971 is pertinent to the commencement of useful operation of the accelerator at the scheduled time and hence to the applicant's research purposes. NBS further advised that the applicant has supplied evidence that the domestic manufacturers who were willing and able to produce the article had their capacity absorbed with current contracts and, therefore, were not able to meet the pertinent delivery date.

Accordingly, we find that the delivery times for domestic instruments of equivalent scientific value to the article for the purposes described in response to Question 7 of the application were excessively within the meaning of § 701.11(c).

(Catalog of Federal Domestic Assistance Program No. 11.106, Importation of Duty-Free Educational and Scientific Materials)

RICHARD M. SEPPA
Acting Director, Special Import Programs Division.

FR Doc.74-5966 Filed 12-3-74; 8:45 am

UNIVERSITY OF MINNESOTA MEDICAL SCHOOL

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket Number: 75-00061-33-46500.

Applicant: University of Minnesota Medical School, 2630 University Avenue South, Minneapolis, Minnesota 55414.

Article: LKB Ultratome III Ultramicrotome 88001-NM with Microscope Holder.

Manufacturer: LKB Produkter AB, Sweden.

Intended use of Article: The article will be used in the execution of research activities involving the determination of the normal structure of nerve endings in human muscle spindles compared to similar endings in muscle spindles from cat, rat, and other mammals, and in the study of the responses of muscle spindles to physiological stimulation and to a variety of pharmaceutical agents to which they will be exposed.

Comments: No comments have been received with respect to this application.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.106, Importation of Duty-Free Educational and Scientific Materials)

RICHARD M. SEPPA,
Acting Director, Special Import Programs Division.

FR Doc.74-29965 Filed 12-23-74; 8:45 am

BEAUMONT HOSPITAL

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scientific article intended to be used in educational, scientific, and cultural materials. The article is intended to be used in studies of muscle spindles compared to similar endings in the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq.).

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C.

Docket number: 74-00197-33-46040.

Applicant: William Beaumont Hospital, 3601 W. 13 Mile Road, Royal Oak, Michigan 48072.


Intended use of article: The article is intended to be used to study the ultrastructure of glolemar and cellular abnormalities in the kidney, both as a means of identifying the disease process and as a method of conducting research.

Suffers from infections and is the criteria of design of an instrument.

The article is intended to be used in studies of muscle spindles compared to similar endings in the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations issued thereunder as amended (37 FR 3892 et seq.).

The Department of Commerce knows of no other instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as this article is intended to be used, which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.106, Importation of Duty-Free Educational and Scientific Materials)

RICHARD M. SEPPA,
Acting Director, Special Import Programs Division.

FR Doc.74-5966 Filed 12-3-74; 8:45 am

FEDERAL REGISTER, VOL 39, NO. 248—TUESDAY, DECEMBER 24, 1974

NOTICES

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tended purposes and that are not possessed by the most closely comparable domestic instrument or apparatus:

1. A microscope, simple in operation, that will be liked by many people, some of them in training;
2. A range of magnification from very low to medium high, while not disturbing the specimen or losing the field of vision;
3. Adequate resolution at higher magnification for differential of small particles and cellular organelles;
4. Inclusion of a low 70 mm camera for large numbers of spatially oriented, sequential pictures in quantitative studies;
5. Ready availability of contracted manufacturer's service and maintenance; and

At the time the article was ordered, two domestically manufactured electron microscopes were available. The Model ETEM 101 (a relatively simple low resolution instrument designed for use by beginners with a minimum of supervision), manufactured by Elektros Incorporated, and the Model EMU-4C, supplied by Adam David Company, HEW advise in its memorandum dated August 7, 1974, that "The most nearly comparable domestic instrument for the work described is the EMU-4C. This instrument has equivalent guaranteed resolution and magnification range without pole piece change (Characteristics 3 and 2, above, respectively). It also provides a selection in cameras or condensers (Characteristics 4 and 6, respectively). Projected service needs (characteristic 5) and other conveniences cited (such as simplicity in operation characteristic 6) are not relevant." Accordingly, HEW recommends that this application be denied since the intended purposes do not establish a pertinent specification of the article, within the meaning of § 701.2(n) of the regulations that justifies duty-free entry.

Therefore, we find that the Model EMU-4C is of equivalent scientific value to the foreign article for such purposes as the intended purposes of the application form. If the delay in obtaining such domestic instrument, apparatus, or accessories (as indicated by the difference between the delivery times of the domestic manufacturer and foreign manufacturer) will seriously impair the accomplishment of the purposes, in determining whether the difference in delivery times is excessive, the Deputy Assistant Secretary shall take into account the relevancy of the applicant's program to other research programs with respect to timing, the applicant's need to have such instrument, apparatus, or accessory available at the scheduled time for the course(s) in which the article is intended to be used, and other relevant circumstances.

The foreign article was ordered December 7, 1973, with a quoted delivery time of six months. The delivery time of the Varian Radiation Division Clinac 35 was 700 days (approximately 23 months). We are advised by the Department of Health, Education, and Welfare (HEW) in its memorandum dated November 10, 1974, that the delivery time for the Clinac 35 is excessive. The Department notes the applicant's intended research and educational programs would be delayed with use of the foreign article.

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 74-00543-35-00530.

Applicant: The Trustees of Indiana University, Bloomington, Indiana 47401. Article: Sagittare 40—MSV Linear Accelerator, manufactured by Tomcat, Cergy, France. Intended use of article: The article is intended to be used in both an electron as well as a photon mode for the treatment of cancer. The article will also be used in combination which will include the effects of high dose rates on in vitro cell survival and also the effects of various energy relations on cell survivals. Physics research projects will be carried out with the instrument.

The following is a decision on an application for duty-free entry of a scientific article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations that justifies duty-free entry of residents in the use of accelerators.

Comments: Comments dated August 7, 1974, were received from Varian Associated Industries (VAI). VAI states that the Varian Radiation Division Clinac 35 radiotherapy linear accelerator with accessories is equivalent in all clinical respects, except maximum electron energy, to the foreign article.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as the article is intended to be used, could have been made available to the applicant without excessive delay within the meaning of § 701.11(c) of the regulations. Reasons: Excessive delivery time is described in § 701.11(c) of the regulations as follows:

Excessive delivery time. Duty-free entry of the article shall be considered justified without regard to whether there is being manufactured in the United States an instrument, apparatus, or accessory of equivalent scientific value for the purposes described in the application form, if the delay in obtaining such domestic instrument, apparatus, or accessory (as indicated by the difference between the delivery times of the domestic manufacturer and foreign manufacturer) will seriously impair the accomplishment of the purposes. In determining whether the difference in delivery times is excessive, the Deputy Assistant Secretary shall take into account the relevancy of the applicant's program to other research programs with respect to timing, the applicant's need to have such instrument, apparatus, or accessory available at the scheduled time for the course(s) in which the article is intended to be used, and other relevant circumstances.

The foreign article was ordered December 7, 1973, with a quoted delivery time of six months. The delivery time of the Varian Model Clinac 35 was 700 days (approximately 23 months). We are advised by the Department of Health, Education, and Welfare (HEW) in its memorandum dated November 10, 1974, that the delivery time for the Clinac 35 is excessive. The Department notes the applicant's intended research and educational programs would be delayed with use of the foreign article.

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.

Docket number: 75-00057-55-17500.

Applicant: University of Washington, Department of Oceanography WB-10 Seattle, Washington 98195. Article: Two Recording Current Meters, Model #4. Manufacturer: Ivar Aanderas, Norway. Intended use of article: The article is intended to be used in experiments involving continuous detailed monitoring of currents and thermal structure of the Arctic Ocean in pursuit of the following objectives:

(a) Definition of special velocity components (diurnal, fortnightly bands, etc.) and differentiation of these from inertial events.
(b) Determination of seasonal and long-term variability of velocity and thermal fields in the region.
(c) Assessment of the role of planetary waves.

UNIVERSITY OF WASHINGTON

Decision on Application for Duty-Free Entry of Scientific Article

The following is a decision on an application for duty-free entry of a scient-

fication article pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89-651, 80 Stat. 897) and the regulations that justifies duty-free entry of residents in the use of accelerators.

Comments: Comments dated August 7, 1974, were received from Varian Associated Industries (VAI). VAI states that the Varian Radiation Division Clinac 35 radiotherapy linear accelerator with accessories is equivalent in all clinical respects, except maximum electron energy, to the foreign article.

Decision: Application approved. No instrument or apparatus of equivalent scientific value to the foreign article, for such purposes as the article is intended to be used, could have been made available to the applicant without excessive delay within the meaning of § 701.11(c) of the regulations. Reasons: Excessive delivery time is described in § 701.11(c) of the regulations as follows:

Excessive delivery time. Duty-free entry of the article shall be considered justified without regard to whether there is being manufactured in the United States an instrument, apparatus, or accessory of equivalent scientific value for the purposes described in the application form, if the delay in obtaining such domestic instrument, apparatus, or accessory (as indicated by the difference between the delivery times of the domestic manufacturer and foreign manufacturer) will seriously impair the accomplishment of the purposes. In determining whether the difference in delivery times is excessive, the Deputy Assistant Secretary shall take into account the relevancy of the applicant's program to other research programs with respect to timing, the applicant's need to have such instrument, apparatus, or accessory available at the scheduled time for the course(s) in which the article is intended to be used, and other relevant circumstances.

The foreign article was ordered December 7, 1973, with a quoted delivery time of six months. The delivery time of the Varian Model Clinac 35 was 700 days (approximately 23 months). We are advised by the Department of Health, Education, and Welfare (HEW) in its memorandum dated November 10, 1974, that the delivery time for the Clinac 35 is excessive. The Department notes the applicant's intended research and educational programs would be delayed with use of the foreign article.

A copy of the record pertaining to this decision is available for public review during ordinary business hours of the Department of Commerce, at the Office of Import Programs, Department of Commerce, Washington, D.C. 20230.
to the applicant's purposes within the
meaning of § 701.2(n) of the
regulations. The most closely comparable domestic
instrument is the Model VACM vector
averaging current meter manufactured by
AMP Sea-Link Systems. The VACM
provides measurement of current speed,
current direction, and water temperature
(−2 to 30° C) with internal data rec-
cording. It utilizes the vector averaging
technique which continuously samples
current velocity every 1/26 rotor turn mini-
malizing the possibility of data aliasing. In
addition, it has a 11.3 x 106 bit data
storage capacity which is equivalent to
or better than that of the article and,
which permits sampling frequency of the
same order and duration required of the
article. NOAA further advises that the
VACM satisfies all the specifications of
the article found pertinent.

For these reasons, we find that the
domestically-manufactured VACM is of
equivalent scientific value to the foreign
article for such purposes as the article is
intended to be used.

(Catalog of Federal Domestic Assistance Pro-
gram No. 11.106, Importation of Duty-Free
Educational and Scientific Materials.)

RICHARD M. SEPPA,
Acting Director,
Special Import Programs Division.

[FR Doc. 74-29969 Filed 12-23-74; 8:45 am]

YALE UNIVERSITY, ET AL.

Consolidated Decision on Application for
Duty-Free Entry of Scientific Articles;
Correction

In the notice of consolidated decision
on applications for duty-free entry of
scientific articles appearing at page
42884 in the Federal Register of Mon-
day, December 8, 1974, the following
docket should be deleted:

Docket number: 74-00437-00-42600.
Applicant: National Aeronautics and
Space Administration, Langley Research
Center (MS 161), Hampton, Virginia
23665. Article: Alpha-numerical Display
Device Made from a Two-Color-Mono-
lithic Array of Light-Emitting Diodes.
Manufacturer: Bowmar Canada Lim-
ited, Mirabel, Canada. Date of denial with
prejudice to resubmission: July 2, 1974.

(Catalog of Federal Domestic Assistance Pro-
gram No. 11.106, Importation of Duty-Free
Educational and Scientific Materials.)

RICHARD M. SEPPA,
Acting Director,
Special Import Programs Division.

[FR Doc. 74-29967 Filed 12-20-74; 8:45 am]

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE

Food and Drug Administration

SACCHARIN AND ITS SALTS

Beverage and Other Food Manufacturers

The Food and Drug Administration
has learned of a seizure made by the
State of New York of nondiet beverages
that contain a mixture of sugar and sac-
charin as sweetening agents. The Food
and Drug Administration has also re-
eived information, as yet unconfirmed,
that other food manufacturers may be
using mixtures of saccharin and nutri-
tive sweeteners in food formulations
which are not labeled as special dietary
foods offered for calorie control.

The use of saccharin or admixtures of
saccharin as a sweetening agent in such
products is illegal. Saccharin and its salts
are food additives within the meaning of
sections 201(a), 409(a)(2)(C) and 409 of
the Federal Food, Drug, and Cosmetic
Act (21 U.S.C. 321(a), 342(a)(2)(C), 346)
and may not be used in food except
under the conditions of use set forth in
21 CFR 121.4001, which restricts use
to valid special dietary foods (i.e., foods
specifically offered for calorie control)
and to certain limited technological uses
other than calorie reduction, as specified
in that regulation. Combinations of nu-
tritive sweeteners and saccharin or its
salts in "diet beverages" or diet beverage
bases are also subject to additional re-
Both regulations set forth restrictions
upon use and require special labeling to
distinguish the valid special dietary food
products from other foods. Furthermore,
all special dietary foods are subject to
applicable labeling requirements of 21
CFR Part 129.

The purpose of this notice is to em-
phasize the existence of the above-refer-
ced regulations and to inform all bev-
erage and other food manufacturers that
the Commissioner of Food and Drugs is
notifying the public, all Food and Drug
Administration field units, and all State
food and drug officials to be alert to this
type of adulteration. Illegal use of sac-
charin or its salts subjects the products
involved, the responsible companies
and individuals to potential regulatory
action, including seizure, injunction, and
criminal prosecution.

Dated: December 18, 1974.

WILLIAM P. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 74-29926 Filed 12-23-74; 8:46 am]

ADVISORY COMMITTEES

Notice of Renewal

Pursuant to the Federal Advisory
Committee Act of October 6, 1972 (Pub.
App.), the Food and Drug Administra-
tion announces the establishment by the
Secretary, Department of Health, Educa-
tion, and Welfare, on November 15,
1974, of the following advisory commit-
tees:

Designation. National Advisory Food
and Drug Committee.

Purpose. The committee will review
and evaluate agency programs and pro-
vide advice and guidance to the Secre-
tary, Assistant Secretary for Health, and
the Commissioner of Food and Drugs on
policy matters of national significance
as they relate to FDA’s statutory mis-
sion in the following areas: Food, drugs,
cosmetics, medical devices, biological
products, and electronic products.

Authority for this committee will ex-
pire November 15, 1976, unless the Secre-
tary formally determines that continu-
ance is in the public interest.

Concurrent with this action, the Secre-
tary abolished the National Advi-
sory Food and Drug Committee, and the
National Advisory Veterinary Medicine
Committee.


WILLIAM P. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 74-30048 Filed 12-23-74; 8:45 am]

TOXICOLOGY ADVISORY COMMITTEE

Notice of Establishment

Pursuant to the Federal Advisory
Committee Act of October 6, 1972 (Pub.
App.), the Food and Drug Administra-
tion announces the establishment by the
Secretary, Department of Health, Educa-
tion, and Welfare, on December 9, 1974, of
the following advisory committee:

Designation. Toxicology Advisory Com-
mittee.

Purpose. The committee will (1) review
and evaluate all available data relating
to evaluation of the safety of chemicals
present in foods, drugs, cosmetics, and
medical devices; (2) advise the Secre-
tary, Assistant Secretary for Health, and
the Commissioner of Food and Drugs on
matters concerning the safety of specific
human drugs, animal drugs, color and
food additives, cosmetic components, and
components of devices; and (3) recom-
mend the development of standardized
methodologies for the toxicity testing of
such materials.

Authority for this committee will ex-
pire December 9, 1976, unless the Secre-
tary formally determines that continu-
ance is in the public interest.


WILLIAM P. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc. 74-30047 Filed 12-23-74; 8:45 am]
NOTICE

The National Council on Educational Research is established under section 405(b) of the General Education Provisions Act (20 U.S.C. 1221e(b)). Its statutory duties include:

(a) Establishing general policies for, and reviewing the conduct of the Institute;
(b) Advising the Assistant Secretary for Education and the Director of the Institute on development of programs to be carried out by the Institute;
(c) Recommending to the Assistant Secretary for Education and the Director ways to strengthen educational research, to improve the collection and dissemination of research findings, and to insure the implementation of educational renewal and reform based upon the findings of educational research.

This meeting will be open to the public except for the closed sessions. The tentative agenda includes:

1. **January 9, 1975.**
   - 10 a.m. to 12 noon: Open Session, Routine Business, Review of FY 1975 Budget and Programs.
   - 12 noon to 1 p.m.: Lunch.
   - 1 p.m. to 5:30 p.m.: Closed Session, Discussion of FY 1976 Budget and Program Planning.

2. **January 10, 1975.**
   - 9:15 a.m. to 3:30 p.m.: Closed Session, Discussion of FY 1976 Budget and Program Planning.

Members of the public are invited to attend the open session. Written statements relevant to an agenda item (or to any other item considered of interest to the Institute) may be submitted at any time and should be sent to the Chairman and the Executive Secretary of the Council at the address shown below. Requests to address the Council meeting should be submitted in writing to the Chairman and the Executive Secretary by the close of business January 3, 1975. The Chairman will determine whether a presentation should be scheduled.

In accordance with Council policy (NCER Resolution No. 013074-8) copies of Council resolutions and minutes of Council meetings can be obtained by contacting the Executive Secretary. Resolutions are available shortly after the meeting, and a draft of the transcript, which adopted because minutes require approval by the Council at a subsequent meeting, they are usually available approximately four to six weeks after the date of the meeting to which they refer.

NOTICES

In order to verify the tentative agenda, assure adequate seating arrangements, or to obtain summaries of this meeting and copies of any resolutions adopted by the Council this meeting, interested persons are requested to contact Ms. Caroline Phillips, Executive Secretary, National Council on Educational Research, 1200 19th Street NW, Washington, D.C. 20036, telephone (202) 336-0100.


Dated: December 20, 1974.

Emerson Elliott, Acting Director, National Institute of Education.

[FR Doc. 74-30006 Filed 12-23-74; 8:45 am]

ADULT DEVELOPMENT AND AGING RESEARCH COMMITTEE

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Adult Development and Aging Research Committee, National Institute of Child Health and Human Development, February 6-7, 1975, Building 31, Conference Room 8, National Institutes of Health, Bethesda, Maryland.

This meeting will be open to the public on February 6 from 9 a.m. to 9:30 a.m. to discuss administrative and current status reports. Attendance by the public will be limited to space available. In accordance with the provisions set forth in sections 552(b)(4) and 552(b)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on February 6 from 9:30 to adjournment on February 7 for the review, discussion and evaluation of individual grant applications. The applications contain information of a proprietary or confidential nature, including detailed research protocols, designs, and personal information; financial data, such as salaries; and personal information concerning individuals associated with the applications and proposals.

Dr. Luis A. Froshlich, Executive Secretary, National Institute of Allergy and Infectious Diseases, Building 31, Room 3A32, Bethesda, Maryland, telephone (301) 496-1757, will provide summaries of meetings and rosters of committee members.

Mr. Robert L. Berner, Chief, Office of Research Reporting and Public Response, National Institute of Allergy and Infectious Diseases, Building 31, Room 3A32, Bethesda, Maryland, telephone (301) 496-1033, will furnish substantive program information.

[FR Doc. 74-29938 Filed 12-23-74; 8:45 am]

AUTOMATION IN THE MEDICAL LABORATORY SCIENCES REVIEW COMMITTEE

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Automation in the Medical Laboratory Sciences Review Committee, January 29-30, 1975, 9 a.m., Dulles Marriott Hotel, Washington, D.C. This meeting will be open to the public on January 29 from 9 a.m. to 12 noon for opening remarks and general discussion. Attendance by the public will be limited to space available. In accordance with the provisions set forth in sections 552(b)(4) and 552(b)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on January 29 from 12 noon to 5 p.m., and January 30 from 9 a.m. to 5 p.m.
9 a.m. to 5 p.m., for the review, discussion, evaluation, and ranking of individual contract proposals. The proposals contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals.

Mr. Paul Deming, Research Reports Officer, NIGTL, Building 31, Room 4A46, Bethesda, Maryland 20014, Telephone: 301-496-5976, will provide a summary of the meeting and a roster of committee members.

Dr. Robert M. Melville, Executive Secretary, Automation in the Medical Laboratory Sciences Review Committee, Westwood Building, Room 854, Bethesda, Maryland 20014, Telephone: 301-496-7081, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13-860, National Institute of General Medical Sciences, National Institutes of Health.)

Suzanne L. Fremau,
Committee Management Officer,
National Institutes of Health.

December 12, 1974.

[FR Doc. 74-29942 Filed 12-31-74; 8:45 am]

BEHAVIORAL SCIENCE CONFERENCE
Notice of Meeting
A notice is hereby given of the Behavioral Science Conference of the Division of Cancer Control and Rehabilitation, National Cancer Institute, to be held January 20, 21, 22, 1975, at the El Tropicano Motor Hotel, River Room, San Antonio, Texas.

The entire meeting will be open to the public from 8 a.m., January 20, 1975 to 1 p.m. until adjournment on January 22, 1975 to discuss the behavioral sciences as they relate to cancer control and rehabilitation. Attendance by the public will be limited to space available.

For additional information please contact: Dr. Joseph Cullen, Blair Building, Room 716A, National Cancer Institute, National Institutes of Health, Bethesda, Maryland 20014, (301) 427-7478.

Suzanne L. Fremau,
Committee Management Officer,
National Institutes of Health.

December 17, 1974.

[FR Doc. 74-29984 Filed 12-3-74; 8:45 am]

IMMEDIATE HISTORICAL ASSISTANCE
Committee
Notice of Meeting
Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Immediate Historical Assistance Committee, National Library of Medicine, on February 5 to discuss administrative reports and program developments. Attendance by the public will be limited to space available. In accordance with provisions set forth in sections 552(b)(4) and 552(b)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on February 5 from 10:30 a.m. to 1 p.m. and from 8:30 a.m. to adjournment on February 6, for the review, discussion, and evaluation of individual grant applications. The applications contain information of a proprietary nature—including detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications in the field of biomedical communications.

Dr. Roger W. Dahlen, Executive Secretary of the Committee, and Chief, Division of Biomedical Information Support, Extramural Programs, National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland 20014, Telephone Number: 301-496-4191, will furnish summaries of the meeting, rosters of committee members, and substantive program information.


Suzanne L. Fremau,
Committee Management Officer,
National Institutes of Health.

December 12, 1974.

[FR Doc. 74-29983 Filed 12-23-74; 8:45 am]

CANCER CONTROL AND REHABILITATION ADVISORY COMMITTEE
Notice of Establishment
The Director, National Institutes of Health, announces the establishment on November 22, 1974, of the advisory committee indicated below by the Director, National Cancer Institute, under the authority of section 410(a) (3) of the Public Health Service Act (42 U.S.C. 286d).

Such advisory committee shall be governed by the provisions of the Federal Advisory Committee Act (Pub. L. 92-463), setting forth standards governing the establishment and use of advisory committees.

Name: Cancer Control and Rehabilitation Advisory Committee.

Purpose: The Committee provides to the Director, NCI and the Director, Division of Cancer Control and Rehabilitation, advice on all matters relating to NCI activities in the field of cancer control and rehabilitation and on coordination of the entire national effort to control cancer. The Committee will termi-
NOTICES

CANCER RESEARCH CENTER REVIEW COMMITTEE
Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the Cancer Research Center Review Committee, National Cancer Institute on February 7 and 8, 1975, to be held in Building 31, C-Wing, Conference Room 7.

This meeting will be open to the public on February 7, 1975, from 8:30 a.m. to 10 a.m. to discuss procedures to be followed in review of applications, assignment of applications to the Cancer Research Center Review Committee and to the Cancer Special Program Advisory Committee. Attendance by the public will be limited to space available. In accordance with the provisions set forth in sections 552(b)(4) and 552(b)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92–463, the meeting will be closed to the public on January 31, 1975 from 10:30 a.m. to adjournment, for the review, discussion and evaluation of the progress of the individual programs and projects of the dental research institutes and centers. These progress reports contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the dental research institutes and centers.

Dr. Emil L. Rieg, Special Assistant for Institutes and Centers, National Institute of Dental Research, National Institutes of Health, Bethesda, Maryland 20014, will provide summaries of meetings, rosters of committee members, and will furnish substantive program information.

SUSANNE L. FREEMAN, Committee Management Officer, National Institutes of Health.

DECEMBER 16, 1974.

[FR Doc 74–29935 Filed 12–23–74; 8:45 am]

EXPERIMENTAL THERAPEUTICS STUDY SECTION
Amended Notice of Meeting

Notice is hereby given of a change in the meeting place of the Experimental Therapeutics Study Section, Division of Research Grants, which was published in the Federal Register on November 29, 1974 (39 FR 41571).

The Experimental Therapeutics Study Section meeting was to have convened at Building 21, Rm. 6, Bethesda, Md., but will be moved to Building 31, C-Wing, Room 8, Bethesda, Md., at 8:30 a.m., January 9–11, 1975.

This meeting will be open to the public for approximately one hour at the beginning of the first session of the first day of the meeting.

SUSANNE L. FREEMAN, Committee Management Officer, National Institutes of Health.

DECEMBER 18, 1974.

[FR Doc 74–29927 Filed 12–23–74; 8:45 am]

GENERAL CLINICAL RESEARCH CENTERS COMMITTEE
Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the General Clinical Research Center Committee, Division of Research Resources, February 10, 1975, National Institutes of Health, Building 31, Conference Room 8, Bethesda, Maryland.

This meeting will be open to the public on February 10 from 9:00 a.m. to 9:30 a.m. to discuss future plans of the Committee and general announcements. Attendance by the public will be limited to space available. In accordance with the provisions set forth in section 552(b)(4) and section 552(b)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92–463, the meeting will be closed to the public on February 10 from 9:30 a.m. to recess on that day for the review, discussion and evaluation of individual grant applications. The applications contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications.

Mr. James Augustine, Information Officer, Division of Research Resources, National Institutes of Health, Building 31, Room 5B–39, Bethesda, Maryland 20014, phone 301–496–6595, will provide summaries of meetings and rosters of Committee members.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
NOTICES

HEART AND LUNG PROJECT COMMITTEE

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Heart and Lung Program Project Committee, National Heart and Lung Institute, Building 31, Conference Room 9. This meeting will be open to the public on January 31, 1975, from 9 a.m. until the adjournment on February 1, 1975, for the review, discussion and evaluation of individual grant applications. The applications contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications.

Mr. York E. Onnen, Chief, Public Inquiries and Reports Branch, NHLI, NIH, Building 31, Room 5A21, Bethesda, Maryland 20014, phone (301) 496-4236, will provide summaries of the meeting and rosters of the committee members. Dr. Alice M. McGill, Prevention, Control and Education Coordinator, NHLI, NIH, Westwood Building, Room 1005, phone (301) 496-1706, will furnish substantive program information.

FR Doc.74-29944 Filed 12-23-74;8:45 am

INFECTIOUS DISEASE COMMITTEE

Notice of Meeting

Pursuant to Public Law 92-468, notice is hereby given of the meeting of the Infectious Disease Committee, National Institute of Allergy and Infectious Diseases, January 16-17, 1975, Wilson Hall, Building 1, National Institutes of Health, Bethesda, Maryland 20014. This meeting will be open to the public from 9 a.m. to 3 p.m. on January 16, 1975 for the review, discussion and evaluation of individual contracts in the hepatitis program. The meeting will be closed to the public from 3 p.m. to 5 p.m. on January 17, 1975 for the review, discussion and evaluation of the Ara-A collaborative study and administrative reports. Attendance by the public will be limited to space available. In accordance with the provisions set forth in sections 552(b)(4) and 552(b)(6), Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on January 31, 1975, from 9 a.m. until the adjournment on February 1, 1975, for the review, discussion and evaluation of individual grant applications. The applications contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with these contracts.

Mr. York E. Onnen, Chief, Public Inquiries and Reports Branch, NHLI, NIH, Building 31, Room 5A21, Bethesda, Maryland 20014, phone (301) 496-4236, will provide summaries of the meeting and rosters of the committee members. Dr. Alice M. McGill, Prevention, Control and Education Coordinator, NHLI, NIH, Westwood Building, Room 1005, phone (301) 496-1706, will furnish substantive program information.

FR Doc.74-29944 Filed 12-23-74;7:48 am

HIGH BLOOD PRESSURE EDUCATION RESEARCH PROGRAM AD HOC REVIEW COMMITTEE

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the High Blood Pressure Education Research Program ad hoc review Committee, National Heart and Lung Institute, Febuary 6-8, 1975, National Institutes of Health, Building 31, Conference Room 9. This meeting will be open to the public on February 6, 1975, from 9 a.m. to 3 p.m. to discuss the Ara-A collaborative study and from 9 a.m. to 3 p.m. on January 17, 1975, for the review, discussion and evaluation of the hepatitis program. The meeting will be closed to the public from 9 a.m. until the adjournment on February 1, 1975, for the review, discussion and evaluation of individual grant applications. The applications contain information of a proprietary or confidential nature, including detailed research protocols, designs, and other technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications.

Mr. York E. Onnen, Chief, Public Inquiries and Reports Branch, NHLI, NIH, Building 31, Room 5A21, Bethesda, Maryland 20014, phone (301) 496-4236, will provide summaries of the meeting and rosters of the committee members. Dr. Alice M. McGill, Prevention, Control and Education Coordinator, NHLI, NIH, Westwood Building, Room 1005, phone (301) 496-1706, will furnish substantive program information.

FR Doc.74-29943 Filed 12-23-74;7:48 am

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
NOTICES

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Neurological Diseases and Stroke Science Information Program Advisory Committee.

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Neurological Diseases and Stroke Science Information Program Advisory Committee, National Institute of Neurological Diseases and Stroke, on January 20-21, 1975, Building 31, Room 8A30, National Institutes of Health, Bethesda, Maryland.

The entire meeting will be open to the public from 9 a.m. to 5 p.m., on January 20th, and from 9 a.m. to adjournment on January 21st, to discuss future activities of the Committee. Attendance by the public will be limited to space available.

This meeting is necessary to advise the Director, NINDS regarding the future of the NINDS Neurological Information Network. This advice is a vital element for the report by the Director, NINDS to the Congress, which in its second supplementary appropriation of 1974 for the DHEW, required reconsideration of a previous decision regarding the information centers in the network. This advisory meeting must be held at this time to permit a prompt timely response to the Congress for which the Director, NINDS is committed.

The Chief, Office of Scientific and Health Reports, Mrs. Ruth Dudley, Bldg. 31, Room 8A03, NIH, NINDS, Bethesda, Maryland, will furnish summaries of the meetings and rosters of committee members.

Mr. Alfred Weisberg, Executive Secretary of the Committee, Room 706, Federal Bldg., Phone. 49-6804, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.317, National Institutes of Health)

Dated: December 13, 1974.

Suzanne L. Freema, Committee Management Officer, National Institutes of Health.

[FR Doc.74-29940 Filed 12-23-74;8:45 am]

NEUROLOGICAL DISEASES AND STROKE SCIENCE INFORMATION PROGRAM ADVISORY COMMITTEE

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Neurological Diseases and Stroke Science Information Program Advisory Committee, National Institute of Neurological Diseases and Stroke, on January 20-21, 1975, Building 31, Room 8A30, National Institutes of Health, Bethesda, Maryland.

The entire meeting will be open to the public from 9 a.m. to 5 p.m., on January 20th, and from 9 a.m. to adjournment on January 21st, to discuss future activities of the Committee. Attendance by the public will be limited to space available.

This meeting is necessary to advise the Director, NINDS regarding the future of the NINDS Neurological Information Network. This advice is a vital element for the report by the Director, NINDS to the Congress, which in its second supplementary appropriation of 1974 for the DHEW, required reconsideration of a previous decision regarding the information centers in the network. This advisory meeting must be held at this time to permit a prompt timely response to the Congress for which the Director, NINDS is committed.

The Chief, Office of Scientific and Health Reports, Mrs. Ruth Dudley, Bldg. 31, Room 8A03, NIH, NINDS, Bethesda, Maryland, will furnish summaries of the meetings and rosters of committee members.

Mr. Alfred Weisberg, Executive Secretary of the Committee, Room 706, Federal Bldg., Phone. 49-6804, will provide substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13.317, National Institutes of Health)

Dated: December 13, 1974.

Suzanne L. Freema, Committee Management Officer, National Institutes of Health.

[FR Doc.74-29940 Filed 12-23-74;8:45 am]
NOTICES

TROPICAL MEDICINE AND PARASITOLOGY STUDY AND BIOMEDICAL COMMUNICATION STUDY

Amended Notice of Meetings

Notice is hereby given of a change in the meeting date or place of the following National Institutes of Health Study Sections which were published in the Federal Register on November 29, 1974 (39 FR 41571).

- The Tropical Medicine and Parasitology Study Section meeting was to have convened at the Connecticut Inn Motel, Washington, D.C., but has been changed to the Bethesda Motor Hotel, 7740 Wisconsin Avenue, Bethesda, Maryland at 9 a.m., January 8-10, 1975.

- The Biomedical Communication Study Section was to have met January 16-17, 1975, but will meet for one day only, January 17, 1975 at 9 a.m. at the Holiday Inn, Chevy Chase, Maryland, the same location for which it was originally scheduled.

These meetings will be open to the public from 9:30 a.m. to 12 noon for a report on the substantive program information.

Dated: December 18, 1974.

SUZANNE L. FREEMAN,
Committee Management Officer,
National Institutes of Health.

Office of Education

RIGHT TO READ STATE GRANTS PROGRAM

Notice of Closing Date for Receipt of Applications

Notice is hereby given that pursuant to section 331a(a)(1) of the Vocational Education Act, as amended, 20 USC 331, applications are being accepted for the Right to Read State Grants Program which are being separately published in the Federal Register in proposed form (45 CFR Part 151, Subpart D).

In order to be considered for support, applications should be received by the U.S. Office of Education Application Control Center on or before January 30, 1975.

A. Applications sent by mail.

An application sent by mail should be addressed as follows: U.S. Office of Education, Application Control Center, 400 Maryland Avenue SW., Washington, D.C. 20202, Attention: 13.533. An application sent by mail will be considered to be received on time by the Application Control Center if:

(1) The Application was sent by registered or certified mail not later than the fifth calendar day prior to the closing date or if such fifth calendar day is a Saturday, Sunday, or Federal Holiday not later than the next following business day, as evidenced by the U.S. Postal Service postmark on the wrapper or envelope, or the postmark on the receipt from the U.S. Postal Service; or

(2) The application is received on or before the closing day by either the Department of Health, Education, and Welfare, or the U.S. Office of Education mail rooms in Washington, D.C. In establishing the date of receipt, the Commissioner will rely on the time-date stamp of such mail rooms or other documentary evidence of receipt maintained by the Department of Health, Education, and Welfare, or the U.S. Office of Education.

B. Hand delivered applications.

An application to be hand delivered must be taken to the U.S. Office of Education Application Control Center, Room 5673, Regional Office Building Three, 7th and D Streets SW., Washington, D.C. 20202.

Hand delivered applications will be accepted daily between the hours of 9:30 a.m. and 4 p.m. Washington, D.C. time except Saturdays, Sundays, or Federal Holidays. Applications will not be accepted after 4 p.m. on the closing date.

C. Authority.

The regulations applicable to this program include the Office of Education General Provisions Regulations (45 CFR 100a), the General Regulations for Right to Read (45 CFR Part 151, Subpart A), published in the Federal Register on June 20, 1974 at 39 FR 22147, and regulations for the State Grants Program which are being separately published in the Federal Register in proposed form (45 CFR Part 151, Subpart D).

Notice is hereby given, pursuant to section 104 of the Vocational Education Act, as amended, 20 USC 2214 (Catalog of Federal Domestic Assistance Program No. 13.533), that the next meeting of the National Advisory Council on Vocational Education will be held on January 16, 1974 from 9 a.m. to 5 p.m., Eastern Standard Time and January 17, 1974 from 9 a.m. to 12 Noon, Eastern Standard Time, at the Ramada Inn, Washington, D.C.

The National Advisory Council on Vocational Education is established under section 104 of the Vocational Education Act, as amended, 20 USC 2214 (Catalog of Federal Domestic Assistance Program No. 13.838). The Council is directed to advise the Commissioner of Education concerning the administration of the Act; and to review the administration and operation of vocational education programs under the Act; including the effectiveness of

Dated: December 17, 1974.

T. H. BELL,
U.S. Commissioner of Education.

NOTICE OF MEETING

PULMONARY DISEASES ADVISORY COMMITTEE

Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Pulmonary Diseases Advisory Committee, National Heart and Lung Institute, February 1, 1975, in Conference Room 8, Research, Building 31, National Institutes of Health, Bethesda, Maryland. The time of the meeting will be open to the public from 9:30 a.m. to 12 noon for a report on the substantive program information.

Mr. York Omnes, Chief, Public Inquiries and Reports Branch, National Heart and Lung Institute, Building 31, Room 5A21, National Institutes of Health, Bethesda, Maryland, phone (301) 496-7208, will furnish substantive program information.

Dated: December 12, 1974.

SUZANNE L. FREEMAN,
Committee Management Officer,
National Institutes of Health.

OFFICE OF EDUCATION

APPLICATIONS

Program information and forms.

Applications and application forms may be obtained from the Right to Read Program, U.S. Office of Education, Room 2131, 400 Maryland Avenue SW., Washington, D.C. 20202.

(20 USC 331a(a))

Dated: December 17, 1974.

(FR Doc.74-39934 Filed 12-23-74; 8:45 am)

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
such programs in meeting the purposes for which they are established and operated, make recommendations with respect thereto, and make annual reports of its findings and recommendations to the Secretary of HEW for transmittal to the Congress; and conduct independent evaluation of programs carried out under the Act and publish and distribute the results thereof.

The meeting of the Council shall be open to the public. The proposed agenda includes:

January 16, 1974, 9 a.m. to Noon: Discussion of meetings with Commissioner of Education, representatives of Domestic Council, and Assistant Secretary of Education.

January 17, 1974, 9 a.m. to Noon: Reports on Committee Meetings, Other General Business.

Records shall be kept of all Council proceedings and shall be available for public inspection at the office of the Council's Executive Director, located in Suite 412, 425-13th Street, NW, Washington, D.C. 20004.

Signed at Washington, D.C., on December 16, 1974.

CALVIN DELLEFIELD, Executive Director.

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Air Brake Systems

Request for Comments

A question has been raised concerning Federal Motor Vehicle Safety Standard No. 121 (49 CFR 571.121) that indicates that a more explicit explanation of the basic assumptions underlying its requirements is in order. (See entry No. 74-10 in this docket.) Specifically, the requirement that tractor-trailers be capable of meeting the braking test requirements without lockup of wheels, except in certain limited circumstances, has been questioned as unduly design restrictive, in that it requires the vehicle to have antilock systems that are not necessary to achieve the required stopping distances in the specified 12-foot lane.

The purpose of these requirements is to assure a minimum safe level of braking system performance when a driver attempts to stop or slow down a motor vehicle under either normal or emergency conditions of real-world use. The tests employed to achieve these ends consist of stopping the vehicle from various initial speeds while traversing a straight path on a smooth, flat roadway. Stops are made under two different conditions of vehicle loading, and on both dry and wet pavement surfaces. The performance requirements associated with these tests deal with two fundamental aspects of performance: (a) The deceleration levels which the vehicle is capable of achieving, and (b) the degree to which the vehicle's directional stability and controllability remain unimpaired by brake application.

Minimum safe levels of deceleration capability are assured by prescribing maximum distances under which the vehicle must be able to stop under the various test conditions. Maintenance of adequate directional stability and controllability is assured by stipulating two independent performance characteristics which must be satisfied during the test maneuvers: (a) That all parts of the vehicle remain within a 12-foot lane, to preclude excessive side-to-side brake imbalance which can be caused by the typical driver, and (b) that all wheels continue rolling until the vehicle's speed falls below 10 mph.

Requirement (b), the one that has been questioned, is based on the fact that a locked wheel, whose tire is sliding against the road surface, is lacking in adequate directional stability. That is, the locked wheel generates forces to change the direction in which it is moving, whether longitudinal or lateral. Thus, a vehicle whose wheels are locked is likely to slide sideways as a result of such conditions as unevenness in the road surface, wind forces, impacts on or by another vehicle, or steering inputs by the driver as a result either of the emergency situation or of curve in the road. One performance characteristic of the air brake systems is often present in a situation where the full braking capability of a vehicle is needed because of an emergency. Consequently, the NHTSA has determined that the capability of keeping the wheels rolling while making a full-torque brake application is a necessary element of any vehicle's safety braking performance.

It is not enough merely to be able to bring the vehicle to a halt within the prescribed length and lane on a flat, straight surface. Safe braking capability must take into account the other variables that affect braking performance, and the prohibition against locking is included in the requirement to assure safe braking under such other conditions. The stipulated performance requirements are compatible with, widely accepted automotive engineering practice, and the safety performance thus measured is found to have a strong correlation with safe real-world braking performance.

The foregoing statement is an amplification of the discussions of Standard No. 121 that have appeared in preambles to previous issuances on this subject. The NHTSA has assumed that interested persons have agreed with these principles, and in the opinion of the NHTSA, the tests and requirements of Standard 121 (in particular, the stipulation that wheels not lock up at speeds above 10 mph) constitute the most objective, meaningful, and efficient experimental methods to measure safety braking performance that are presently available.

It is not now anticipated that there will be any further amendment to the rule on the basis of this statement. To ensure that all relevant comments are included in the public record, however, this agency is interested in receiving any comments that interested persons may wish to submit on the subject discussed in this notice.

Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5108, 400 Seventh Street, SW, Washington, D.C. 20590. It is requested but not required that 10 copies be submitted. All comments received will be available for examination at the above address.

(See 103, 119, Pub. L. 89-583, 80 Stat. 718, (15 U.S.C. 1399, 1407); delegation of authority at 49 CFR 1.51)

Issued on December 18, 1974.

JAMES B. GREGORY, Administrator.

[FR Doc.74-39906 Filed 12-20-74; 10:36 am]

ATOMIC ENERGY COMMISSION

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS PROCEDURES SUBCOMMITTEE

Notice of Meeting

December 19, 1974.

In accordance with the purposes of sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b.), the ACRS Procedures Subcommittee will hold a closed meeting at 2 p.m. on January 8, 1975, in Washington, D.C., to discuss ACRS policy and internal practices with regard to the functioning of the Committee and the conduct of its activities.

I have determined, in accordance with subsection 10(d) of Public Law 92-463, that the meeting will consist of exchanges of opinions and formulation of recommendations, the results of which, if written, would fall within exemption (5) of 5 U.S.C. 552(b). Any factual material that may be presented during the meeting will be inextricably intertwined with such exempt material, and no separation of this material is considered practical. It is essential to close this meeting to protect the free interchange of internal views and to avoid undue interference with Subcommittee and agency operation.

JOHN C. RYAN, Advisory Committee Management Officer.

[FR Doc.74-30019 Filed 12-23-74; 8:45 am]

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS WORKING GROUP ON LMFBH HYPOTHETICAL CORE DISRUPTIVE ACCIDENTS (HCDA'S)

Notice of Meeting

December 19, 1974.

In accordance with the purposes of sections 29 and 182b. of the Atomic Energy Act (42 U.S.C. 2039, 2232b.), the Advisory Committee on Reactor Safe-
NOTICES

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974

44481

John C. Ryan
Advisory Committee
Management Officer.

Regulatory Guide
Notice of Issuance and Availability

The Atomic Energy Commission has issued two new guides in its Regulatory Guide series. This series has been developed to describe and make available to the public methods acceptable to the AEC Regulatory staff of implementing specific parts of the Commission's regulations, guidelines, etc. 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 1.70.15, "Information for Safety Analysis Reports—Industrial Security for Nuclear Power Plants," and Regulatory Guide 1.70.16, "Information for Safety Analysis Reports—Missile Barrier Design Procedures," identify information that is needed in safety analysis reports at the construction permit and operating license stages of review.

These guides are two of a number being issued in the 1.70.X series to identify information that has often been missing from applicants' safety analysis reports or to provide a well-defined base from which to evaluate proposed changes in the scope and requirements of reviews. A complete Revision 2 of the Standard Format incorporating the changes presented in this 1.70.X series will be issued following completion of publication of the SRPs.

Comments and suggestions in connection with improvements in all published guides are encouraged at any time. Public comments on Regulatory Guides 1.70.15 and 1.70.16 will, however, be particularly useful in developing the forthcoming revision of the Standard Format if received by February 28, 1975.

Comments should be sent to the Secretary of the Commission, U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Docketing and Service Section.

Regulatory Guides are available for inspection at the Commission's Public Document Room, 1717 H Street NW, Washington, D.C. Requests for single copies of issued guides (which may be reproduced) or for placement on an autorotation list for single copies of future guides should be made in writing to the Director of Regulatory Standards, U.S. Atomic Energy Commission, Washington, D.C. 20545. Telephone requests cannot be accommodated. Reproduction of copies of issued guides (which may be copyrighted and Commission approval is not required to reproduce them.

(5 U.S.C. 552(a))

Dated at Rockville, Maryland this 17th day of December 1974.

For the Atomic Energy Commission.

Lester Rogers,
Director of Regulatory Standards.

Advisory Committee on Reactor Safeguards
Notice of Meeting

December 20, 1974.

In accordance with the purposes of sections 29 and 182b of the Atomic Energy Act (42 U.S.C. 2030a, 2323b), the Advisory Committee on Reactor Safeguards will hold a meeting on January 9-11, 1975 in Room 1045, 1717 H Street NW, Washington, D.C.

The following constitutes that portion of the Committee's agenda for the above meeting which will be open to the public:

Thursday, January 9, 1975, 9:30 a.m.—12:30 p.m.: River Bend Station, Units 1 and 2 (Open)—The Committee will meet with representatives of Gulf States Utilities Company and the AEC Regulatory Staff to hear presentations and hold discussions regarding its review of the request for a construction permit for this station. Portions of this meeting will be closed if required to discuss proprietary information related to the design, construction and/or operation of this station and to discuss security arrangements for this station. Closed portions will also be held for Committee deliberative sessions.

2:15 p.m.—5 p.m.: Douglas Point Nuclear Generating Station (Open). The Committee will meet with representatives of the Potomac Electric Power Company to hear presentations and hold discussions regarding the request for a construction permit for this station. Portions of this meeting will be closed if required to discuss proprietary information related to the design, construction and/or operation of this station and to discuss security arrangements for this plant. Closed portions will also be held for Committee deliberative sessions.

Friday, January 10, 1975, 10 a.m.—11 a.m.:

River Bend Station, Units 1 and 2 (Open)—The Committee will hear presentations and hold discussions with representatives of the AEC Regulatory Staff regarding recent reactor operating experience and recent licensing actions.

11 a.m.—12:30 p.m. and 1:30 p.m.—2:30 p.m. —WASH-1400, Reactor Safety Study (Open). The Committee will meet with representatives of the AEC Staff to discuss presentations in the reactor safety study report. Portions of this session will be closed if required, under the provisions of section 10(d) of Public Law 92-463 (the Federal Advisory Committee Act) to exclude proprietary information. Portions of recommendations, the discussion of which, if written, would fall within exemption (5) of 5 U.S.C. 552(b).

It should be noted that, in addition to the closed portions of the agenda items noted above, the Committee will hold other sessions not open to the public under the authority of section 10(d) of Public Law 92-463 (the Federal Advisory Committee Act), to consider the above applications and other matters. I have determined in accordance with subsection 10(d) of Public Law 92-463 that it is necessary to close portions of the meeting to protect proprietary data (5 U.S.C. 552(b)(4)), and to protect the free interchange of internal views to avoid undue interference with agency or Committee operations. Undisclosed privileged information (5 U.S.C. 552(b)(5)). Any non-exempt material that may be discussed during the closed portions of the meeting will be inextricably intertwined with discussion of exempt material and no further separation is practical. Practical considerations may dictate alterations in the above agenda or schedule.

The chairman of the Committee is empowered to conduct the meeting in a manner that, in his judgment will facilitate the orderly conduct of business, including provisions to carry over an in-progress session to the next day.

With respect to public participation in the open portion of the meeting, the following requirements shall apply:

(a) Persons wishing to submit written statements regarding the agenda items may do so by mailing 25 copies thereof, postmarked no later than December 31, 1974, to the Executive Secretary, Advisory Committee on Reactor Safeguards.
NOTICES

U.S. Atomic Energy Commission, Washington, D.C. 20545. Such written comments shall be based on documents related to the agenda items noted above, and related documents on file and available for public inspection at the Atomic Energy Commission's Public Document Room, 1717 H Street NW, Washington, D.C. 20545, and as follows:

River Bend Station, Units 1 & 2
Audubon Library, West Feliciana Branch, St. Francisville, Louisiana 70775.
Douglas Point Nuclear Generating Station
St. Charles County Library, Garret and Charles Street, La Plata, Maryland 20646.
WASH-1400, Reactor Safety Study
AEC's field information offices in Albuquerque; Chicago; King of Prussia, Pennsylvania; Idaho Falls, Idaho; Las Vegas, Nevada; Grand Junction, Colorado; Oak Ridge, Tennessee; Richland, Washington; San Francisco; Aiken, South Carolina; Atlanta, and Denver.

(b) Those persons submitting a written statement in accordance with paragraph (a) above may request an opportunity to make oral statements concerning the written statement. Such requests shall accompany the written statement and shall set forth reasons justifying the need for such oral statement and its usefulness to the Committee. To the extent that the time available for the meeting permits, the Committee will receive oral statements during a period of not more than 30 minutes at an appropriate time, chosen by the Chairman of the Committee.

(c) Requests for the opportunity to make oral statements shall be ruled on by the Chairman of the Committee, who is empowered to apportion the time available among those selected by him to make oral statements.

(d) Information as to whether the meeting or portions of the meeting have been cancelled or rescheduled, and in regard to the Chairman's ruling on requests for the opportunity to present oral statements, and the time allotted, can be obtained by a prepaid telephone call on January 8, 1975, to the Office of the Executive Secretary of the Committee (Telephone: 202-634-1371 between 8:30 a.m. and 5:15 p.m., Eastern Time. It should be noted that the schedule noted above is tentative, based on the anticipated availability of related information, etc. It may be necessary to reschedule items during the same day to accommodate required changes. The ACSR Executive Secretary will be prepared to describe these changes on January 8, 1975.

(e) Questions may be propounded only by members of the Committee and its consultants.

(f) The use of still, movie, and television cameras, the physical installation and presence of which will not interfere with the course of the meeting, will be permitted both before and after the meeting and during any recess. The use of such equipment will not, however, be allowed while the meeting is in session.

(g) Persons desiring to attend portions of the meeting where proprietary information is being discussed may do so by providing to the Executive Secretary 7 days prior to the meeting a copy of an executed agreement with the owner of the proprietary information providing for access to this information.

(h) A copy of the transcript of the open portions of the meeting will be available for inspection during the following workday at the Atomic Energy Commission's Public Document Room, 1717 H Street NW, Washington, D.C. On request, copies of the minutes of the meeting will be made available for inspection at the Atomic Energy Commission's Public Document Room, 1717 H Street NW, Washington, D.C. on or after April 11, 1975. Copies may be obtained upon payment of appropriate charges.

John C. Ryan, Advisory Committee
[FR Doc. 74-30087 Filed 12-23-74; 8:45 am]

JERSEY CENTRAL POWER AND LIGHT COMPANY
Availability of Final Environmental Statement, Oyster Creek Nuclear Generating Station, Unit 1
Pursuant to the National Environmental Policy Act of 1969 and the United States Atomic Energy Commission's regulations in 10 CFR Part 51, notice is hereby given that the Final Environmental Statement prepared by the Commission's Directorate of Licensing, related to the issuance of a full term operating license for the Oyster Creek Nuclear Generating Station currently being operated by the Jersey Central Power and Light Company located in Lacey Township, Ocean County, New Jersey is available for inspection by the public in the Commission's Public Document Room at 1717 H Street NW, Washington, D.C., and in the Ocean County Library in Toms River, New Jersey. The Final Environmental Statement is also being made available at the Division of State and Regional Planning, Department of Community Affairs, P.O. Box 2708, Trenton, New Jersey 08625, and at the Ocean County Planning Board, Court House Square, Toms River, New Jersey 08753.

The notice of availability of the Draft Environmental Statement for the Oyster Creek Nuclear Generating Station, Unit 1, and requests for comments from interested persons was published in the Federal Register on July 5, 1973 (38 FR 17870). The comments received from Federal, State, local and interested members of the public have been included as appendices to the Final Environmental Statement.

Robert A. Clark, Chief, Gas Cooled Reactors Branch, Directorate of Licensing.

[FR Doc. 74-30088 Filed 12-23-74; 8:45 am]

NOTICES

PUBLIC SERVICE COMPANY OF COLORADO
Issuance of Amendment to Facility Operating License

Notice is hereby given that the U.S. Atomic Energy Commission (the Commission) has issued Amendment No. 5 to Facility Operating License No. DPR-34, issued to Public Service Company of Colorado which revised Technical Specifications for operation of the Fort St. Vrain Nuclear Generating Station, located in Weld County, Colorado. The amendment is effective as of its date of issuance.

The amendment permits revised staffing requirements for plant operating shifts.

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 required by the Act and the Commission's rules and regulations in 10 CFR Chapter 1, which are set forth in the license amendment.

For further details with respect to this action, see (1) the application for amendment dated October 23, 1974, (2) Amendment No. 5 to License No. DPR-34, with any attachments, 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, NW, Washington, D.C. and at the Greeley Public Library, City Complex Building, Greeley, Colorado 80631.

A copy of items (2) and (3) may be obtained upon request addressed to the United States Atomic Energy Commission, Washington, D.C. 20545, Attention: Deputy Director for Reactor Projects, Directorate of Licensing.

Dated at Bethesda, Maryland, this 19th day of December 1974.

For the Atomic Energy Commission.

WM. H. REAGAN, JR., Chief, Environmental Projects Branch, Directorate of Licensing.

[FR Doc. 74-30089 Filed 12-23-74; 8:45 am]

NOTICES

JERSEY CENTRAL POWER AND LIGHT COMPANY
Availability of Final Environmental Statement, Oyster Creek Nuclear Generating Station, Unit 1

NOTICES

PUBLIC SERVICE COMPANY OF COLORADO
Issuance of Amendment to Facility Operating License

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A copy of items (2) and (3) may be obtained upon request addressed to the United States Atomic Energy Commission, Washington, D.C. 20545, Attention: Deputy Director for Reactor Projects, Directorate of Licensing—Regulation.

Dated at Bethesda, Maryland, this 19th day of December 1974.

For the Atomic Energy Commission.

ROBERT A. CLARK, Chief, Gas Cooled Reactors Branch, Directorate of Licensing.

[FR Doc. 74-30088 Filed 12-23-74; 8:45 am]
TEXAS UTILITIES GENERATING CO., ET AL. (COMANCHE PEAK STEAM ELECTRIC STATION, UNITS 1 AND 2)

Assignment of Members of Atomic Safety and Licensing Appeal Board
Notice is hereby given that, in accordance with the authority in 10 CFR 2.787 (a), the Chairman of the Atomic Safety and Licensing Appeal Panel has assigned the following panel members to serve as the Atomic Safety and Licensing Appeal Board for these proceedings:
Dr. Lawrence R. Quarles, Member
Michael C. Farrar, Member
Alan S. Rosenthal, Chairman

The panel members to serve as the Atomic Safety and Licensing Appeal Board for these proceedings:
Alan S. Rosenthal, Chairman
Michael C. Farrar, Member
Dr. Lawrence R. Quarles, Member

Dated: December 17, 1974.

MARGARET E. DU FLO,
Secretary to the Appeal Board.

[F.R.Doc.74-29968 Filed 12-23-74; 8:45 a.m.]

UNIVERSITY OF MISSOURI—COLUMBIA
Notice of Proposed Issuance of Amendment to Facility Operating License
The Atomic Energy Commission (the Commission) is considering the issuance of an amendment to Facility Operating License No. R–103 issued to the University of Missouri (the licensee) for operation of the University of Missouri Research Reactor (UMRR) located in Columbia, Missouri.

The proposed amendment would reissue provisions in the Technical Specifications to increase the maximum allowable average fuel burnup from 99 megawatt days (MWD) for the UAI intermetallic fuel to 150 megawatt days (MWD) per element. It would also increase the allowable time between inspections of the fuel elements.

The notice provides that within 30 days after publication of notice in the Federal Register, any member of the public whose interest may be affected by the proposed amendment may file a petition for leave to intervene with respect to whether the amendment to the facility operating license should be issued.

Petitions for leave to intervene must be filed under oath or affirmation and in accordance with the provisions of 10 CFR 2.714 of 10 CFR Part 2 of the Commission's regulations. Petitions for leave to intervene must be filed with the Chairman of the Atomic Energy Commission, Washington, D.C. 20545, Attention: Deputy Secretary to the Atomic Safety and Licensing Appeal Board.

For the Atomic Energy Commission.

GEORGE LEAHY,
Chief, Operating Project Directors
Branch No. 3, Directorate of Licensing.

[F.R.Doc.74-29792 Filed 12-23-74; 8:45 a.m.]

CIVIL AERONAUTICS BOARD
[Airlift International, Inc. (Airlift) proposes a penalty charge for compliance with the tariff restriction on acceptance of containerized restricted articles, and that such cost non-acceptance is a matter outside the authority of the Board to enforce. In support of its request for rejection, COSTHA alleges, inter alia, that the proposal is based on purported costs incurred by the carrier in voluntary action in contravention of the carrier's enforcement of the tariff restriction on acceptance of containerized restricted articles, and that such cost non-acceptance is a matter outside the authority of the Board to enforce. On the other hand, the Board finds that Airlift is inadequate to support the charges assessed, since it is a summary of the man-minutes counted; and that the surcharge will divert traffic to other modes and will be tantamount to an embargo of restricted articles.

With respect to COSTHA's request for rejection, we believe the imposition of a surcharge to be an economic matter under the purview of the Board. Airlift has essentially complied with the Board's Economic Regulations on filing tariffs (14 CFR Part 211), and, consequently, we find no basis for rejection.

Upon consideration of all relevant matters, however, the Board finds that Airlift's proposal may be unreasonable, unjustly discriminatory, unduly preferential, unduly prejudicial, or otherwise unlawful, and should be investigated. The Board further concludes that the proposal should be suspended pending investigation.

In support of its assertion that restricted articles require additional services peculiar to such articles, Airlift submits the results of a man-minute study designed to quantify the costs of such services and presents a purported partial list of non-labor costs, not quantified. The man-minute study indicates that a restricted service requires an average of 50 man-minutes at a cost of $5.29, including benefits.

We believe that the foregoing submission has significant defects. There is no identification of the specific sample upon which the man-minute data are based; without such indication, it is impossible to establish a surcharge of $5.00 per shipment of articles subject to the Restricted Articles Tariff, C.A.B. No. 82.

Airlift asserts, in support of its proposal and in answer to a complaint, inter alia, that the proposed surcharge of $5.29 per restricted article be tendered outside of containers under container charges has resulted in Airlift's absorbing additional costs; that these costs, which are adequately justified, amount to $5.29 in additional direct labor costs per shipment plus certain non-labor costs; that the proposal would generate $33,400 in additional revenue over the next twelve months; and that Airlift does not favor embargoes, but it must recover its extra costs of handling restricted articles.

The Council for Safe Transportation of Hazardous Articles (COSTHA) filed a complaint requesting rejection, or alternatively, suspension and investigation.

In support of its request for rejection, COSTHA alleges, inter alia, that the proposal is a penalty charge for compliance with the tariff restriction on acceptance of containerized restricted articles, and that the carrier's enforcement of the tariff restriction on acceptance of containerized restricted articles is a matter outside the authority of the Board to enforce. In support of its request for rejection, COSTHA alleges, inter alia, that the proposal is based on purported costs incurred by the carrier in voluntary action in contravention of the carrier's enforcement of the tariff restriction on acceptance of containerized restricted articles, and that such cost non-acceptance is a matter outside the authority of the Board to enforce.
This order will be published in the Federal Register.

By the Civil Aeronautics Board.

[SEAL] EDWIN Z. HOLLAND, Secretary.

[FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, T974]

EASTERN AIR LINES, INC.

Suspension/Deletion of Service at Mayaguez, Puerto Rico; Prehearing Conference

Notice is hereby given that a prehearing conference in the above-entitled matter is assigned to be held on January 30, 1975, at 10:00 a.m. (local time), in Room 1031, North Universal Building, 1875 Connecticut Avenue, N.W., Washington, D.C., before Chief Administrative Law Judge Robert L. Park.

In order to facilitate the conduct of the conference, parties are instructed to submit, in one copy to each party and four copies to the Judge of (1) proposed statements of issues; (2) proposed stipulations; (3) requests for information; (4) statement of positions of parties; and (5) proposed procedural dates. The Bureau of Operating Rights will circulate its material on or before January 17, 1975, and the other parties on or before January 24, 1975. The submissions of the other parties shall be limited to points on which they differ with the Bureau of Operating Rights, and shall follow the numbering and lettering used by the Bureau to facilitate cross-referencing.


[FEDERAL REGISTER, VOL. 39, NO. 249—TUESDAY, DECEMBER 24, 1974]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Order Regarding Minimum Charges for Cargo Rates

Adopted by the Civil Aeronautics Board at its office in Washington, D.C. on the 19th day of December, 1974.

An agreement has been filed with the Board pursuant to section 412(a) of the Federal Aviation Act of 1958 (the Act) and Part 261 of the Board's Economic Regulations, between various air carriers, foreign air carriers, and other carriers, embodied in the resolutions of the Joint Traffic Conferences of the International Air Transport Association (IATA). The agreement, adopted by mail vote for expedited January 1, 1976 effectiveness at the 58th Meeting of TCI Specific Commodity Rates Board, has been assigned the above-designated C.A.B. agreement number.

The agreement would amend IATA Resolution 501 relating to minimum charges for cargo within TCI by increasing by $2 the existing charges which range from $10 to $27. IATA alleges that the increase is required because cargo rates within TCI have been increased three times in recent months while the minimum charges have remained status quo.

We will approve the agreement as the proposed new minimum charges appear consistent with similar charges for the distances involved and which are currently in effect in various world areas, including charges which the Board has permitted to become effective within the United States.

The Board, acting pursuant to sections 102, 204(a), 412 and 1002 of the Act, does not find that Resolution 100 (Mail 968) 501, incorporated in Agreement C.A.B. 24815, is adverse to the public interest or in violation of the Act.

Accordingly, it is ordered, That: 1. Agreement C.A.B. 24815 be and hereby is approved;

2. The carriers are hereby authorized to file tariffs implementing the approved agreement on not less than one day's notice for effectiveness not earlier than January 1, 1975. The short-notice authority thus granted in this paragraph expires on January 31, 1975; and

3. Tariffs implementing the agreement shall be marked to expire not later than September 30, 1975.

This order will be published in the Federal Register.
In the September 23, 1974 issue of the Federal Register 39 FR 34068, the Environmental Protection Agency published a notice of intent to evaluate the environmental impact of plutonium and the transuranium elements. Public Hearing

In the September 23, 1974 issue of the Federal Register 39 FR 34068, the Environmental Protection Agency published a notice of intent to evaluate the environmental impact of plutonium and the transuranium elements.
the other transuranium elements and to consider whether new guidelines or standards under the authorities of this Agency are needed to assure adequate protection of the general ambient environment and public health from potential contamination of the environment by radionuclides of the transuranium elements. This notice requested information from interested parties relevant to the development of standards and guidelines.

In accordance with the above request, this Agency in the October 24, 1974, issue of the Federal Register 39 FR 37810 announced public hearings on the above subject to be held in Washington. Further hearings were to be scheduled if deemed advisable.

Response from those interested parties in the Western United States has made it advisable to continue the public hearing in that region. Accordingly, the Environmental Protection Agency will hold a continuance of the public hearing on the environmental impact of plutonium and the other transuranium elements on January 10, 1975, at 9 a.m. at the U.S. Post Office Auditorium, 1832 Stout Street, Denver, Colorado.

Pursuant to Section 512(f), the Agency presents an oral statement at this hearing shall give written notice to the Director, Criteria and Standards Division (AW-560), Office of Radiation Programs, U.S. Environmental Protection Agency, 401 M Street SW., Washington, D.C. 20460 no later than January 3, 1975, in order to be placed on the agenda.

The procedures and rules announced in the Federal Register notice of public hearing, 39 FR 37810 shall also apply to this hearing. A transcript of the hearing will be made and a copy of the transcript, together with copies of all documents presented at this hearing, will constitute the record of the hearing. Copies of the transcript will be available for public inspection within 30 days after conclusion of the hearings at locations to be announced.

ROGER STEWAL
Assistant Administrator for Air and Waste Management.

DECEMBER 18, 1974.

[FR Doc 74-3977 Filed 12-23-74; 8:45 am]

| OPP-32000/198 (TFL-307-B) |

RECEIPT OF APPLICATIONS FOR PESTICIDE REGISTRATION

Data To Be Considered in Support of Applications

On November 19, 1973, the Environmental Protection Agency (EPA) published in the Federal Register (38 FR 31862) its interim policy with respect to the administration of section 3(c)(1)(D) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. This policy provides that EPA will, upon receipt of every application for registration, publish in the Federal Register a notice containing the information shown below. The labeling furnished by the applicant will be available for examination at the Environmental Protection Agency, Room EB-31, East Tower, 401 M Street SW., Washington, D.C. 20460.

Any person who (a) is or has been an applicant, (b) believes that data he desires to assert a claim for compensation under Section 3(c)(1)(D) for such use of his data, and (c) wishes to preserve his right to have the Administrator determine the amount of reasonable compensation to which he is entitled for such use of the data, must notify the Administrator in accordance with the information listed in the notice in the Federal Register of his claim by certified mail on or before February 24, 1975. Notification to the Administrator should be addressed to the Information Coordination Section, Technical Services Division (WH-569), Office of Pesticide Programs, 401 M Street SW., Washington, D.C. 20460. Every such claimant must include, at a minimum, the registration number and the interim policy of November 19, 1975.

Application submitted under 2(a) or 2(b) of the interim policy will be processed in accordance with the procedures established under 2(c) of the interim policy cannot be made final until the 60 day period has expired. If no claims are received within the 60 day period, the 2(c) application will be processed in accordance with normal procedure. However, if claims are received within the 60 day period, the applicants against whom the claims are asserted will be advised of the alternatives available under the Act. No claims will be accepted for possible EPA adjudication which are received after February 24, 1975.

APPLICATIONS RECEIVED

EPA File Symbol 3931-FT. Agricultural Products Co., PO Box 860566, ACOD DMEP 150 DUST. Active Ingredients: Bacillus thuringiensis, Berliner, Formulation contains 5 L.95 million viable spores per g. 0.04 percent, Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 3932-10. Mr. Bar-B-Q, Inc., 50 Lexington Avenue, Bethpage NY 11714. TRITON FUEL WITH CITRONELLA. Active Ingredients: Petroleum Naphtha 99 percent; Citronella 1 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 7048-RR. Edmar Chemical Co., 7800 Bessemer Ave., Cleveland OH 44127. BISOACO RINSER Q FOWDER FABRIC SOFTENER. Active Ingredients: 2,4,5-Trichlorophenoxyacetic Acid, Butoxypropyl Ester 26.9 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 7186-G. General Drug & Chemical Corp., PO Box 5952, Kansas City MO 64122. PETROCRUDE HYDE. Active Ingredients: Formamide 37 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 802-LEI. The Chas. H. Lilley Co., 109 SE Alder, Portland OR 97214. MILLER'S ROSE AND FLORAL SPRAY. Active Ingredients: Pyrethrins 0.026 percent; 2,4-Dinitro-6-octy phenyl phenyl crotolate 0.149 percent; 2,4-Dinitro-4-octy phenyl phenyl crotocate Nitrophenyl (pentanediyl dinitro) Oxime: Petroleum Distillate 0.026 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 802-LET. The Chas. H. Lilley Co. SPRAY OIL 90 SUPERIOR TYPE FOR DORMANT AND SUMMER USE. Active Ingredients: Petrolatum 99.90 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 802-LEO. The Chas. H. Lilley Co. MILLER'S BRUSH KILLER. Active Ingredients: 2,4,5-Trichlorophenoxyacetic Acid, Butoxypropyl Ester 12.7 percent; 2,4,4-trichloro-p-cresol, 35 percent, Butoxypropyl Ester 25.9 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 802-LEH. The Chas. H. Lilley Co. MILLER'S MULTI-PURPOSE HOUSE FLIGHT DISCCT. Active Ingredients: Tetramethrin (1-Cyclohexene-1,2-dicarboximidomethyli 2.3-dimethyl 3 -(2-methylpropenyl) cylopentanebasecarboxylate) 0.250 percent, Butoxypropyl Ester 0.254 percent; (5-Benzyl3-furalyl) methyl 2,4-dimethyl-(3-(2-methylpropenyl) cyclopentane-1,2-dicarboxylate 0.094 percent, Butoxypropyl Ester 0.094 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 802-LEI. The Chas. H. Lilley Co. Pesticide INTERMEDIATE 7286. Active Ingredients: Pyrethrins 3.00 percent. Piperonyl butoxide tech grade 10 percent; Sodium N-methyldithiocarbamate 2.57 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 802-LEI. The Chas. H. Lilley Co. SPRAY OIL 90 SUPERIOR TYPE FOR DORMANT AND SUMMER USE. Active Ingredients: Butoxypropyl Ester 26.9 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 802-LFI. The Chas. H. Lilley Co. MILLER'S MULTI-PURPOSE HOUSE FLIGHT DISCCT. Active Ingredients: Tetramethrin (1-Cyclohexene-1,2-dicarboximidomethyli 2.3-dimethyl 3 -(2-methylpropenyl) cylopentanebasecarboxylate) 0.250 percent, Butoxypropyl Ester 0.254 percent; (5-Benzyl3-furalyl) methyl 2,4-dimethyl-(3-(2-methylpropenyl) cyclopentane-1,2-dicarboxylate 0.094 percent, Butoxypropyl Ester 0.094 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 802-LEI. The Chas. H. Lilley Co. Pesticide INTERMEDIATE 7286. Active Ingredients: Pyrethrins 3.00 percent. Piperonyl butoxide tech grade 10 percent; Sodium N-methyldithiocarbamate 2.57 percent. Method of Support: Application proceeds under 2(b) of interim policy.

EPA File Symbol 802-LEI. The Chas. H. Lilley Co. SPRAY OIL 90 SUPERIOR TYPE FOR DORMANT AND SUMMER USE. Active Ingredients: Butoxypropyl Ester 26.9 percent. Method of Support: Application proceeds under 2(c) of interim policy.

EPA File Symbol 802-LFI. The Chas. H. Lilley Co. MILLER'S MULTI-PURPOSE HOUSE FLIGHT DISCCT. Active Ingredients: Tetramethrin (1-Cyclohexene-1,2-dicarboximidomethyli 2.3-dimethyl 3 -(2-methylpropenyl) cylopentanebasecarboxylate) 0.250 percent, Butoxypropyl Ester 0.254 percent; (5-Benzyl3-furalyl) methyl 2,4-dimethyl-(3-(2-methylpropenyl) cyclopentane-1,2-dicarboxylate 0.094 percent, Butoxypropyl Ester 0.094 percent. Method of Support: Application proceeds under 2(c) of interim policy.
FEDERAL COMMUNICATIONS COMMISSION

Domestic Public Radio Services
Applications Accepted for Filing

Pursuant to §§ 1.227(b) (3) and 21.30 (b) of the Commission’s rules, an application, in order to be considered with any domestic public radio service application appearing on the list below, must be substantially complete and tendered for filing by whichever date is earlier: (a) The close of business 1 business day preceding the day on which the Commission takes action under the Act; or (b) within 60 days after the date of the public notice listing the first prior filed application (with which subsequent filing is in conflict) for consideration with that application by that time pursuant to the alternative—applications will be entitled to consideration with those listed below if filed by the end of the 60 day period, only if the Commission has not acted upon the application by that time pursuant to the first alternative earlier date.

The mutual exclusivity rights of a new application are governed by the earliest application date of the Commission's rules for provisions under 2(c) of interim policy.

The attention of any party in interest desiring to file pleadings pursuant to section 309 of the Communications Act of 1934, as amended, concerning any domestic public radio services application accepted for filing, is directed to § 21.27 of the Commission’s rules for provisions governing the time for filing and other requirements relating to such pleadings.

FEDERAL COMMUNICATIONS COMMISSION

[Seal] VINCENT J. MULLINS,
Secretary.

APPLICATIONS ACCEPTED FOR FILING
DOMESTIC PUBLIC LAND MOBILE RADIO SERVICE

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974

2,2-dichlorovinyi dimethyl phosphate (DDVP) 5.26 percent; Related compounds 0.39 percent; Chlordane Technical 16.62 percent; Aromatic Petroleum Derivative 45.20 percent. Method of Support: Application proceeds under 2(c) of Interim policy.

EPA Pile Symbol 9782-LE. Woodbury Chiminh in the list of Applications Received published in the Federal Register of December 4, 1974 (39 FR 43922).

EPA Pile Symbol 2780-EOOA. PMC Corp., Agricultural Chem. Div., 100 Niagara St., Mid­dieport NY 14105. CODE 920.0 PYREXFONE 5.0-8.6 & 26.8 K. E. REPPELLENT INSECTICIDE. Originally published as CODE 920.0 PYREXFONE 5.60-9.8 & 26.8 E. REPPEL­LENT INSECTICIDE.


JOHN B. RITCH, Jr.,
Director, Registration Division.

FEDERAL COMMUNICATIONS COMMISSION

[Seal] VINCENT J. MULLINS,
Secretary.

APPLICATIONS ACCEPTED FOR FILING
DOMESTIC PUBLIC LAND MOBILE RADIO SERVICE

20850-CD-P—(2)—75, General Telephone Company of the Northwest, Inc. (KON912), C.P. to change antenna system operating on 454.425 & 454.425 MHz, located at 496 Casino Road, Everett, Washington.

20851-CD-P—(4)—75, Page A Fone Corporation (KFC410), C.P. to relocate facilities and change antenna system operating on 454.025, 454.025 MHz, & 454.425 MHz to be located at Fort Worth National Bank Building, 500 Throckmorton Street, Fort Worth, Texas.

20852-CD-P—75, Airlsign of Colorado, Inc. (new). C.P. for a new one-way station to operate on 35.58 MHz, to be located at Cheyenne Mountain, Manitou Springs, Colorado.

20833-CD-P—75, Tel-Illinois, Inc. (KWH104). C.P. to add Transmitter Loc. #2 operating on 158.70 MHz. to be located at Existing WSMF (FM) Tower, Edwardsville, Illinois.

20834-CD-P—(1)—75, Tel-Illinois, Inc. (KWH105). C.P. to add Transmitter Loc. #2 operating on 43.22 MHz. to be located at Existing WSMF (FM) Tower, Edwardsville, Illinois.

20856-CD-P—(3)—75, Tele-Beacon, Inc. (KWH108). C.P. for additional facilities to operate on 43.58 MHz. at Loc. #6; Summit of Round­top Peak, east of Oakland, California, and same facilities at Loc. #24: 1200 Lakeshore Avenue, Oakland, California.

20858-CD-P—75, Mobile Radio Communication Service, Inc. (KRS691). C.P. to increase power operating on 152.24 MHz. located at Ensign Park, Salt Lake City, Utah.

20867-CD-P—(2)—75, Airsign of Colorado, Inc. (KAA276). C.P. for additional control facilities to operate on 2175.2 MHz. at Loc. #1: 1816 Gilman Place, Denver, Colorado, and repeater facilities to operate 2112.4 MHz. at Loc. #24: 2.2 miles due south from Gilman Lookout Mountain Public Radio Service, Inc. (KRS908). C.P. to add antenna facilities operating on 152.4 MHz. at Loc. #7: 310 Southwest 4th Avenue, Portland, Oregon.

20869-CD-P—(4)—75, Summit Mobile Radio Company (KCR306). C.P. for additional facilities operating on 152.06 & 152.12 MHz. Base and 459.225 MHz. Repeater at Loc. #1: 1816 Gilman Place, Denver, Colorado, and additional facilities operating on 454.230 MHz. Control at Loc. #23: 32 Cook Street, Astoria, Maine.

20868-CD-P—75, Victor Bay Radio Service, Inc. (KRH634). C.P. to add antenna facilities operating on 152.24 MHz. at Loc. #23: 1020 Industrial Road, Boulder City, Nevada.

20861-CD-P—(6)—75, Mobile Radio Telephone Service, Inc. (KOE253). C.P. to relocate facilities from KOA272 operating on 152.03 MHz. and change antenna system operating on 152.09, 152.12, 154.15, 454.125, & 454.225 MHz. at Loc. #7: Oquirrh Range, 8.2 mi. SW. of Buhl, Idaho.

20862-CD-P—75, Metoret, Inc. (KTS283). C.P. to add antenna Loc. #2 operating on 35.58 MHz. to be located 3 miles NE. of Bollivar, Ohio.

20863-CD-P—75, Vegas Instant Page (KFI 934). C.P. to add antenna Loc. #2 operating on 35.58 MHz. to be located at 160 Industrial Road, Boulder City, Nevada.

20867-CD-P—(1)—75, (KDK292), South Cen­tral Bell Telephone Company, New Orleans, Louisiana. Amend to add base frequencies on 454.375 and 454.525 MHz. Also, add test frequencies on 459.375 and 459.425 MHz. All other particulars to remain as reported on PN #721 dated September 30, 1974.

20883-CD-P—75, Comex, Inc. (ECC797). C.P. for short wave radiograms to operate on 35.58 MHz. All other particulars to remain the same as reported on PN #731, dated December 9, 1974.

20897-CD-P—(3)—75, (KCR309), Mobile Radio Communication Company. Correction to delete Call Sign KRS908. File number should read: 20827­ CD-P—75. All other particulars to remain the same as reported on PN #731, dated December 9, 1974.

20897-CD-P—(3)—75, Samuel W. Waldenbarg (new). Correction to include PN #20850-CD-P—75. All other particulars to remain the same as reported on PN #731, dated December 9, 1974.
1878—CF-P-75, American Telephone and Telegraph Company (KPS98), 4.6 miles NNE of Boone, Iowa. Lat. 40°09'55" N., Long. 93°47'31" W. C.P. to add 6093.5V MHz towards Point of communication at Ames, Iowa, on azimuth 136 degrees/45 minutes.

1878—CP-P-75, The Pacific Telephone and Telegraph Company (WJM33), 3.8 miles NNE of Parma, California, Lat. 37°56'37" N., Long. 120°58'06" W. Mod. of License to add facilities 4198V and 6404.8H MHz towards Patterson, California, on azimuth 225 degrees/25 minutes; 4198V and 4604.8H MHz towards Patterson, California, on azimuth 301 degrees/37 minutes; formerly licensed to American Telephone and Telegraph Company (WDE77).
<table>
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<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>1794-12-30</td>
<td>CF-P-75, Same (KEL61), 2.8 miles South of Warwick, New York</td>
<td>Lat. 41°12'30&quot; N., Long. 74°21'28&quot; W. C.P. to add frequencies 3770V MHz, 3850V MHz, 4170V MHz to</td>
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<td>Vermont, New York, on azimuth 253°47'</td>
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<tr>
<td>1795-12-30</td>
<td>CF-P-75, Same (KNJ72), 5 Miles WSW.</td>
<td>Lat. 41°12'08&quot; N., Long. 74°29'51&quot; W. C.P. to add frequencies 10815V MHz and 1093V MHz toward</td>
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<td></td>
<td>Los Angeles, CA, California, on azimuths 276°04' toward Golden Valley (Studios of WTCN), Minnesota;</td>
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<td>to increase azimuth 199°38' toward Edina (Studios of KMSP), Minnesota.</td>
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<tr>
<td>1796-12-30</td>
<td>CF-P-75, Same (WQQ40), 1.7 miles SW.</td>
<td>Lat. 41°12'08&quot; N., Long. 74°29'51&quot; W. C.P. to add power split frequency 10775V MHz on corrected</td>
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<td>azimuth 201°34' toward St. Louis, Missouri, on azimuth 174°44' minutes; 4150V MHz toward Pargo,</td>
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<td>Georgia, on azimuth 03°30' themes/30 minutes.</td>
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<tr>
<td>1797-12-30</td>
<td>CF-P-75, Same (WQQ41), 1.1 miles SW.</td>
<td>Lat. 41°12'08&quot; N., Long. 74°29'51&quot; W. C.P. to add 10815V MHz and 1093V MHz toward Los Angeles, CA,</td>
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<td>California, on azimuths 276°04' toward Golden Valley (Studios of WTCN), Minnesota; to increase</td>
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<td>azimuth 199°38' toward Edina (Studios of KMSP), Minnesota.</td>
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<tr>
<td>1798-12-30</td>
<td>CF-P-75, Same (WQQ44), 3.8 miles SW.</td>
<td>Lat. 41°12'08&quot; N., Long. 74°29'51&quot; W. C.P. to add frequencies 10815V MHz and 1093V MHz toward</td>
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<td>Vermont, New York, on azimuths 276°04' toward Golden Valley (Studios of WTCN), Minnesota; to increase</td>
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<td>azimuth 199°38' toward Edina (Studios of KMSP), Minnesota.</td>
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<tr>
<td>1799-12-30</td>
<td>CF-P-75, Same (WQQ41), 3.8 miles SW.</td>
<td>Lat. 41°12'08&quot; N., Long. 74°29'51&quot; W. C.P. to add frequencies 10815V MHz and 1093V MHz toward</td>
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<td>Vermont, New York, on azimuths 276°04' toward Golden Valley (Studios of WTCN), Minnesota; to increase</td>
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<td>azimuth 199°38' toward Edina (Studios of KMSP), Minnesota.</td>
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<tr>
<td>1800-12-30</td>
<td>CF-P-75, Same (WQQ41), 3.8 miles SW.</td>
<td>Lat. 41°12'08&quot; N., Long. 74°29'51&quot; W. C.P. to add frequencies 10815V MHz and 1093V MHz toward</td>
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<td></td>
<td>Vermont, New York, on azimuths 276°04' toward Golden Valley (Studios of WTCN), Minnesota; to increase</td>
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<td>azimuth 199°38' toward Edina (Studios of KMSP), Minnesota.</td>
</tr>
</tbody>
</table>

**NOTICES**

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1953-12-30</td>
<td>CF-M-75, Midwestern Relay Company (WIV45), Dow Center, Rangely,</td>
<td>Lat. 40°05'17&quot; N., Long. 108°56'30&quot; W. C.P. to add 2150V MHz toward Grand J., Colorado, on azimuth 145°</td>
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<td>degrees/30 minutes.</td>
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<tr>
<td>1954-12-30</td>
<td>CF-P-75, Same (KMJ85), 3 miles North of Benton, Florida</td>
<td>Lat. 30°31'05&quot; N., Long. 82°40'23&quot; W. C.P. to add 4150V MHz toward Benton, Lake City, Florida, on</td>
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<td>azimuth 183 degrees/44 minutes; 4150V MHz toward Fargo, Georgia, on azimuth 03°30' themes/30 minutes.</td>
</tr>
<tr>
<td>1955-12-30</td>
<td>CF-P-75, Same (WQN86), 4.7 miles SE.</td>
<td>Lat. 29°56'30&quot; N., Long. 82°33'29&quot; W. C.P. to add 3830V MHz toward Lake City, Florida, on azimuth 034°</td>
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<td>degrees/48 minutes.</td>
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<tr>
<td>1956-12-30</td>
<td>CF-P-75, The Mountain States Telephone and Telegraph Company (KSP73),</td>
<td>Lat. 42°54'41&quot; N., Long. 72°04'11&quot; W. C.P. to add 11262.0H MHz toward Manchester, New Hampshire (new)</td>
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<td>on azimuth 183°20', and 4150V MHz toward Saginaw, Michigan, on azimuth 172°35'.</td>
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<tr>
<td>1957-12-30</td>
<td>CF-P-75, Same (KQG59), 502 Beach St.</td>
<td>Lat. 30°31'05&quot; N., Long. 108°56'30&quot; W. C.P. to add 2150V MHz toward Grand J., Colorado, on azimuth 145°</td>
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<td></td>
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<td>degrees/30 minutes.</td>
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</table>

**Correction**

1513-12-30, American Telephone and Telegraph Company (ESSP7), Correct station location to read: 1.2 miles SE. of Hardinsburg, Indiana. (Rest same as reprinted on Public Notice dated November 25, 1974.)

[Report No. 790]
NOTICES

DOMESTIC PUBLIC LAND MOBILE RADIO SERVICE:

6256-CF-P-75, A.F. computer (KCA965). C.P. to relocate facilities operating on 454.250 and 454.300 MHz located at 6228 Skyline Drive, Houston, Texas.

RURAL RADIO SERVICE:

6055-OF-P-75, Rural Telephone Company of Michigan (new), within the operating territory served by the Grantee. C.P. to add 2126.8H MHz toward Owingsville, Kentucky on azimuth 141°33'.

MULTI-POINT COMMUNICATIONS SERVICE:

6154-CP-P-75, The Mountain States Telephone and Telegraph Company (new), Crystal Dam, 13.8 miles East of Montrose, Colorado, Lat. 38°39’30” N., Long. 109°47’48” W. C.P. for a new station on 2172.0V MHz toward Fitzpatrick, Mesa, Colorado via passive reflector.

6153-CF-P-75, Same (KAN29), 25 miles East of Montrose, Colorado, Lat. 38°23’50” N., Long. 107°25’46” W. C.P. to add 2126.0V MHz toward a new pt. of communication at Crystal Dam, Colorado via passive reflector.

DOMESTIC PUBLIC LAND MOBILE RADIO SERVICE:

5996-CF-P-75, Crystal Dam, 13.8 miles East of Montrose, Colorado, Lat. 38°40’32” N., Long. 109°48’42” W. C.P. for a new station on 2172.0V MHz toward Fitzpatrick, Mesa, Colorado via passive reflector.

FEDERAL COMMUNICATIONS COMMISSION, VINCENT J. MULLINS, Secretary.

APPLICATIONS ACCEPTED FOR FILING:

5979-CF-P-75, John R. Wilcox, d/b/a Wilcox Communications (KJJU908). C.P. to reactivate expired license operating on 152.12 MHz at U.S. Highway 241, Lake City, Florida.

5986-CD-MP-75, Industrial Communications, Inc., d/b/a Port Arthur Mobile Phone (KBJ569). C.P. to relocate facilities operating on 152.21 MHz to be located at Church House Rd., 8 miles S. of Vidor, Texas.

5987-CP-P-75, Services Unlimited, Inc. (KHF596), C.P. to add standby facilities to operate on 152.24 MHz at Loc. #2, Wachovia Building, Winston-Salem, North Carolina.

5998-CD-P-75, Southeastern Telecommunications, Inc., d/b/a Mobile Telephone Company, Inc., C.P. for a new 2-way station to operate on 152.87 MHz located 400 feet N. of 215 E. Robert Toombs Avenue, Washington, Georgia.

6000-CD-P-75, Amelia Telephone Corporation (new). C.P. for a new 2-way station to operate on 152.66 MHz to be located at Lot 123, near corner of Third Avenue and Fifth Street, Collinston, Louisiana.

6002-CD-P-75, Wilkes Telephone and Electric Company (KIM912). C.P. and License to reactivate expired facilities operating on 152.87 MHz located 400 feet N. of 215 E. Robert Toombs Avenue, Washington, Georgia.

6005-CP-P-75, Dodge County Telephone Company (new). C.P. for a new 2-way station to operate on 152.51 MHz to be located 1.8 miles SW of Amor Road, Amor, Virginia.

6003-CD-MP-(4)-75, Hawaiian Telephone Company (KQU261). Mod. Permit to replace transmitter operating on 152.76 & 152.78 MHz at Loc. #7, 8 miles S. of Hawaii Kai P.O., Koko Head, Hawaii.

6004-CD-P-(4)-75, Mt. Vernon and Southern Telephone Service (KKE987). C.F. for additional facilities to operate on 454.025 and 454.075 MHz at Loc. #1, Mt. Vernon, 10.5 miles SSE of Salem, Oregon.

6005-CD-MP-75, Salinas Valley Radio Telephone Company (KAM87). Mod. Permit to change antenna system and relocate facilities operating on 2161 MHz to be located at 590 Valenzuela Road, Monterey, California.

6006-CD-P-75, Summit Mobile Radio Company (KCI903). C.P. to relocate facilities operating on 454.075 MHz at Loc. #2, 32 Cook Street, Auburn, Maine, control.

6008-CP-P-75, Cinatti Radio Telephone Systems, Inc. Should have been listed as an additional channel and location to KQK710. All other particulars are to remain as reported on the Commission's PN #273 dated October 15, 1973.

6009-CP-P-(3)-75, Radio Dispatch Company (KTA928). C.P. for a new 2-way station to operate on 152.66 MHz to be located at 4.9 miles NW of Pacific City, Oregon.

6010-CF-P-75, Continental Telephone Company of Texas (new). C.P. for a new rural subscriber-fixed station to operate on 157.80 & 158.04 MHz located 20.5 miles SSE of Pecos, Texas.

6016-CF-P-75, Continental Telephone Company of Texas (new). C.P. for a new rural subscriber-fixed station to operate on 157.80 & 158.04 MHz located 12.5 miles ESE of Pecos, Texas.

6018-CP-P-75, Continental Telephone Company of Texas (new). C.P. for a new rural subscriber-fixed station to operate on 157.80 & 158.04 MHz located 11 miles WNW of Pecos, Texas.

6019-CF-P-75, Continental Telephone Company of Texas (new). C.P. for a new rural subscriber-fixed station to operate on 157.80 & 158.04 MHz located 11 miles WNW of Pecos, Texas.

6020-CF-P-75, Continental Telephone Company of Texas (new). C.P. for a new rural subscriber-fixed station to operate on 157.80 & 158.04 MHz located 38 miles NW of Pecos, Texas.

POINT-TO-POINT MICROWAVE RADIO SERVICE:

1511-CP-P-75, American Telephone and Telegraph Company (KIZ921), 4.5 miles NW of Roanoke, Texas. Lat. 33°10’49” N., Long. 97°18’05” W. C.P. to change coordinates as indicated above; add 37000 MHz and change distance in kilometers and azimuth toward Ft. Worth, Texas on azimuth 184°08’; change distance in kilometers and azimuth toward Grapevine, Texas to 115°08’; change distance in kilometers and azimuth toward Kennedale, Texas to 107°32’; change distance in kilometers and azimuth toward Adams, Texas to 71°46’.

1512-CF-MP-75, Same (WDD900), 3 miles SSE of Hawley, Pennsylvania. Lat. 41°27’01” N., Long. 76°07’49” W. Mod. C.P. to change polarization from Vertical to Horizontal at 11265, 11845, 11425, 11585 and 11586 MHz toward Bowland, Pennsylvania on azimuth 74°08’.

1513-CF-MP-MP-75, Same (WDD900), 3 miles SSE of Hawley, Pennsylvania. Lat. 41°27’01” N., Long. 76°07’49” W. Mod. C.P. to change polarization from Vertical to Horizontal at 11265, 11845, 11425, 11585 and 11586 MHz toward Bowland, Pennsylvania on azimuth 74°08’.

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FEDERAL REGISTER, VOL. 39, NO. 248 — TUESDAY, DECEMBER 24, 1974

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### American Telephone & Telegraph Co. (Call sign) vs. Station name

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FEDERAL REGISTER, VOL 39, NO. 240—TUESDAY, DECEMBER 24, 1974
### TABLE OF ALLOCATIONS FOR VHF AND UHF TELEVISION

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1. Limitation to protect CBUAT-2 Crawford Bay, B.C.
2. Limitation to protect CKSA-TV Lloydminster, Sack., and CHCT-TV Calgary, Alberta.
3. Limitation 18 dbk and 500 feet EHAAT.

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**FEDERAL COMMUNICATIONS COMMISSION,**

Secretary

**CANADIAN-U.S.A. TELEVISION AGREEMENT**

TABLE OF ALLOCATIONS FOR VHF AND UHF TELEVISION

(Declared by Province)

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1. Limitation to protect CBUAT-2 Crawford Bay, B.C.
2. Limitation to protect CKSA-TV Lloydminster, Sack., and CHCT-TV Calgary, Alberta.
3. Limitation 18 dbk and 500 feet EHAAT.
4. Limited Allocation

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L₁—Limitation to protect CHBC-TV-1, Penticton, B.C.
L₁—Limitation to protect CFCH-TV-1, Drumheller, Alberta.
L₁—Limitation to protect CHBC-TV-1, Salmon Arm, B.C.
L₁—Limitation to protect CHBC-TV-4, Salmon Arm, B.C.
L₁—Limitation of 8.9 kW ERP, 493 feet EHAATspecified directional pattern, to protect KCTS, Seattle, Wash.
L₁—1 kW ERP and 100 feet EHAAT.
L₁—Limitation to protect CJOC-TV-5, Burnaby, B.C., and 790 watts maximum ERP and 2,000 feet EHAAT.
L₁—Limitation to protect CJLC-TV-2, Burnaby, B.C., and 1,000 watts maximum ERP and 1,000 feet EHAAT.
L₁—Limitation to protect CBUT-2, Chilliwack, B.C., and CHBC-TV-1 Penticton, B.C.
L₁—Limitation to protect CHEK-TV, Victoria, B.C.
L₁—Limitation to protect CBUT-2, Chilliwack, B.C.
L₁—Limitation to protect CBUT-2, Chilliwack, B.C.
L₁—Limitation to protect CBUT-1, Penticton, B.C., and CBUAT-3, Crawford Bay, B.C.
L₁—Limitation to protect CBUT-2, Chilliwack, B.C.
L₁—Limitation to protect CBUT-2, Chilliwack, B.C.
L₁—Limitation to protect CBUT-2, Chilliwack, B.C.
L₁—Limitation to protect CBUT-2, Chilliwack, B.C.
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L₁—Limitation to protect CBUT-2, Chilliwack, B.C.
L₁—Limitation to protect CBUT-2, Chilliwack, B.C.
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<td>Winnipeg-St. Boniface</td>
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**L¹**—Limitation to protect CKX-TV-1, Foxwarren, Manitoba.  
**L²**—Limitation to protect CKBQ-TV, Melfort, Sask., and an allocation at Brandon, Manitoba.  
**L³**—Limitation to protect CKBL-TV-3, Greenwater Lake, Sask.  
**L⁴**—Limitation to be located no less than 170 miles from cochannel assignment at Grand Forks, North Dakota, with site coordinates 48°08'24" North Latitude, 97°59'28" West Longitude, and limited to 100 kilowatts maximum ERP and 1,000 feet EHAAT, or the equivalent, in the general direction of Grand Forks, North Dakota.  
**L⁵**—Limitation to protect CHSS-TV, Wynyard, Sask., CBWAT, Winnipeg, Manitoba, and an allocation at The Pas, Man.  
**L⁶**—Limitation to protect an allocation at Wynyard, Sask.  
**L⁷**—Limitation to protect 200 kW ERP 600 feet EHAAT to protect CBWAT-5, Red Lake, Ontario.  
**L⁸**—Limitation to protect CKX-TV-2, Melita, Manitoba, CBKRT, Regina, Saskatchewan, and an allocation at Winnipeg, Manitoba.  
**L⁹**—Limitation to protect CKSS-TV, Dauphin, Manitoba, and CBWAT, Kenora, Ontario.  
**L¹⁰**—Limitation to protect allocations at Dryden, Ontario, and Brandon, Manitoba.  
**L¹¹**—Limitation to protect CKX-TV, Brandon, Manitoba, and CBWCT, Fort Frances, Ontario.  
**L¹²**—Limitation to protect Channel 9 at Regina, Saskatchewan, and Channel 9 at Winnipeg, Manitoba.  
**L¹³**—Limitation to protect CKY-TV, Winnipeg, Manitoba, and CFSS-TV, Carlyle Lake, Saskatchewan.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
### NEW BRUNSWICK

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<tr>
<td>Campbellton</td>
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<tr>
<td>Upsalquitch Lake</td>
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L1—Limitation 18 dbk and 500 feet EHAAT and Toward Channel 7, CKRT-TV, Riviere du Loup, P.Q.
L2—Limitation to protect CJCH-TV, Halifax, Nova Scotia, CHAU-TV, Carleton (New Carlisle), Quebec, and WABI-TV, Bangor, Maine.
L3—Limitation to protect CHSJ-TV, Saint John, N.B., CFCM-TV, Quebec, P.Q., and a cochannel allocation at Ste. Anne des Monts, P.Q.
L4—Limitation to protect Channel 5, CJBR-TV, Rimouski, P.Q.
### NORTHWEST TERRITORIES

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### NOVA SCOTIA

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L1—Limitation 17.78 dbk and 500 feet EHAAT.
L2—Limitation to protect cochannel stations CBCT, Charlottetown, P.E.I. and WMD-7TV, Calais, Maine.
L3—Limitation to protect CHSJ-TV, Saint John, N.B., and CJCB-TV, Sydney, N.S.
L4—Limitation to protect Channel 11, CBART, Moncton, N.B.
L5—Limitation to protect CBHT, Halifax, N.S.

### ONTARIO

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FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
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<td>Sarnia</td>
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<td>Sault Ste. Marie</td>
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<td>Stratford</td>
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<td>Timmins</td>
<td>25 – 41 +</td>
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<td>Toronto</td>
<td>9 + 14 – 1</td>
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<td>22 – 4, 26 – 8</td>
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<td>Woodstock</td>
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<td>32 + 73</td>
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</table>

1. Limitation to protect cochannel assignment at Wiarton, Ontario. Limitation to protect WGR-TV, Buffalo, N.Y. Bancroft assignment to be located no less than 170 miles from WGR-TV.

2. - Limitation to protect CBFOT-2, Hearst, Ontario.

3. - Limitation to protect CBFOT, Timmins, Ontario.

4. - Limitation to protect CKSO-TV, Sudbury, Ontario.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
NOTICES

L1—Limitation to protect CFCL-TV-6, Chapleau, CBFOT-2, Hearst and CBFST, Sturgeon Falls.
L2—Limitation to protect WHEN-TV, Syracuse, New York.
L3—Limitation to protect CBFOT, Timmins, Ontario.
L4—Limitation to protect CBFOT-1, Kapuskasing, Ontario.

Approximate site locations:
- 43°15'35" North Latitude, 80°26'39" West Longitude.
- 42°23'40" North Latitude, 82°07'14" West Longitude.
- 42°27'00" North Latitude, 82°05'00" West Longitude.
- 43°21'00" North Latitude, 81°28'48" West Longitude.
- 43°06'00" North Latitude, 81°02'00" West Longitude.
- 42°57'15" North Latitude, 81°15'08" West Longitude.
- 42°08'00" North Latitude, 82°10'00" West Longitude.
- 42°17'42" North Latitude, 83°05'00" West Longitude.
- 42°09'09" North Latitude, 82°57'05" West Longitude.
- 42°08'28" North Latitude, 82°51'40" West Longitude.
- 43°15'35" North Latitude, 80°26'39" West Longitude.

PRINCE EDWARD ISLAND

Charlottetown, P.E.I.  8+, 13+  31 57  31
Summerside__  37 75  37

QUEBEC

Alma  48+, 74+, 80+
Asbestos...  53
Baie Comeau-Hauterive  29 57+, 79+
Baie St. Paul  73
Buckingham  63+
Chapais  11+ 4+  36 58  70
Chicoutimi-Arvilla  2+  36 70-, 82-
Clermont-La Malbaie  19- 41+
Coaticook  75-
Cowansville  75-
Dolbeau  75-
Donnacona  24+
Dorchester County  19- 41+  43-
Drummondville  22
Estcourt  75-
Forestville  22
Fox River  73-
Granby...
Hull (see Ottawa, Ontario)...
Jolliette...
Jonquiere-Kenogami  12+  14 20-, 30-, 42
Lac Etchemin...
Lac Mégantic  55+
La Tuque  42+
Magog...
Malartic  38
Manicouagan...
Marieville  43+
Matane  6+ 4+  24 49+
Mont Cluny...
Mont Joli...
Mont Laurier...
Mont Tremblant...
Montreal-Verdun...
Montmagny...
New Carlisle...
Normandin...
Perce...
Plattsburgh...
Port Alfred-Bagotville...
Quebec-Levis...

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
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<th>UHF channel No.</th>
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<tr>
<td>Rimouski</td>
<td>3</td>
<td>16, 51</td>
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<tr>
<td>Riviere du Loup</td>
<td>7</td>
<td>38, 71</td>
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<td>Roberval</td>
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<td>26</td>
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<td>Ste. Adele</td>
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<td>Ste. Anne des Monts</td>
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<td>Ste. Anne de la Pocatiere</td>
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<td>65</td>
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<td>St. Felicien</td>
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<td>St. Georges de Beauce</td>
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<td>St. Hyacinthe</td>
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<td>St. Jean-Baptiste</td>
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<td>Ste. Marguerite-Marie</td>
<td>2</td>
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<td>Sept-Res</td>
<td>3</td>
<td>L3, L4, L5, L7</td>
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<td>Shawinigan Falls</td>
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<td>14, 30, 50</td>
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<td>Verdun (see Montreal)</td>
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<td>Victoriaville</td>
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</table>

L1—Limitation to protect CHAU-TV, Carleton (New Carlisle).
L3—Limitation to protect CHCTV, Mont Laurier, Quebec.
L4—Limitation to protect CBOT, Ottawa, Ontario, and CFCM-TV, Quebec, P.Q.
L5—Limitation to protect CHSJ-TV-1, Bon Accord, N.B., and CJPM-TV, Chicoutimi, P.Q.
L6—Limitation ERP 1.25 dbk EHAAT 732 feet with specified antenna pattern.
L7—Limitation toward CKWS-TV, Kingston, Ont. and CBVT, Quebec, P.Q.
L8—Limitation toward Channel 2+, CHAUV-TV, Ste. Marie-de-l'île-Marie, P.Q.
L9—Limitation to protect CBFT, Montreal, Quebec, and CKRS-TV-2, Chicoutimi, Quebec, and Quebec City site to be located not less than 170 miles from WLBZ-TV, Channel 2, Bangor, Maine.
L10—Limitation to protect CKBR-TV-2, Huntsville, Ontario, CJSSTV, Cornwall, Ontario, and CJTG-TV, Lithium Mines, P.Q.
L11—Limitation toward Channel 2+, CKRS-TV-2, Chicoutimi, P.Q.
L12—Limitation to protect CJBR-TV, Rimouski, Quebec.
L13—Limitation to protect CBFT, Ottawa, Ontario, and WMUR-TV, Manchester, New Hampshire. Assignment to be located no less than 170 miles from WMUR-TV, Manchester, New Hampshire.
L14—Limitation 18 dbk and 560 feet EHAAT and specified radiation pattern.
### SASKATCHEWAN

<table>
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<tr>
<td>Caron</td>
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<td>Carlyle Lake</td>
<td>7 L1</td>
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<tr>
<td>Colgate</td>
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<td>Esteban</td>
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<tr>
<td>Regina</td>
<td>2, 9, 13</td>
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</table>

**Limitation**

- L1—Limitation 20 dbk and 500 feet EHAAT and toward CKMJ-TV, Marquis (Moose Jaw), Saskatchewan.
- L2—Limitation to protect CHAB-TV, Moose Jaw, Saskatchewan.
- L3—Limitation to protect Channel 10+, CKBI-TV-1, Alricane, Sask.
- L4—Limitation to protect CKMJ-TV, Channel 7+, Marquis, (Moose Jaw), Saskatchewan.
- L5—Limitation to protect Channel 5, CKOS-TV-3, Wynyard, Sask.
- L6—Limitation to protect CJFB-TV-3, Riverhurst, Saskatchewan.

### YUKON TERRITORY

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<td>Dawson</td>
<td>8, 12 + L1</td>
<td>31 + L1</td>
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<tr>
<td>Elsa</td>
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<td>14, 20</td>
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<td>Faro</td>
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<td>Keno Hill</td>
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<td>Mayo</td>
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<td>Watson Lake</td>
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<tr>
<td>Whitehorse</td>
<td>2 + 2</td>
<td>14, 20</td>
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</table>

**Limitation**

- L1—Limitation 20 dbk and 500 feet EHAAT and toward CKMJ-TV, Marquis (Moose Jaw), Saskatchewan.
- L2—Limitation to protect CHAB-TV, Moose Jaw, Saskatchewan.
- L3—Limitation to protect Channel 10+, CKBI-TV-1, Alricane, Sask.
- L4—Limitation to protect CKMJ-TV, Channel 7+, Marquis, (Moose Jaw), Saskatchewan.
- L5—Limitation to protect Channel 5, CKOS-TV-3, Wynyard, Sask.
- L6—Limitation to protect CJFB-TV-3, Riverhurst, Saskatchewan.
- L7—Limitation to protect Channel 12, CKCK-TV-1, Colgate, Saskatchewan, and an allocation at Swift Current, Sask.

**Wallace E. Johnson,**
Chief, Broadcast Bureau,
Federal Communications Commission.

[FR Doc. 74-20818 Filed 12-23-74: 8:45 am]
KENNEBEC WESTERN BROADCASTING CO. AND WILLSON BROADCASTING CO.

Application for Construction Permits

In re applications of Kennebec Western Broadcasting Company, Hanford, California; Requests: 103.7 MHz; Channel No. 279; 50 kW (H&V); 497.6 feet; Willson Broadcasting Company, Hanford, California; Requests: 103.7 MHz; Channel No. 279; 50 kW (H&V); 500 feet; For construction permits.

Accordingly, it is ordered, That, pursuant to section 309(d) of the Communications Act of 1934, as amended, the applications for consolidation with the following issues:

1. The Commission, by the Chief of the Broadcast Bureau, acting pursuant to delegated authority, has under consideration the two above-captioned applications which are mutually exclusive in that they seek the same channel in Hanford, California.

2. Both applicants request a waiver of § 73.210 of the Commission’s rules in order that they may locate the main studio of the proposed facility at the site of the tower and transmitter, outside of the city limits of Hanford. In light of the potential hazards that a tower would pose if located closer to Hanford, and thus within the area of the Lemoore Naval Air Station as well as other airports, and because of the demonstrated accessibility of the proposed site to the residents of the city of license, good cause has been established, and permission will be granted, to locate the main studio of the proposed facility outside of the city limits of Hanford, consistent with § 73.210 (a) (3) of the Commission’s rules.

3. 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 on the issues specified below.

4. 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 relative strengths of the proposals, with a comparative basis, better serve the public interest.

(2) To determine, in the light of the evidence adduced pursuant to the foregoing issues, whether a grant of the application would serve the public interest, convenience and necessity.

5. It is further ordered, That, the applicants having demonstrated that good cause exists for the location of the main studio outside the city limits of Hanford and that the location is consistent with operation of the station in the public interest, permission to so locate the main studio is granted.

6. It is further ordered, That, to avail themselves of the opportunity to be heard, the applicants herein, pursuant to § 1.221(e) of the Commission’s rules, in person or by attorney, shall, within 20 days of the mailing of this Order, file with the Commission in triplicate, a written appearance stating an intention to appear at the hearing and present evidence on the issues specified in this Order.

7. It is further ordered, That, the applicants herein shall, pursuant to section 311 (a) (2) of the Communications Act of 1934, as amended, and § 1.594 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 § 1.594(g) of the rules.

Adopted: December 8, 1974.

Released: December 13, 1974.

FEDERAL COMMUNICATIONS COMMISSION,

[seal]

WALLACE E. JOHNSON,

Chief, Broadcast Bureau.

[FR Doc.74-30078 Filed 12-23-74;8:45 am] STANDARD BROADCAST APPLICATION

Availability for Processing

The following application, seeking the facilities of station KAVE, Carlsbad, New Mexico, was accepted for filing on November 14, 1974. The former licensee of KAVE failed to file an application for renewal of its license, and the KAVE license expired on October 1, 1974. The Commission will accept any other applications for consolidation with the following application which proposes essentially the same facilities. The Commission will also entertain a request for joint interim operation by all interested and qualified applicants.

BP-18837, NEW, Carlsbad, New Mexico, Zia Telecommunications, Inc., Req: 1240 kHz, 250 W, 1 kW-LS, U.

Pursuant to the provisions of §§ 1.227 (b) (1) and 1.581(b) of the Commission’s rules, an application, in order to be considered with this application must be tendered no later than January 31, 1975. Any request for joint interim operation must be filed no later than March 5, 1975.

The attention of any party in interest desiring to file pleadings concerning this application, pursuant to section 309(d) (1) of the Communications Act of 1934, is directed to § 1.585(e) of the Commission’s rules for the provisions governing the time of filing and other requirements relating to such pleadings.

Adopted: December 17, 1974.

Released: December 18, 1974.

FEDERAL COMMUNICATIONS COMMISSION,

[seal]

VINCENT J. MULLINS,

Secretary.

[FR Doc.74-30077 Filed 12-23-74;8:45 am]

FEDERAL ENERGY ADMINISTRATION

ALLOCATION OF FEEDSTOCKS TO SYNTHETIC NATURAL GAS FACILITIES

Public Hearing

The Federal Energy Administration (FEA) hereby gives notice that public hearings will be held in accordance with the provisions of two Synthetic Natural Gas (SNG) manufacturers for assignment or adjustment of base period volumes under 10 CFR 211.29. Specific information on each petition is set forth in the Appendix to this notice.

Notice of these petitions was originally issued on October 25, 1974 and written comments regarding the petitions were solicited at that time. Fourteen comments from interested persons have been received and several of the comments contain requests that the FEA hold public hearings on individual petitions. In view of these requests and because the FEA believes that factual disputes between interested parties respecting these petitions are likely, the FEA has determined that public hearings on such petitions will materially advance consideration of the issues involved.

Therefore, a public hearing on the petitions set forth in the Appendix to this notice will be held beginning at 9:30 a.m. on January 7, 1975 in the Auditorium, Room 2105, at 2000 First Street, NW, Washington, D.C. 20036, in order to receive further comments from interested persons. Each petition set forth in the Appendix to this notice will receive separate consideration during the hearing.

Any person who has an interest in the petitions set forth in the Appendix to this notice or who is a representative of a group or class of persons which has an interest in the petitions, may make a written request for an opportunity to make oral presentation. Such a request should be directed to Executive Communications, FEA, Box BR, Room 3309, Federal Energy Building, 12th and Pennsylvania Avenue, NW, Washington, D.C. 20461, and must be received before 4:30 p.m., e.d.t., January 2, 1975. Such a request may be hand delivered to Room 3309, Federal Building, 12th and Pennsylvania Avenue, NW, Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Since the petitions set forth in the Appendix to this notice are to be considered separately, requests for an opportunity to make oral presentation should identify the petition or petitions to be addressed. The FEA will make every effort to prepare a concise summary of the proposed oral presentation and a telephone number where he may be contacted through January 3, 1975. Each person selected to be heard will be so notified by the FEA before 4:30 p.m.,
NOTICES

Executive Communications, FEA Room 3309, Federal Building, Washington, D.C. 20461, before 4:30 p.m., E.D.T., January 6, 1975. It should be emphasized that, in holding these hearings, the FEA intends to receive comments addressing the specific application of 10 CFR § 211.29 and Special Rule No. 1 thereunder to the individual petitions under consideration. Accordingly, persons requesting an opportunity to make an oral presentation should be prepared to provide information which is directed toward consideration of the criteria set forth in § 211.29 and Special Rule No. 1 with specific regard to the petitions set forth in the Appendix to this notice. General comments respecting the propriety or legality either of the Special Rule itself or of the FEA's policy regarding the use of petroleum feedstocks in the manufacture of SN0, except in the extent that such comments address the propriety or legality of application of the Special Rule in a specific instance, are not regarded as germane for the purpose of these hearings and are therefore discouraged.

The FEA reserves the right to select the persons to be heard at these hearings to schedule their respective presentations and to establish the procedures governing the conduct of the hearings. The length of each presentation may be limited, based on the number of persons requesting to present.

An FEA official will be designated to preside at the hearings. These will not be judicial or evidentiary-type hearings. Questions may be asked only by those conducting the hearings and there will be no cross-examination of persons presenting statements. Any decision made by the FEA with respect to the subject matter of the hearings will be based on all information available to the FEA. At the conclusion of all initial oral statements, each person who has made an oral statement will be given the opportunity, if he so desires, to make a rebuttal statement. The rebuttal statements will be given in the order in which the initial statements were made and will be subject to time limitations. Any interested person may submit questions, to be asked of any person making a statement at the hearings, to Executive Communications, FEA, before 4:30 p.m., E.D.T., January 6, 1975. Any person who makes an oral statement and who wishes to ask a question at the hearings may submit the question, in writing, to the presiding officer. The FEA or the presiding officer, if the question is submitted at the hearings, will determine whether the question is relevant, and whether time limitations permit it to be presented for answer.

Any further procedural rules needed for the proper conduct of the hearings will be announced by the presiding officer.

A transcript of the hearings will be made and the entire record of the hearings, including the transcript, will be retained by the FEA and made available for inspection at the Administrator's Reception Area of the FEA, Room 3400, The Federal Building, 12th and Pennsylvania Avenue, NW, Washington, D.C., between the hours of 8 a.m. and 4:30 p.m., Monday through Friday. Any person may purchase a copy of the transcript from the reporter.

Issued in Washington, D.C., December 18, 1974.

ROBERT E. MONTGOMERY, Jr., General Counsel.

APPENDIX

<table>
<thead>
<tr>
<th>Petitioner (specific chemical content)</th>
<th>Annual capacity (millions of cubic feet per day)</th>
<th>Assignment of adjustment of base (per volumerequested)</th>
<th>Supplier Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Columbia LNG Corp. Natural Gas Liquid, LPG, Naphtha.</td>
<td>250,837,000 bbls for each base period.</td>
<td>Dominion Petroleum, La Guerta, Ohio.</td>
<td>Complete.</td>
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<tr>
<td>Northern Illinois Gas Co. Liquid Petroleum gas, Natural gas liquids, Naphtha.</td>
<td>166,348,980 bbls for each base period.</td>
<td>UPG, Inc., ARCO, San Juan Oil Co.</td>
<td>Do.</td>
</tr>
</tbody>
</table>

SOUTHERN CALIFORNIA OUTER CONTINENTAL SHELF

Notice of Public Symposium

The Federal Energy Administration hereby announces that it will hold a public symposium in Los Angeles, California, on January 22 and 23, 1975, to examine issues and problems surrounding possible accelerated exploration and development of the Outer Continental Shelf (OCS) lying off the coast of Southern California. Representatives of industries, local and Federal Government officials, members of university staffs and members of the public have been selected to present views on various aspects of the subject. The public is invited to attend and to submit written views upon the issues. The symposium will be held in Room 8544, Federal Building, 300 N. Los Angeles Street, Los Angeles, California 90012, beginning at 9 a.m. on January 22, 1975.

Recent events have shown that undue reliance upon foreign oil imports has a severely unfavorable impact upon the United States' balance of trade and can constitute a threat to the national security and economy. One of the options to reduce this reliance upon imports is to increase domestic oil and gas production by further exploring and developing any resources that might exist on the Outer Continental Shelf.

The Federal Energy Administration (FEA) believes the option of exploring and developing the Outer Continental Shelf must be examined in all its facets with a complete airing of varying views. The Department of the Interior has issued a draft environmental statement concerning exploration and development of the OCS and will conduct public hearings in the near future regarding the draft statement. Those hearings are expected to develop in great detail the environmental considerations involved in exploring and developing the Outer Continental Shelf.

In view of the fact that environmental issues will be considered in the hearing of the Department of the Interior, the symposium commencing on January 22, 1975, to be conducted by the FEA will focus on the following listed issues:

(a) The place of the OCS in U.S. energy supply/demand balance.
(b) Operating conditions and technical constraints regarding operating on the OCS.
(c) Applicable laws, rules and regulations.
(d) Social impacts of OCS exploration and development.

The FEA encourages representatives of recognized regional groups, environmental and consumer organizations, officials of State and local governments, representatives of the oil, gas and chemical industries, and the general public to attend the symposium and to submit written comments on the above issues. Written comments should be submitted no later than February 7, 1975, and should be addressed to the Federal Energy Administration, Executive Communications, Box BS, 12th Street and Pennsylvania Avenue, NW, Washington, D.C. 20461.

PROCEDURE FOR THE SYMPOSIUM

Persons selected to address the symposium have been asked to limit their oral presentation to about twenty minutes. A few minutes for questions will be reserved at the end of each presentation. The symposium will be open to the public and to the press and other media. A complete record of the proceedings will be compiled and made available to the public in Room 3400, Administrator's Reception Area, between the hours of 8 a.m. and 4:30 p.m. daily.

Any questions concerning the symposium should be directed to the Office of Oil and Gas, 205-961-7478.

ROBERT E. MONTGOMERY, Jr., General Counsel.

DECEMBER 18, 1974.

[FR Doc. 74-29903 Filed 12-19-74; 11:12 am]

ALLOCATIONS OF OLD OIL

Availability of Reporting Forms

On December 10, 1974, the Federal Energy Administration mailed FEA Forms P-102-MO (Refiners Monthly Report) P-104-MO (Importers Monthly
FEA mailed copies of the reporting forms for November 1974 under FEA's Old Oil Entitlements Program:

- Firms listed in the Appendix to this notice believes that it qualifies as an eligible firm under the program, it should contact FEA at (202) 634-7610 to obtain copies of the appropriate reporting forms.

Issued in Washington, D.C., on December 19, 1974.

ROBERT E. MONTGOMERY, Jr., General Counsel, Federal Energy Administration.

APPENDIX

The following is a list of firms to which FEA mailed copies of the reporting forms for November 1974 under FEA's Old Oil Entitlements Program:

- Allied Materials Corporation
- Amerada Hess Corporation
- American Oil Company
- A. John Bruce, Inc.
- American Petrofina, Inc.
- APCC Oil Corporation
- Arizona Petroleum Corporation
- Ashland Oil Company
- Atlantic Richfield Company
- Bay Refining Company
- Bayou State Oil Corporation
- Beacon Oil Company
- Belcher Oil Company
- Blue Ridge Fuel Co., Inc.
- CRA-Parmindustries, Inc.
- Calumet Refining Company
- Canal Refining Company
- Caribou Four Corners Oil Co.
- Castle Coal & Oil Company, Inc.
- Central Petroleum Corporation
- C & H Refinery
- Champion Petroleum Company
- Charter International Oil Co.
- Circle Brothers Oil Company
- Cities Service Oil Company
- Clara Gasoline Company
- Clark Oil Refining Corporation
- Coastal States Gas Corporation
- Colonial Oil Company
- Colonial Oil Industries, Inc.
- Common wealth Oil Refining Co., Inc.
- Continental Oil Company
- Cross Oil & Refining Co. of AR
- Crown Central Petroleum Corporation
- Crystal Refining Company
- Crystal Oil Company
- Deepwater Oil Terminals, Inc.
- Delta Refining Company
- Diamond Shamrock Corporation
- Dinman Oil & Refining Co., Inc.
- Dorchester Gas Producing Co.
- Eastern of New Jersey, Inc.
- Eddy Refining Company
- Edgington Onond Refinery
- Elm City Filling Stations, Inc.
- Evangeline Refining Co., Inc.
- Exxen Corporation
- Famaries Oil & Refining Co.
- Edgington Oil Company
- Farnum Union Central Exchange
- Fletcher Oil & Refining Co.
- Flint Chemical Corporation
- Ford Neck Terminal Corp.
- Gary Operating Company
- George Hall Corporation
- Gettysburg Oil Co. of the U.S.
- Giant Industries Inc.
- Gladieux Refining Company
- Good Oil Corporation
- Golden Eagle Refining Co., Inc.
- Good Hope Refiners, Inc.
- Guam Oil & Refining Co., Inc.
- Gulf Oil Corporation
- Gulf States Oil & Ref. Co.
- H. M. Hartman Son, Inc.
- Hawaiian Independent Refinery, Inc.
- Howard Oil Company
- Howell Corporation
- Hunt Oil Corporation
- Husky Oil Company
- Indiana Farm Bureau Cooperatives Association.
- Irving Oil Corporation
- J. W. Refining, Inc.
- Jet Fuel Refinery
- The Kaiser Trading Co.
- Kentucky Oil & Refining Co.
- Kerr-McGee Corporation
- The King Service, Inc.
- Koch Refining Co.
- La Gloria Oil & Gas Company
- Lakeside Refining Co.
- Laketon Asphalt Refining, Inc.
- Little America Refining Co.
- Mackinac Island Refining Co., Inc.
- Marathon Oil Company
- Marion Corporation
- Meeman Oil Co., Inc.
- Mid-America Refining Co., Inc.
- Midland Cooperatives, Inc.
- Mid-Tex Refinery
- Mobil Oil Company
- Mohawk Petroleum Corporation
- Mountaineer Refining Co., Inc.
- Murphy Corporation
- National Cooperatives Refinery Association
- National Oil Recovery Corp.
- Navajo Refining Company
- New England Petroleum Corporation
- Newhall Refining Company, Inc.
- B. B. Newman Fuel Corporation
- North American Petroleum Corp.
- Northeast Petroleum Industries, Inc.
- Northern New Jersey Oil Company
- Northland Oil & Refining Co.
- Northville Industries Corporation
- Monsanto Company
- Morrison Petroleum Company
- Oil Shale Corporation
- Oriental Refining Company
- Pace Oil Company
- Paco Income Co.
- Patchogue Oil Terminal Corp.
- Patterson Fuel Oil Co., Inc.
- Pennzoil Company
- Petroleum Heat & Power Co., Inc.
- Stamford, Conn.
- Petroleum Heat & Power Co., Inc.
- Phila., Pa.
- Phillips Petroleum Company
- Pioneer Refining Company
- Pitkin Corp.
- Plateau, Incorporated
- Powerline Oil Company
- Pride Refining Incorporated
- Publicherk, Industries, Inc.
- Quaker State Oil Refining Corp.
- The Refinery Corporation
- Remington Oil Company, Inc.
- Rlo Petroleum Corporation
- Road Oil Sales, Inc.
- Rock Island Refining Corporation
- OKC Refining Incorporated
- Rockaway Fuel Oil Corporation
- Royal Petroleum Corporation
- Saber Petroleum Corporation
- Sage Creek Refining Company, Inc.
- San Joaquin Refining Co.
- Sears Oil Co. & Sears Petroleum & Transport Corp.
- Seminole Asphalt Refining Co.
- Shaheen Natural Resources Co.
- Shell Oil Company
- Signor Corporation
- Signal Companies, Inc.
- Somerset Refining Company
- Sound Refining Inc.
- Southern Terminal & Transport Co.
NOTICES

[Federal Register: 1974-25933]

CONSUMERS POWER CO.
Filing of Contract for Electric Service

DECEMBER 17, 1974.

Take notice that on December 9, 1974, Consumers Power Company (Consumers) tendered for filing with the Federal Power Commission a Contract for Electric Service with the Village of Union City, Michigan. The Contract, when it becomes effective under its terms, will cancel and supersede an earlier Contract between the same two parties, as amended, that has been in effect since October 19, 1965, and designated as FPC Rate Schedule No. 11. The rates to be charged under the new Contract are the same as those established by Commission Order in Docket No. E-7803 dated August 30, 1974. The new Contract increases the capacity reservation from 2000 kilowatts to 5000 kilowatts. Consumers states that this increase could affect the minimum charge established under the terms of the Contract, but is not expected to affect revenues actually collected by Consumers from the Village of Union City.

Consumers states that the proposed effective date of the new Contract will be "the date that the Company completes all work required to provide the reserve capacity of 5000 kw from its said 46,000/2400/4160 volt plant. Consumers estimates this completion to occur during the first week of January, 1975. Consumers states that copies of the filings were mailed to the Village of Union City and to the Michigan Public Service Commission.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Power Commission, 225 North Capitol Street, NE, Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's rules of practice and procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before December 31, 1974. Protestors will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

KENNETH F. PLUMS
Secretary

[FR Doc.74-29889 Filed 12-22-74;7:34 am]

[FR Doc.74-29888 Filed 12-23-74;8:45 am]
305(b) of the Federal Power Act, Applicant seeks authority to hold the following position:

President & Director, Ohio Electric Company, Public Utility.

Ohio Electric Company, whose principal office is located at 301 Cleveland Avenue, SW, Canton, Ohio 44702 owns and operates the General James M. Gavin Plant at Gallipolis, Ohio which, when completed, will have two 1300 megawatt generating units. All of Ohio Electric Company’s available electrical energy is sold to Ohio Power Company, of which it is a wholly owned subsidiary.

Any person desiring to be heard or to make any protest with reference to said application should on or before December 31, 1974, file with the Federal Power Commission, Washington, D.C. 20426, petitions to intervene or protests in accordance with the Commission’s rules of practice and procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to a proceeding. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission’s rules. The application is on file with the Commission and available for public inspection.

KENNETH F. PLUMB, Secretary.

[South Carolina Electric and Gas Co.]

Further Extension of Procedural Dates

December 17, 1974.

On December 10, 1974, Saluda River Electric Cooperative, Inc., filed a motion to extend the procedural dates fixed by order issued August 2, 1974, as most recently modified by notice issued October 29, 1974, in the above-designated matter. The motion states that the parties have been notified and have no objection.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of Counsel’s Testimony, December 30, 1974.

Further Extension of Procedural Dates

December 17, 1974.

On December 13, 1974, Southern Services, Inc., Alabama Power Company, Georgia Power Company, Gulf Power Company and Mississippi Power Company, the Cities of Acworth, et al., and the Water, Light and Sinking Fund Commission of the City of Dalton, Georgia, jointly filed a motion to extend the procedural dates fixed by order issued May 8, 1974, as most recently modified by notice issued November 19, 1974 in the above-designated matter. The motion states that Staff Counsel has no objection to the extension.

Upon consideration, notice is hereby given that the procedural dates in the above matter are modified as follows:

Service of Evidence by Intervenors, January 30, 1975.

Service of Evidence by Staff, February 20, 1975.


Hearing, March 17, 1975 (10 a.m. e.d.t.)

KENNETH F. PLUMB, Secretary.
Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street NE., Washington, D.C. 20426, in accordance with §§1.118 and 1.110 of the Commission's Rules of Practice and Procedure (18 CFR 12.6, 12.110). All such petitions on or before December 30, 1974. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

KENNETH F. PLUMB, Secretary.

FEDERAL RESERVE SYSTEM

AMERICAN BANCORP, INC.

Formation of Bank Holding Company

American Bancorp, Inc., Hammond, Indiana, 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 through acquisition of 80.25 percent or more of the voting shares of American State Bank, North Judson, Indiana. 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 office of the Board of Governors or at the Federal Reserve Bank of Chicago, pursuant to 12 CFR 225, 18 CFR 1.8, and 18 CFR 1.10. All such petitions on or before December 30, 1974, will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this application are on file with the Commission and are available for public inspection.

By order of the Board of Governors, effective December 16, 1974.

[SEAL] THEODORE E. ALLISON, Secretary of the Board.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974

NOTICES

FIRST MACOMB CORP.

Order Approving Formation of Bank Holding Company

First Macomb Corporation, Mount Clemens, Michigan, 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 through acquisition of 100 percent of the voting shares of the successor by merger to First Miss­issippi National Bank, Hattiesburg, Miss­issippi (“Bank”). The bank into which Bank is to be consolidated has no significance in accordance with section 3(b) of the Act. The time for filing comments and views has expired, and the Board has considered the application and all comments received in light of the factors set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant is a recently-organized corporate formation for the purpose of becoming a bank holding company through the acquisition of Bank. The proposed transaction essentially involves the transfer of control of Bank from individuals to a corporation owned by the same individuals. Bank holds deposits of approximately $91.5 million, representing 0.62 of one percent of the total deposits in commercial banks in the Detroit banking market, and ranks as the 20th largest of 45 banks operating in that market. Upon acquisition of Bank, Applicant would control less than 0.34 of one percent of the total commercial bank deposits in that market. Since the proposed transaction is essentially a reorganization of Bank’s ownership and Applicant presently has no subsidiaries, consideration of the proposal would not have an adverse effect on competition, nor would it increase the concentration of banking resources or have an adverse effect on other banks in any of the relevant areas. Therefore, the Board concludes that the competitive considerations are consistent with approval of the application.

The financial condition of Bank is considered generally satisfactory in view of Applicant’s success to date. Since the proposed transaction would be in the public interest and the future prospects of Applicant, which will depend on the managerial resources and future prospects of Bank, are considered generally satisfactory. Accordingly, the Board concludes that the acquisition of shares of Bank should be approved.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall not be made (a) before the thirtieth calendar day following the effective date of this Order, or (b) later than three months after the effective date of this Order, unless such period is extended for good cause by the Board, or by the Federal Reserve Bank of Chicago, pursuant to delegated authority.

1 All banking data are as of December 31, 1973.
2 The Detroit banking market is approximated by Macomb, Oakland, and Wayne Counties, Michigan.

FIRST MISSISSIPPI NATIONAL CORP.

Order Approving Formation of Bank Holding Company

First Mississippi National Corporation, Hattiesburg, Mississippi, 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 through acquisition of the voting shares of the successor by merger to First Miss­issippi National Bank, Hattiesburg, Miss­issippi (“Bank”). The bank into which Bank is to be merged has no significance, except as a means to facilitate the acquisition of the voting shares of Bank. Accordingly, the Board has concluded that the voting shares of the successor organization is treated herein as the proposed acquisition of the shares of Bank.

The factors that are considered in acting on the application, affording opportunity for interested persons to submit comments and views, has been given in accordance with section 3(b) of the Act. The time for filing comments and views has expired, and the Board has considered the application and all comments received, including those submitted by The People's Bank of Biloxi, Biloxi, Mississippi (“Protestant”), in light of the factors set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant is a recently-organized corporate formation for the purpose of becoming a bank holding company through the acquisition of Bank, which presently has no subsidiaries. Since the proposed transaction represents a shifting of Bank’s ownership from individuals to a corporation owned by the same individuals, consideration of the proposal would have no adverse effects on competition in any relevant area. Accordingly, the Board concludes that competitive considerations are consistent with approval of the application.

The managerial resources and future prospects of Applicant, which will depend on the financial condition of Bank, are considered generally satisfactory. Accordingly, the Board concludes that the acquisition of shares of Bank should be approved.

By order of the Board of Governors, effective December 16, 1974.

[SEAL] THEODORE E. ALLISON, Secretary of the Board.

FEDERAL REGISTER, VOL. 39, NO. 249—TUESDAY, DECEMBER 25, 1974

NOTICES

FIRST MACOMB CORP.

Order Approving Formation of Bank Holding Company

First Macomb Corporation, Mount Clemens, Michigan, 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 through acquisition of 100 percent of the voting shares of the successor by merger to First Miss­issippi National Bank, Hattiesburg, Miss­issippi (“Bank”). The bank into which Bank is to be merged has no significance, except as a means to facilitate the acquisition of the voting shares of Bank. Accordingly, the Board has concluded that the voting shares of the successor organization is treated herein as the proposed acquisition of the shares of Bank.

The factors that are considered in acting on the application, affording opportunity for interested persons to submit comments and views, has been given in accordance with section 3(b) of the Act. The time for filing comments and views has expired, and the Board has considered the application and all comments received, including those submitted by The People's Bank of Biloxi, Biloxi, Mississippi (“Protestant”), in light of the factors set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant is a recently-organized corporate formation for the purpose of becoming a bank holding company through the acquisition of Bank, which presently has no subsidiaries. Since the proposed transaction represents a shifting of Bank’s ownership from individuals to a corporation owned by the same individuals, consideration of the proposal would have no adverse effects on competition in any relevant area. Accordingly, the Board concludes that competitive considerations are consistent with approval of the application.

The managerial resources and future prospects of Applicant, which will depend on the financial condition of Bank, are considered generally satisfactory. Accordingly, the Board concludes that the acquisition of shares of Bank should be approved.

By order of the Board of Governors, effective December 16, 1974.

[SEAL] THEODORE E. ALLISON, Secretary of the Board.

FEDERAL REGISTER, VOL. 39, NO. 249—TUESDAY, DECEMBER 25, 1974

NOTICES
served will remain unchanged; however, such considerations are consistent with approval. It is the Board's judgment that consummation of the transaction would be in the public interest and that the application to acquire Bank should be approved.

At noted above, an objection was received to the proposed bank holding company formation. In acting on the present application, the Board has fully considered the arguments offered by the Pro-


testant as well as Applicant's response thereto. Protestant's main contentions appear to be as follows: (1) The close relation relevant State law to a holding company formed for the purpose of acquiring a bank in Mississippi being incorporated in the State of Delaware. According to the basis of the facts of record, the Board concludes that Pro-


testant raises no significant issues that would warrant denial of the application.

On the basis of the record, it is the Board's judgment that, although a corres-

pondent relationship does exist between the two banks, there is no substantial evidence to indicate that Deposit Guaranty controls or has a controlling influence over either Collier or ACA.

Under the provisions of section 2(g) of the Act, 10-year grandfather rights under section 2(g) be, and hereby is, obtained by NCNB in connection with its purchase of American Commercial Agency, Inc. ("ACA") and, further, notwithstanding that Collier is currently indebted to NCNB's subsidiary bank, North Carolina National Bank ("Bank"), and may borrow additional funds from Bank in the future, Bank has retained possession of all ACA shares sold by NCNB to Collier as security for indebtedness incurred by Collier to NCNB and Bank arising from the sale transaction and subsequent transactions of Collier to North Carolina National Bank ("Bank"). The Board finds, with approval of the application. Finally, above, that such factors are consistent with any instructions the Board may issue.

 Accordingly, it is ordered that NCNB's request for a determination pursuant to section 2(g) (3) be, and hereby is, granted.

By order of the Board of Governors, effective December 16, 1974.

[SEAL] Theodore E. Allison, Secretary of the Board.

[FR Doc.74-29914 Filed 12-23-74;8:45 am]

NCNB CORP.

Order Granting Determination Under Bank Holding Company Act

In the matter of the request by NCNB Corporation, Charlotte, North Carolina ("NCNB"), for a determination pursuant to section 2(g) (3) of the Bank Holding Company Act of 1956, as amended.

NCNB, a bank holding company formed for the purpose of acquiring a bank in Mississippi being incorporated in the State of Delaware. According to the basis of the facts of record, the Board concludes that Protestant raises no significant issues that would warrant denial of the application.

On the basis of the record, it is the Board's judgment that, although a correspondent relationship does exist between the two banks, there is no substantial evidence to indicate that Deposit Guaranty controls or has a controlling influence over either Collier or ACA.

Under the provisions of section 2(g) of the Act, 10-year grandfather rights under section 2(g) be, and hereby is, obtained by NCNB in connection with its purchase of American Commercial Agency, Inc. ("ACA") and, further, notwithstanding that Collier is currently indebted to NCNB's subsidiary bank, North Carolina National Bank ("Bank"), and may borrow additional funds from Bank in the future, Bank has retained possession of all ACA shares sold by NCNB to Collier as security for indebtedness incurred by Collier to NCNB and Bank arising from the sale transaction and subsequent transactions of Collier to North Carolina National Bank ("Bank"). The Board finds, with approval of the application. Finally, above, that such factors are consistent with any instructions the Board may issue.

Accordingly, it is ordered that NCNB's request for a determination pursuant to section 2(g) (3) be, and hereby is, granted.

By order of the Board of Governors, effective December 16, 1974.

[SEAL] Theodore E. Allison, Secretary of the Board.

[FR Doc.74-29914 Filed 12-23-74;8:45 am]

PENTAGON BANKSHARES, INC.

Order Denying Formation of Bank Holding Company

Pentagon Bankshares, Inc., Minneapolis, Minnesota, has applied for the formation of a bank holding company.

Voting for this action: Vice Chairman Mitchell, Governors Sheehan, Bucher, Holland, Wallich, and Coldwell. Absent and not voting: Chairman Burns.

Voting for this action: Vice Chairman Mitchell, Governors Sheehan, Bucher, Holland, Wallich, and Coldwell. Absent and not voting: Chairman Burns.

Voting for this action: Vice Chairman Mitchell, Governors Sheehan, Bucher, Holland, Wallich, and Coldwell. Absent and not voting: Chairman Burns.
Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) of formation of a bank holding company through acquisition of 87.4 percent of the voting shares of the State Bank of St. Anthony Village, St. Anthony Village, Minnesota ("Bank").

Notice of the application, affording opportunity for interested persons to submit comments and views, has been given in accordance with section 3(b) of the Act. The time for filing comments and views has expired, and the Board has considered the application and all comments received in light of the factors set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Applicant is a recently organized non-operating corporation, formed for the purpose of becoming a bank holding company through the acquisition of Bank. The purpose of the proposed transaction is to effect a transfer of ownership of Bank from individuals to a corporation owned by the same individuals with no change in the Bank's management. The deposits of Bank (deposits of $17.6 million) is the 27th largest of 103 banking organizations in the relevant banking market, controlling less than 3 of one percent of the total commercial bank deposits therein. (All banking data are as of December 31, 1973.) Since Applicant presently has no subsidiaries, consummation of the proposal would not have an adverse effect on existing or potential competition, nor would it increase the concentration of banking resources or have an adverse effect on other banks in the relevant market. Therefore, the Board concludes that the competitive considerations are consistent with approval of the application.

As it has indicated on previous occasions, the Board believes that a holding company should be a source of financial and managerial resources to its subsidiary bank(s) and every proposed acquisition or formation is closely examined with this consideration in mind. Regarding the subject proposal, the Board concludes that the financial and managerial resources of Applicant, in particular, the Board notes that Applicant proposes to service the debt that it will incur as a part of this transaction entirely through dividends from Bank. In the Board's view, the debt retirement program does not provide Applicant with the necessary financial flexibility to service the acquisition debt while maintaining Bank's capital at an acceptable level. Moreover, Bank has paid no dividends in recent years and the introduction of dividends at this time would place an undue strain on Bank's overall financial condition. Accordingly, on the basis of the foregoing and other facts of record, the Board concludes that the considerations relating to the managerial and financial aspects of Applicant's proposal weigh against approval of the application.

As noted above, the proposed formation represents merely a restructuring of the ownership of Bank with no significant changes in Bank's operations or the services offered to customers. Consequently, considerations relating to the convenience and needs of the community to be served lend no weight toward approval of the application. On the other hand, the servicing requirements of the acquisition debt incurred by Applicant could impair Bank's ability to continue to serve the community as a viable banking organization.

On the basis of all the facts in the record, the Board concludes that the financial considerations involved in this proposal present adverse circumstances bearing upon the financial condition and prospects of Applicant and Bank. These adverse factors are not outweighed by any procompetitive effects or benefits to the convenience and needs of the community. Accordingly, it is the Board's judgment that consummation of the proposal would not be in the public interest, and that the application should be, and is hereby, denied.

By order of the Board of Governors, effective December 16, 1974.

[Seal.]

THEODORE E. ALLISON
Secretary of the Board.

GENERAL ACCOUNTING OFFICE
REGULATORY REPORTS REVIEW
Notice of Receipt of Report Proposals

The following requests for clearance of reports intended for use in collecting information from the public were received by the Regulatory Reports Review Staff, GAO, on December 19, 1974. See 44 U.S.C. 3512(c) and (d). The purpose of publishing this list in the Federal Register is to inform the public of such receipt.

The list includes the title of each request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed TCC form are invited from all interested persons, organizations, public interest groups, and affected businesses. This proposed form is being reviewed expeditiously and a decision regarding approval is expected on or before January 7, 1975. Comments should be addressed to Mr. Monte Canfield, Jr., Director, Office of Special Programs, United States General Accounting Office, 425 I Street NW., Washington, D.C. 20548.

Further information about the items on this list may be obtained from the Regulatory Reports Review Officer, 202-376-5425.

INTERSTATE COMMERCE COMMISSION

Request for clearance of a new annual performance report to be filed by Household Goods Carriers with the Interstate Commerce Commission and furnished each prospective customer. The purpose of the report is to provide information to prospective customers which will permit them to intelligently compare the services of competing carriers. The requirement and data to be included in the report are specified in 49 CFR 1056.7(b). Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Regional Public Advisory Panel on Architectural and Engineering Services, Region I, January 18 and 19, 1975, from 9 a.m. to 4 p.m., Room 1250, Fritz G. Lanham Federal Building, 819 Taylor Street, Fort Worth, Texas. The meeting will be devoted to the initial step of the procedures for screening and evaluating the qualifications of architect-engineers under consideration for selection to furnish professional services for the proposed Federal Youth Center, Bastrop, Texas, Project NTX74997. Frank and open discussion of the proposals and qualifications of the firms being considered is essential to insure selection of the best qualified firms. Accordingly, pursuant to a determination that it will be concerned with a matter listed in 5 U.S.C. 552(b)(5) the meeting will not be open to the public.

L. N. STEWART,
Acting Regional Administrator.

GENERAL SERVICES ADMINISTRATION
REGIONAL PUBLIC ADVISORY PANEL ON ARCHITECTURAL AND ENGINEERING SERVICES

Notice of Meeting

December 6, 1974.

Pursuant to Pub. L. 92-463, notice is hereby given of a meeting of the Regional Public Advisory Panel on Architectural and Engineering Services, Region I, January 20, 1975 from 10 a.m. to noon, Room 711, John W. McCormack Post Office and Courthouse Building, Postoffice Square, Boston, Mass. 02109.
The meeting will be concerned with the review of the conceptual design for the proposed new Federal Office Building, New Haven, Connecticut. Frank and open critical analysis of the proposed design is essential to insure that the design approach produces the best possible design solution. Accordingly, pursuant to a determination that it will be concerned with a matter listed in 5 USC 552(b)(5) the meeting will not be open to the public.

ALBERT A. GAMMAL, JR.,
Regional Administrator.

Federal Register, Vol. 39, No. 248—Tuesday, December 24, 1974

NOTICES

AD HOC ADVISORY SUBCOMMITTEE TO REVIEW PROPOSALS FOR PARTICIPATION IN THE SCIENTIFIC DEFINITION OF SPACE SHUTTLE MISSIONS FOR SOLAR PHYSICS SPACELAB PAYLOADS

Notice of Meeting

The NASA Ad Hoc Advisory Subcommittee of the Space Science and Applications Steering Committee for review of proposals for participation in the scientific definition of Space Shuttle Missions for Solar Physics payloads will meet at the Goddard Space Flight Center in Greenbelt, Maryland on January 8, 9, and 10, 1975. The meetings will be held in Room 200 in Building 26 from 9 a.m. to 5 p.m.

The Subcommittee will discuss, evaluate and categorize proposals for participation on Facility Definition Teams which will define Space Shuttle Missions for Solar Physics Spacelab Payloads. Throughout the Subcommittee sessions, the professional qualifications of the proposers and their potential scientific contributions to the Facility Definition Teams will be candidly discussed and appraised. Discussion of these matters in a public session would invade the privacy of the proposers and the other individuals involved. The meeting will be closed to members of the public.

Since the Subcommittee session will be concerned throughout with matters listed in 5 U.S.C. 552(b)(6), it is hereby determined that the session will be closed to the public.

For further information please contact Dr. Adrienne F. Timothy at (202) 755-8400.

BOYD C. MYERS, II,
Assistant Associate Administrator for Organization and Management, National Aeronautics and Space Administration.

DECEMBER 10, 1974.

OFFICE OF MANAGEMENT AND BUDGET

ADVISORY COMMITTEE ON THE BALANCE OF PAYMENTS STATISTICS PRESENTATION

Notice of Meeting

The NASA Research and Technology Advisory Council, Committee on Energy Technology and Space Propulsion will meet January 19, 1975, at NASA Headquarters, 600 Independence Avenue, SW., Washington, D.C. The meeting will be held in Room 625. Members of the public will be admitted on a first-come, first-served basis, up to the seating capacity of the room which is about 40 persons. All visitors must register at the reception desk in Room 625.

The NASA Research and Technology Advisory Council, Committee on Energy Technology and Space Propulsion serves in an advisory capacity only. The Chairman is Dr. Beno Sternlicht, and there are 11 members. The following list sets forth the approved agenda and schedule for the January 10, 1975, meeting of the Committee on Energy Technology and Space Propulsion. For further information, please contact Mr. R. D. Ginter, Area Code 202, 755-8475, or Mr. W. H. Woodward, Area Code 202, 755-8501.

JANUARY 10, 1975

Time: Topie

8:30 a.m. Reports of working groups (Preliminary). Chairman of the four working groups listed below will report to the members on the status of the work being done by the respective groups: (1) power and propulsion, (2) NASA's terrestrial energy capabilities, (3) potential joint industry/NASA terrestrial energy projects, and (4) NASA surface propulsion technology. An opportunity will be provided for members to ask questions and to make comments. The discussions will be recorded. The work of the four working groups will be published in a report to be presented at the next meeting of the committee.

1 p.m. Discussion of issues raised by NASA (Purpose: To afford the opportunity for the committee to discuss issues regarding: (1) Early distribution of NASA research results to U.S. manufacturers, (2) workshops or seminars which would be useful to committees, (3) emphasis to be placed on particular technology problems, and (4) most fruitful potential areas of research to reduce aircraft fuel consumption.)

2 p.m. Future plans (Purpose: The committee chairman will review the outstanding actions to be taken by the working groups and will propose a tentative agenda and schedule for the next committee meeting.)

2:30 p.m. Adjournment.

BOYD C. MYERS, II
Assistant Associate Administrator for Organization and Management, National Aeronautics and Space Administration.

DECEMBER 18, 1974.

RESEARCH AND TECHNOLOGY ADVISORY COUNCIL, COMMITTEE ON ENERGY TECHNOLOGY AND SPACE PROPULSION

Notice of Meeting

The NASA Research and Technology Advisory Council, Committee on Energy Technology and Space Propulsion will meet January 19, 1975, at NASA Headquarters, 600 Independence Avenue, SW., Washington, D.C. The meeting will be held in Room 625. Members of the public will be admitted on a first-come, first-served basis, up to the seating capacity of the room which is about 40 persons. All visitors must register at the reception desk in Room 625.

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2:30 p.m. Adjournment.

BOYD C. MYERS, II
Assistant Associate Administrator for Organization and Management, National Aeronautics and Space Administration.

DECEMBER 18, 1974.

NOTICES

Office of Management and Budget

Advisory Committee on the Balance of Payments Statistics Presentation

Establishment

Determination pursuant to Executive Order 11769 (Advisory Committee Management) and Pub. L. 92–463 (Federal Advisory Committee Act).

The objectives and scope of the Advisory Committee on the Balance of Payments Statistics Presentation is to provide advice on improvements in the presentation of the balance of payments accounts, which are developed and published by the Department of Commerce, to facilitate a more meaningful interpretation of the U.S. balance of payments and to aid the government in formulating policy on balance of payments issues. Particular attention will be paid to the continued adequacy of the overall summary balances in reflecting pressures on the price of the dollar in international exchange markets.

It is determined that the Advisory Committee on the Balance of Payments Statistics Presentation is essential in providing assistance necessary to carry out my responsibilities under the Budget and Accounting Procedures Act of 1950, as amended, Executive Order No. 8248, September 1939 and Executive Order No. 10255, June 1951. It is also determined that the Advisory Committee on the Balance of Payments Statistics Presentation is in the public interest.

The Advisory Committee on the Balance of Payments Statistics Presentation will terminate on September 30, 1975 unless renewed prior to that date. The authority to make determinations as to the formation and utilization of an advisory committee pursuant to the Advisory Committee Act is hereby delegated to the Deputy Associate Director for Statistical Policy. This authority may be redelegated.


Roy L. Ash, Director.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974

CLEARANCE OF REPORTS

Lists of Requests

The following is a list of requests for clearance of reports intended for use in collecting information from the public made by the Office of Management and Budget on 12/19/74 (44 USC 3509).

The purpose of publishing this list in the Federal Register is to inform the public.

The list includes the title of each request received, the name of the agency sponsoring the proposed collection of information, the agency form number(s), if applicable; the frequency with which the information is proposed to be collected; the name of the reviewer or reviewing division within OMB, and an indication of who will be the respondents to the proposed collection.

The symbol (x) identifies proposals which appear to raise no significant issues, and are to be approved after brief notice thru this release.

Further information about the items on this daily list may be obtained from the Clearance Office, Office of Management and Budget, Washington, D.C. 20503, (202–395–4529), or from the reviewer listed.
**NOTICES**

**SECURITIES AND EXCHANGE COMMISSION**

[File No. 500-1]

I-T-E IMPERIAL CORP.

Notice Amending Notice of Suspension of Trading

**FR Doc. 74-29954 Filed 12-23-74; 8:45 am**

By the Commission.

**FR Doc. 74-29959 Filed 12-23-74; 8:45 am**

**POSTAL RATE COMMISSION**

**SAN ANTONIO, TEXAS**

Notice of Visit to Postal Facilities

**FR Doc. 74-30103 Filed 12-23-74; 8:45 am**

**EXECUTIVE OFFICE OF THE PRESIDENT**

Office of Management and Budget: Federal grant application award notification, annually, agencies applying for grant applications, Lowry, R. L., 395-3772.

Phillip D. Larsen, Budget and management officer.

**REGISTRATION OF FOREIGN INVESTMENT COMPANIES**

Request for Public Comments

Introduction. Recent years have seen a developing trend towards internationalization of the capital markets, including our own, together with a general policy favorable to the free flow of capital between nations. In view of these developments, the Commission is now considering various questions concerning foreign access to United States markets by foreign securities exchanges and the special rules adopted by them to channel substantial sums into securities of United States issuers through United States investment companies. In 1973, sales of United States open-end investment companies to foreigners aggregated $291.4 million. The foreigners were afforded the opportunity to invest their funds and, at the same time, provided the United States economy with a source for significant amounts of capital.

At the present time, foreign investment companies are restricted in their ability to attract United States investor interest. Although the concept of the investment company is well accepted in Europe and has spread from there to the United States and the other commercial nations of the world, most foreign investment companies are not now permitted to sell their securities in this country. For proprietary reasons they cannot, in any meaningful way, serve as an instrument for private United States investment in foreign securities or as a vehicle for foreign economic activities to obtain capital from private United States sources.

A foreign investment company must be registered under the Act in order to sell its shares in the United States, but such registration is permitted only if the Commission can make the special, and often difficult, findings called for by section 7(d) of the Act 11 U.S.C. 80a-7(d). As more fully discussed below, the United States participated in a conference of the Organisation for Economic Co-operation and Development ("OECD") which resulted in the development of certain rules for foreign investment companies and a recommendation, supported by the Commission, that member countries take those rules into account when considering their existing registration laws and policies for foreign investment companies.

In line with this action, the Commission believes it appropriate to consider the extent to which to which and should act to facilitate the registration under the Act of investment companies which are domiciled in countries which are members of the OECD and which comply with the rules it adopted. On the other hand, the Commission believes it should not encourage the registration of foreign investment companies under circumstances where necessary regulatory modifications would significantly lessen investor protection on offers for such companies with an uncompleted competitive advantage over United States investment companies. The Commission therefore seeks the assistance of the international financial community, interested agencies of the United States and foreign government, state regulatory authorities in the United States, and members of the See footnotes at end of document.
bar and the public generally, on the policy questions posed below. The Commission recognizes that many of these questions may also arise in the case of companies domiciled in non-OECD member countries. Accordingly, comments on these questions will be considered separate from any other submissions applicable to such companies may also be

Background. The statutory provisions. The Commission has previously permitted the registration of foreign investment companies to register under the Act and offer their securities in the United States. The only provisions of the Act specifically dealing with the Commission’s authority to permit a foreign investment company to register under the Act and publicly offer its securities in the United States are contained in section 7(d) of the Act (15 U.S.C. 80a-7(d)). Section 8(a) of the Act authorizes only a domestic investment company to register and section 7(d) prohibits a foreign investment company from registering the most or any instrumentality of interstate commerce to publicly offer its securities in the United States. However, section 7(d) also authorizes the Commission to permit a foreign investment company to register under the Act and make a public offering of its securities, but only:

* * * if the Commission finds that, by reason of special circumstances or arrangements made or practiced, the company is fairly effective to enforce the provisions of this Act against such company and that this company, under such arrangements, will cooperate fairly and effectively with the public interest and protection of investors.

This then is the statutory standard which section 7(d) requires the Commission to apply in considering the registration of a foreign investment company under the Act. However, section 6(c) (15 U.S.C. 80a-6(c)) of the Act empowers the Commission by rule or order to exempt a company completely from any provisions of the Act if and to the extent that such exemption is necessary or appropriate in the public interests and consistent with the protection of investors. The purposes intended by the policy and the provisions of the Act; and section 38(a) of the Act authorizes the Commission to make, issue, amend, and rescind such rules and regulations and such orders as are necessary or appropriate to the exercise of the power conferred upon the Commission elsewhere in the Act.

Rule 7d-1. In 1984, the Commission adopted Rule 7d-1 (17 CFR 270.7d-1) under the Act to enumerate the conditions and special arrangements to be entered into by Canadian management investment companies in order to permit them to obtain an order permitting registration. In announcing that it had under consideration the adoption of the rule, the Commission described the standards of the rule as special arrangements” formulated “"(1) in line with the policy of this government to facilitate and encourage foreign investments * * * and (2) after extended discussions with certain Canadian companies which had applied for registration. * * * *.

The Commission worked on a state:

The conditions and arrangements have been established in the light of the high degree of comity that has prevailed between this country and Canada, the existing treaties, the possibilities of the two countries sharing their joint heritage of the common law, and the essential similarity of statutes and law relating generally to corporations and the rights of stockholders. Accordingly, the rule is applicable only to Canadian management investment companies, and the arrangements proposed by investment companies organized under the laws of other foreign countries will be considered on a case by case basis in the light of the statutory standards.

The special arrangements specified in Rule 7d-1, generally speaking, provide that the charter and by-laws of the company contain the substantive provisions of the Act which the company must agree may be enforced as a matter of contract right in the United States or Canada by shareholders. At least a majority of the company’s officers and directors must agree to be citizens of the United States and a majority of each such majority must be residents of the United States. The officers and directors must also agree to cooperate fairly and effectively with the public interest and protection of investors.

In furtherance of this purpose the rule also requires the company to retain its assets in the United States and agree to the liquidation and distribution upon direction of the Commission, the courts, upon a finding of noncompliance by the company or its officers and directors with their agreements or the Commission’s order. The Commission indicated its belief that these provisions “in the over-all * * * will accord protection to investors. At least a majority of the officers and of the directors are required by the company or its officers and directors to agree to the terms of the order. The Commission has taken additional action looking to internationalization of the capital markets with respect to investment company securities. In 1972, representatives of the United States, including a representative of the Commission, participated in the deliberations of the OECD which led to the promulgation by that body of a set of "Standard Rules for the Operations of Institutions for Collective Investments" ("Standard Rules"). The Standard Rules are applicable only to Canadian companies, they have come to be used as guidelines in the consideration of applications of other foreign companies for permission to register.

The OECD rules. The Commission has taken additional action looking to internationalization of the capital markets with respect to investment company securities. In 1972, representatives of the United States, including a representative of the Commission, participated in the deliberations of the OECD which led to the promulgation by that body of a set of “Standard Rules for the Operations of Institutions for Collective Investments” ("Standard Rules"). The Standard Rules are applicable only to Canadian companies, they have come to be used as guidelines in the consideration of applications of other foreign companies for permission to register.

Sales abroad of securities of United States investment companies. The Commission has also taken action to facilitate the sales overseas of securities of United States investment companies. In its “Guidelines Concerning the Applicability of the Federal Securities Laws to the Sale and Sale Outside of the United States of Shares of Registered Investment Companies” ("Guidelines") promulgated on June 23, 1970 (Investment Company Act Release No. 6082), the Commission has included a provision to administer the Act in light of developments in foreign securities regulation and recent adoption of an OECD Code of proposed uniform standards for the regulation of investment companies.

The Commission supported these recommendations. Proposed legislation. Shortly thereafter, the Commission proposed enactment of the “Foreign Portfolio Sales Act of 1972.” The provision of that proposal would amend section 7(d) of the Act to authorize the Commission, in considering applications by a foreign investment company to register, to “take into account the differing laws, regulations, customs and business conditions of particular countries and the adequacy of existing regulations in such countries. The purpose of the suggested provision, as described by the Commission, is to:

* * * provide greater flexibility under section 7(d) of the Act in allowing registration of foreign investment companies under the Act.

In addition to the Act, the Commission proposed legislation to enable foreign investment companies to register under the Act and offer their securities in the United States. Among other things, the Guidelines made clear the

See footnotes at end of document.
Commission's view that the registration requirements of the Securities Act of 1933 apply to shares of a registered open-end investment company offered and sold outside the United States to foreign nationals and that the issuer should be required to meet the Standard Rules and which company should be kept in the United States unless the Commission finds that the foreign investment companies can be effectively subjected to the same type of regulation as domestic investment companies.

This objective has proven to be difficult to accomplish except in the case of some Canadian investment companies, which essentially are controlled by Americans. Many foreign investment companies find it difficult, if not impossible, to comply fully with the Act because of the requirements of foreign law and practice; other investment companies may be permitted to sell their shares in Germany. In addition, a number of United States companies have been permitted to sell their shares in Germany. In addition, a number of United States companies have been permitted to sell their shares in Germany. In addition, a number of United States companies have been permitted to sell their shares in Germany.
(b) How should they be measured and should such measurement take into account varying distances from the United States?

(c) If such additional costs should be borne by the registered foreign investment companies themselves, what procedure should be followed to assess and obtain payment of the additional costs and from whom should payment be obtained (e.g., as a class or otherwise)?

5. Could foreign-exchange problems adversely affect United States investors in the case of United States investors in foreign investment companies domiciled in non-OECD countries, and what, if any, regulatory standards would be needed in this regard?

6. Would the domestic investment company industry be unfairly disadvantaged if foreign investment companies were permitted to operate in the United States without being required to comply fully with the Act in essentially the same manner as domestic investment companies?

7. (a) If all registered investment companies, whether foreign or domestic, are required to meet essentially the same regulatory standards under the Act, what would prevent any investment company, domestic or foreign, from organizing or reorganizing under the laws of the foreign country whose investment companies registered under the Act are subject to the regulation deemed least restrictive?

(b) If such sanction were not prevented would not the quality of regulation tend to deteriorate?

(c) How can such action be prevented?

8. Should the Commission retain an application for registration by a foreign investment company even if it has had an operating history of not less than a specified period, say five years?

9. Did the flexible standard proposed for Section 7(d) of the Foreign Portfolio Sales Corporation Act (H.R. 8256, 93d Cong. 1st Sess.) provide adequate assurance that such foreign companies to which it applied would not discriminate in favor of United States investors?

10. If so, why? If not, how might the bill be changed to clarify the Commission’s authority?

11. (a) In the light of United States law and policy, particularly the policies of the National Banking Act of 1933 (the “Glass-Steagall Act”), which is generally interpreted to restrict bank participation in the management of an investment company, would it be in the public interest and consistent with the protection of investors if a United States bank permitted a foreign investment company to register under the Act and thereby to sell its shares in the United States?

(b) If so, how? If not, what would be changed to clarify the Commission’s authority?

12. (a) If all registered investment companies, whether foreign or domestic, are required to meet essentially the same regulatory standards under the Act, what would prevent any investment company domiciled in non-OECD countries from registering under the Act and offer their securities in the United States, in view of this possibility, comments and data and other information also may be submitted with respect to important questions from the respective of companies established in such other jurisdictions. Any such submissions should be made at the time and in the manner noted above.

By the Commission.

[Signature]

George A. Fitzsimmons, Secretary.

December 2, 1974.

(PDF Doc. 74-29632 Filed 12-23-74: 8:45 am)

Information concerning the meeting, including the procedures for submitting statements to the Group, may be obtained by contacting: Mr. Daniel J. Fitzsimmons, Secretary, Securities and Exchange Commission, 1750 Pennsylvania Avenue, NW., Suite 1207, Washington, D.C. 20549. Comments and data should be directed to George A. Fitzsimmons, Secretary, United States Securities and Exchange Commission, 1750 Pennsylvania Avenue, NW., Suit 1207, Washington, D.C. 20549. Comments and data may be submitted in writing, in electronic form, or orally.

NOTICES

PUBLIC MEETINGS

Notice of Public Meeting

Pursuant to section 10(a)(2) of the Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770, the Securities and Exchange Commission announces a public advisory committee meeting.

The Commission’s Report Coordinating Group (Advisory), will hold a meeting on January 17, 1975, at 55 Water Street, Twenty-third Floor, New York, New York. The meeting will commence at 10 a.m. local time and will be for the purpose of discussing the FOCUS Report of findings, reporting required information and the development of simplified trading forms and assessment forms.

The Group’s meetings are open to the public. Any interested person may attend and appear before or file statements with the advisory committee. Said statements, if in written form, may be filed before or after the meeting. Oral statements shall be made at the time and in the manner permitted by the Report Coordinating Group.

The Report Coordinating Group was formed to assist the Commission in developing a coherent, coordinated reporting system. In carrying out this objective, the Report Coordinating Group is to review all reports, forms and similar materials required of brokers-dealers by the Commission, the self-regulatory community and others. The Group is expected to advise the Commission on such matters as eliminating unnecessary duplication in reporting, reducing reporting requirements where feasible, and developing the FOCUS Report of financial and operational information. (Securities Exchange Act Release No. 10612; Securities Exchange Act Release No. 10698.)

Notice of Public Meeting

Public comments have been submitted to the Commission on this matter pursuant to the Commission’s invitation. (Securities Exchange Act Release No. 10694, February 8, 1974.)


In 1973, Congressman Harley O. Staggers introduced this proposed bill as H.R. 8256. No further action has been taken in the Congress and the bill is still pending.


At June 30, 1974, seven foreign companies with total net assets of about $650 million were registered under the Act. Of the seven registered, four are Canadian companies, one is a South African company, one is an Australian company, and one is an English company.

—Sec. 807, 71st Cong., 3rd Sess. (1940), 13; H.R. Rep. No. 2639, 70th Cong., 3rd Sess (1940). 13. The original bill which became the Investment Company Act, 1940, would have specified that no foreign investment company from making a public offering in the United States and would have prohibited any company to register. The change to the present language was made in committee for reasons that are entirely clear.

When used in the following questions, the term “foreign investment company” means a foreign investment company domiciled in the foreign country whose investment companies are registered under the Act. Only the following questions were intended to be covered under the Act. Of the seven registered, four are Canadian companies, one is a South African company, one is an Australian company, and one is an English company.

[FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974]

NOTICES

GOLD PURCHASING AND INVESTING

Recommendations

As of December 31, 1974 the Federal restrictions on the purchase, sale and ownership of gold will be lifted. The President's Special Assistant for Consumer Affairs, the Department of Justice, the Federal Trade Commission (FTC), the U.S. Postal Inspection Service and the Securities and Exchange Commission (SEC) have today issued the recommendations set forth below to prospective gold purchasers and investors.

The Department of Treasury recently announced that the U.S. Government will offer for sale 2 million ounces of gold in 400-ounce bars on January 6, 1975, at public auction. The Department will consider at a later date whether subsequent sales of gold would be appropriate.

As in the instance of other precious metals, investors and unsophisticated purchasers must often rely upon the representations of others and the integrity of the seller or promoter. Accordingly, it is recommended that purchasers and investors obtain as much information as possible about the companies and individuals with whom they are dealing. In other words, investigate before you invest.

Various Federal and State regulatory agencies will regulate gold trading. The SEC regulates public interstate offerings of gold and gold securities related to gold. Federal law prohibiting unfair or deceptive acts in interstate commerce is enforced by the FTC. Trading in gold commodity futures and transactions involving margin accounts and gold bullion and bulk gold coins will be regulated effective April 21, 1975 by the recently created Commodity Futures Trading Commission. Federal laws against securities and mail fraud will be enforced by the SEC, the Postal Inspection Service, and the Department of Justice. Justice Department has under way a major effort to detect and prosecute the growing number of frauds involving gold and other precious metals.

The purchase of and investment in gold is a potentially fertile area for unscrupulous promoters and fraudulent schemes. Moreover, the price of gold is oftentimes dictated by speculative interests rather than industrial supply and demand, and is subject to significant and rapid fluctuations.

Inquiries or complaints regarding unfair or deceptive trade practices, including false or misleading advertisements, should be addressed to the FTC's Division of Special Statutes, 7th Street and Pennsylvania Avenue NW., Washington, D.C. 20580. With respect to investment programs, prospective investors should first look up a prospectus or offering circular before making an investment decision. A copy of the prospectus may be reviewed at the public reference facilities maintained by the federal regulatory state securities agencies, and in the instance of registered interstate offerings or registered companies, at the public reference rooms of the SEC in Washington, D.C., New York City, Chicago and Los Angeles. To determine whether any particular company is registered with the SEC call or write the SEC, Public Reference Section, 500 North Capitol Street, Washington, D.C. 20549, (202) 553-5506. Information concerning buyer-investor experience with specific companies may be obtained from your nearest Better Business Bureau.

The following guidelines are suggested (but should not be considered to be all inclusive) before purchasing or investing in gold:

1. Be wary of unsolicited correspondence or calls from strangers offering to sell you gold or gold investments;
2. Be skeptical of promises of spectacular profits. Ask yourself why am I being offered this golden opportunity;
3. Resist pressures to make hurried, uninformed decisions;
4. Be suspicious of claims of new, secret or exotic processes to extract gold;
5. Secret processes promised to extract gold;
6. Consider the risks in relation to your own financial position and needs;
7. Find out if the company has registered with the SEC or state securities agency;
8. Attempt to determine the seller's mark-up (or how much it cost the seller to purchase the gold);
9. Ascertain what state costs, in addition to the quoted price of gold, are involved. For example, you may be required to pay a refining charge, assay fees, commissions, shipping and storage fees, insurance costs, and taxes;
10. Demand a written guarantee concerning weight and fineness (purity). Some gold bears a refiner's mark assaying its weight and fineness; however, there are no Federal standards;
11. Attempt to make your purchases through local reputable firms. (Firms including the term "Exchange" in their name should not be assumed to constitute an association or group of firms which provide a public market for buyers and sellers);
12. Obtain in writing the terms of your purchase, for example, when and how the gold will be delivered and stored, including what security precautions will be taken to insure that your gold is not shaved or that counterfeit gold is not substituted;
13. Ask whether the gold will be segregated and stored in your name (not the seller's or supplier's). Make sure you receive a written receipt showing that the requisite amount of gold is being stored for your account by a reputable concern; and
14. Ask whether there will be a ready market for the gold in the form being offered and whether you may have to have your gold re assayed, re cast into a different shape, size and/or transported to a distant market before you can sell it.

The areas which are fraught with the greatest potential for fraud are representations concerning the existence, amount and purity of gold, accuracy of assays and geological surveys and secret refining processes. Several schemes that appear to have already surfaced involve the following situations:

1. False mining claims were used to inflate a company's financial position and to tout its investment merit. Bogus or speculative geological surveys by a purported expert or misleading ore samples were used by the company as the basis for unwarranted high estimates of mineral value.
2. Purportedly large quantities of gold located outside of the United States and obtained from underdeveloped countries were being offered in the form of certificates of ownership through off-shore banks.
3. An unscrupulous assayer conspired with a seller to certify that bars of almost pure lead were pure gold.
4. Gold coins of low purity have been issued within the past year or two by small foreign entities. (The Certification Service of the American Numismatic Association, P.O. Box 87, Ben Franklin Station, Washington, D.C. 20044, will, for a fee, authenticate gold coins.)
5. Secret processes promised to extract gold from ore which had been previously labeled as worthless. Investors were induced to finance the construction of the secret-process machinery necessary for the production of the gold.

If you believe that you may have been the victim of a fraud, you should consult your attorney to determine what steps to take to assert and protect your rights. You should also communicate such information to any of the agencies listed above or to the Consumer Protection Division of the Attorney General's Office in your state or your State Securities Commissioner, and to your nearest local Better Business Bureau. Consider authorizing your attorney to inform the agencies of any problem that may arise. Although the agencies cannot intervene in your behalf or offer legal representation to obtain redress of your individual rights, your complaint may prevent others from being defrauded.

Remember, investigate before you make a purchase or investment.

By the Commission.

[FR Doc.74-30107 Filed 12-23-74; 8:45 am]

GEORGE A. FITZSIMMONS, Secretary.

December 9, 1974.
INTERSTATE COMMERCE COMMISSION

IRREGULAR-ROUTE MOTOR COMMON CARRIERS OF PROPERTY

Elimination of Gateway Letter Notices

DECEMBER 19, 1974.

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 1065). Notice thereof for convenience 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 January 3, 1975. A copy must also be served upon applicant or its representative. Protests against the elimination of such gateway will not be entertained 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.

No. MC 37203 (Sub-No. E7), (Correction), filed June 4, 1974, published in the FEDERAL REGISTER December 11, 1974. Applicant: MILLSTAD VAN LINES, INC., P.O. Drawer 878, Bartlesville, Okla. 74003. Applicant's representative: Thomas J. Sedberry, Suite 1102, Perry-Brooks Bldg., Austin, Tex. 78701. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Household goods, as defined by the Commission, between points in Wisconsin, on the one hand, and, on the other, points in Iowa, Minnesota, Nebraska, Kansas, Missouri, and Texas. The purpose of this filing is to eliminate the gateway indicated by asterisks above.

No. MC 61403 (Sub-No. E6), filed May 31, 1974. Applicant: THE MASON AND DIXON TANK LINES, INC., P.O. Box 969, Kingsport, Tenn. 37662. Applicant's representative: Charles E. Cox (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Chemicals, in bulk, in tank vehicles, between points in Georgia, on the one hand, and, on the other, points in Kentucky, Tennessee, and Texas. The purpose of this filing is to eliminate the gateway indicated by asterisks above.

No. MC 61403 (Sub-No. E8), filed May 31, 1974. Applicant: THE MASON AND DIXON TANK LINES, INC., P.O. Box 969, Kingsport, Tenn. 37662. Applicant's representative: Charles E. Cox (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Chemicals, in bulk, in tank vehicles, between points in Georgia, on the one hand, and, on the other, points in Kentucky, Tennessee, and Texas. The purpose of this filing is to eliminate the gateway indicated by asterisks above.

No. MC 61403 (Sub-No. E10), filed May 31, 1974. Applicant: THE MASON AND DIXON TANK LINES, INC., P.O. Box 969, Kingsport, Tenn. 37662. Applicant's representative: Charles E. Cox (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Chemicals, in bulk, in tank vehicles, between points in Georgia, on the one hand, and, on the other, points in Kentucky, Tennessee, and Texas. The purpose of this filing is to eliminate the gateway indicated by asterisks above.

No. MC 61403 (Sub-No. E11), filed May 31, 1974. Applicant: THE MASON AND DIXON TANK LINES, INC., P.O. Box 969, Kingsport, Tenn. 37662. Applicant's representative: Charles E. Cox (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Chemicals, in bulk, in tank vehicles, between points in Georgia, on the one hand, and, on the other, points in Kentucky, Tennessee, and Texas. The purpose of this filing is to eliminate the gateway indicated by asterisks above.

No. MC 61403 (Sub-No. E12), filed May 31, 1974. Applicant: THE MASON AND DIXON TANK LINES, INC., P.O. Box 969, Kingsport, Tenn. 37662. Applicant's representative: Charles E. Cox (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Chemicals, in bulk, in tank vehicles, between points in Georgia, on the one hand, and, on the other, points in Kentucky, Tennessee, and Texas. The purpose of this filing is to eliminate the gateway indicated by asterisks above.
on and west of U.S. Highway 321 (Kingsport, Tenn.). The purpose of this filing is to eliminate the gateways indicated by asterisks above.

No. MC 76168 (Sub-No. E18) (Correction), filed May 14, 1974, published in the FEDERAL REGISTER November 5, 1974. Applicant: SOUTHERN TRUCKING CORP., P.O. Box 7195, Memphis, Tenn. 38107. Applicant's representative: Fred F. Bradley, Frankfurt, Ky. 40601. Authority sought too perate as a common carrier, by motor vehicle, over irregular routes, transporting: Structural steel, steel piling, iron, steel, culverts, and contractors' equipment, wire, nails, roofing materials, and fabricated metal pipe, which are iron, steel, or steel products, between Greenville, Miss., on the one hand, and, on the other, points in Tennessee. The purpose of this filing is to eliminate the gateways of points in Arkansas and Memphis, Tenn. The purpose of this correction is to omit the restriction.

No. MC 76177 (Sub-No. E70), filed May 21, 1974. Applicant: BAGGETT TRANSPORTATION COMPANY, 2 South 32nd St., Birmingham, Ala. 35233. Applicant's representative: T. C. Sinclair (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Classes A and B explosives and blasting supplies, between points in Delaware, New Jersey, and points within 15 miles thereof. No. MC 76177 (Sub-No. E71), filed May 21, 1974. Applicant: BAGGETT TRANSPORTATION COMPANY, 2 South 32nd St., Birmingham, Ala. 35233. Applicant's representative: T. C. Sinclair (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Classes A and B explosives and blasting supplies, between points in New York and Pennsylvania, on the one hand, and, on the other, points in Tennessee. The purpose of this filing is to eliminate the gateways of points in Arkansas and Memphis, Tenn. The purpose of this filing is to eliminate the gateway of Carthage, Mo., and points within 15 miles thereof.

No. MC 76177 (Sub-No. E72), filed May 21, 1974. Applicant: BAGGETT TRANSPORTATION COMPANY, 2 South 32nd St., Birmingham, Ala. 35233. Applicant's representative: T. C. Sinclair (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Classes A and B explosives and blasting supplies, between points in New York and Pennsylvania, on the one hand, and, on the other, points in Tennessee. The purpose of this filing is to eliminate the gateways of points in Arkansas and Memphis, Tenn. The purpose of this filing is to eliminate the gateway of Carthage, Mo., and points within 15 miles thereof.

No. MC 76177 (Sub-No. E73), filed May 6, 1974. Applicant: BAGGETT TRANSPORTATION COMPANY, 2 South 32nd St., Birmingham, Ala. 35233. Applicant's representative: T. C. Sinclair (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Classes A and B explosives, and blasting supplies, from points in Maryland to points in Oklahoma. The purpose of this filing is to eliminate the gateways of (1) points in that part of Illinois, on the one hand, and, on the other, points in Colorado and Utah. The purpose of this filing is to eliminate the gateway of points in that part of Illinois, on the one hand, and, on the other, points in Colorado and Utah. The purpose of this filing is to eliminate the gateways of (1) Grafton, Ill., between Greenville, Miss., on the one hand, and, on the other, points in Colorado, Utah, and Wyoming. The purpose of this filing is to eliminate the gateway of Carthage, Mo., and points within 15 miles thereof.

No. MC 76177 (Sub-No. E74), filed May 6, 1974. Applicant: BAGGETT TRANSPORTATION COMPANY, 2 South 32nd St., Birmingham, Ala. 35233. Applicant's representative: T. C. Sinclair (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Classes A, B, and C explosives, and blasting supplies, from points in Alabama, Florida, and Mississippi to points in Nebraska. The purpose of this filing is to eliminate the gateway of the plant site of Trojan-U.S. Powder, division of Commercial Solvents Corporation, at or near Ordill, Ill.

No. MC 76177 (Sub-No. E81), filed May 6, 1974. Applicant: BAGGETT TRANSPORTATION COMPANY, 2 South 32nd St., Birmingham, Ala. 35233. Applicant's representative: T. C. Sinclair (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Classes A and B explosives, and blasting supplies, between points in Mississippi, on the one hand, and, on the other, points in Pennsylvania. The purpose of this filing is to eliminate the gateway of the plant site of Trojan-U.S. Powder, division of Commercial Solvents Corporation, at or near Ordill, Ill.

No. MC 76177 (Sub-No. E83), filed May 6, 1974. Applicant: BAGGETT TRANSPORTATION COMPANY, 2 South 32nd St., Birmingham, Ala. 35233. Applicant's representative: T. C. Sinclair (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Classes A and B explosives, and blasting supplies, from points in New Mexico, Texas, Louisiana, and Mississippi, on the one hand, and, on the other, points in Indiana. The purpose of this filing is to eliminate the gateway of points in that part of Illinois that are within 25 miles of Energy, Ill., and also within 15 miles of Wolf Lake, Ill.

No. MC 76177 (Sub-No. E87), filed May 6, 1974. Applicant: BAGGETT TRANSPORTATION COMPANY, 2 South 32nd Street, Birmingham, Ala. 35233. Applicant's representative: T. C. Sinclair (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Classes A and B explosives, and blasting supplies, from points in Colorado, Utah, and Wyoming to points in Tennessee. The purpose of this filing is to eliminate the gateway of points in that part of Illinois that are within 25 miles of Energy, Ill., and also within 15 miles of Wolf Lake, Ill.
Georgia, North Carolina, and South Carolina to points in Georgia, South Carolina, and North Carolina. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Broken and discarded vehicles, complete, knocked down, or in sections, and component parts, materials, supplies, and equipment when shipped with such buildings and components used in the erection, construction, and completion thereof, from points in South Dakota, Nebraska, and Kansas.

Applicant's representative: S. Truitt (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Prefabricated buildings, complete, knocked down, or in sections, and component parts, materials, supplies, and equipment when shipped with such buildings and components used in the erection, construction, and completion thereof, from points in South Dakota, Nebraska, and Kansas. The purpose of this filing is to correct the "E" number, previously published as E14.

Applicant: TRI-STATE MOTOR TRANSPORT CO., P.O. Box 113, Joplin, Mo. 64801. Applicant's representative: E. S. Gordon (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Source, special nuclear and byproducts materials, and radioactive materials, between points in Illinois, that part of Wisconsin on and east of a line between Neillsville and Robins, Thrusdale, New York, to points in Alabama and those parts of Missouri State line and extending along a line beginning at the Arkansas-Missouri State line and extending along the Henry County, Mo. branch of Union Pacific Railroad, to within 2 miles of the Missouri-Missouri State line.

Applicant: TRI-STATE MOTOR TRANSPORT CO., P.O. Box 113, Joplin, Mo. 64801. Applicant's representative: E. S. Gordon (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Source, special nuclear and byproducts materials, and radioactive materials, between points in Anderson and Roane Counties, Tenn., on the one hand, and, on the other, points in those parts of Illinois on and west of U.S. Highway 66, restricted to the transportation of traffic moving under Government bills of lading. The purpose of this filing is to eliminate the gateways of the facilities of the General Electric Co., located near Morris, Grundy County, Ill. The purpose of this correction is to omit the exception.
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No. MC 109397 (Sub-No. E9) (Correction), filed May 15, 1974, published in the Federal Register July 29, 1974. Applicant: TRI-STATE MOTOR TRANSPORT CO., P.O. Box 113, Joplin, Mo. 64801. Applicant's representative: E. S. Gordon (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Explosives, (1) from points in Arizona, Florida, Georgia, Louisiana, Mississippi, New Mexico, Texas, and that part of Tennessee on and west of U.S. Highway 27, to points in New Jersey; (2) from points in Florida, Georgia, Louisiana, Mississippi, New Mexico, Texas, and Pennsylvania, to points in Pennsylvania; (3) from points in Maryland and Virginia; and (4) from points in Georgia to points in Delaware, Maryland, and Virginia; and that part of Virginia on and east of U.S. Highway 15, and (1) Ammunition and explosives, and component parts of ammunition and explosives when moving in the same vehicle therewith (except such commodities which, because of size or weight, require the use of special equipment or special handling), from points in Clay and Duval Counties, Fla., to points in North Carolina, Delaware, Maryland, New Jersey, Pennsylvania, Virginia, and the District of Columbia. The purpose of this correction is to eliminate the gateway of the facilities of the General Electric Co., located near Morris, Grundy County, Ill. The purpose of this correction is to omit the exception.

No. MC 109397 (Sub-No. E10) (Correction), filed May 15, 1974, published in the Federal Register July 29, 1974. Applicant: TRI-STATE MOTOR TRANSPORT CO., P.O. Box 113, Joplin, Mo. 64801. Applicant's representative: E. S. Gordon (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Special, nuclear, radioactive, and byproduct materials, and radioactive materials, between points in Washington, Idaho, Oregon, Montana, Nevada, and California, on the one hand, and on the other, points in Illinois, restricted to the transportation of traffic under Government bills of lading. The purpose of this correction is to eliminate the gateway of the facilities of the General Electric Co., located near Morris, Grundy County, Ill. The purpose of this correction is to omit the exception.

No. MC 109397 (Sub-No. E38) (Correction), filed May 14, 1974, published in the Federal Register October 22, 1974. Applicant: TRI-STATE MOTOR TRANSPORT CO., P.O. Box 113, Joplin, Mo. 64801. Applicant's representative: E. S. Gordon (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Special, nuclear, radioactive, and byproduct materials, between the Nuclear Generating Stations located at or near Monticello, Minn., and Two Rivers, Wis., on the one hand, and, on the other, points in that part of South Carolina on and east of U.S. Highway 121, restricted to the transportation of traffic moving under Government bills of lading. The purpose of this filing is to eliminate the gateway of the facilities of the General Electric Co., located near Morris, Grundy County, Ill., and (2) Sheffield, Ill. The purpose of this correction is to omit the exception.

No. MC 111545 (Sub-No. E581) (Correction), filed May 26, 1974, published in the Federal Register September 11, 1974. Applicant: HOME TRANSPORTATION CO., INC., P.O. Box 6426, Station A, Marietta, Ga. 30062. Applicant's representative: Robert E. Born (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Prefabricated buildings, unmemblered from Florida points in Indiana, Massachusetts, and Ohio. The purpose of this filing is to eliminate the gateway of Marietta, Ga. The purpose of this correction is to clarify the territorial description.
No. MC 114211 (Sub-No. E177), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Cast iron pressure pipe (except pipe 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), fittings and accessories, therefore, when moving with such pipe, from points in that part of Michigan on, south and west of a line beginning at the Indiana-Michigan State line, thence along U.S. Highway 127 to junction Interstate Highway 96, thence along Interstate Highway 96 to Muskegon, that part of Indiana on and north of U.S. Highway 40, 40, to points in Idaho, Utah, and Arizona. The purpose of this filing is to eliminate the gateways of the plant site of Griffin Pipe Co., located at or near Council Bluffs, Iowa.

No. MC 114211 (Sub-No. E178), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Cast iron pressure pipe (except pipe 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), fittings and accessories, therefore, when moving with such pipe, from points in that part of Michigan on, south and west of a line beginning at the Indiana-Michigan State line, thence along U.S. Highway 127 to junction Interstate Highway 96, thence along Interstate Highway 96 to Muskegon, that part of Indiana on and north of U.S. Highway 40, 40, to points in Idaho, Utah, and Arizona. The purpose of this filing is to eliminate the gateways of the plant site of Griffin Pipe Co., located at or near Council Bluffs, Iowa.

No. MC 114211 (Sub-No. E179), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Agricultural machinery, implements, and parts thereof, as described in Appendix XII to the report in Descriptions in Motor Carrier Certificates, 61 M.C.C. 209, and farm tractors, from points in that part of Iowa on and north of Interstate Highway 70 at the Minnesota-Iowa State line, thence along U.S. Highway 71 to junction U.S. Highway 30, thence along U.S. Highway 30 to junction U.S. Highway 69, thence along U.S. Highway 69 to junction U.S. Highway 65, thence along U.S. Highway 65 to junction Iowa Highway 330, thence along Iowa Highway 330 to junction U.S. Highway 30, thence along U.S. Highway 30 to junction Iowa Highway 14, thence along Iowa Highway 14 to junction Iowa Highway 96, thence along Iowa Highway 96 to junction U.S. Highway 63, thence along U.S. Highway 63 to the Iowa-Minnesota State line, to points in Louisiana. The purpose of this filing is to eliminate the gateways of Des Moines, Iowa, points in that part of Missouri within 15 miles of Martin City, Kane, and Claremore, Okla.

No. MC 114211 (Sub-No. E180), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Farm machinery and parts thereof (except commodities which, because of size or weight, requires the use of special equipment and special handling, and those described in Mercer Extension-Oil Field Commodities, 74 M.C.C. 469), from points in that part of Iowa on and north of a line beginning at the Iowa-Minnesota State line, thence along U.S. Highway 63 to junction U.S. Highway 30, thence along U.S. Highway 30 to junction Iowa Highway 330, thence along Iowa Highway 330 to junction Interstate Highway 80, thence along Interstate Highway 80 to the Iowa-Nebraska State line, to points in that part of Nebraska on and south of Interstate Highway 80. The purpose of this filing is to eliminate the gateways of Council Bluffs, Iowa, and Omaha, Nebr.

No. MC 114211 (Sub-No. E181), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Building and machinery, from points in that part of Minnesota on and north of a line beginning at the South Dakota-Minnesota State line, thence along Minnesota Highway 5, thence along Minnesota Highway 5 to junction U.S. Highway 12, thence along U.S. Highway 12 to the Minnesota-Wisconsin State line, to points in Indiana, Kentucky, Ohio, West Virginia, Virginia, Maryland, Delaware, New Jersey, Pennsylvania, New York, Rhode Island, Connecticut, Massachusetts, Vermont, New Hampshire, Maine, and that part of Michigan on and south of Interstate Highway 96, and of the District of Columbia. The purpose of this filing is to eliminate the gateways of Minneapolis, Minn., and Horscon, Wis.

No. MC 114211 (Sub-No. E182), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Road building and machinery, from points in that part of North Dakota on and east of a line beginning at the International Boundary line between the United States and Canada, thence along North Dakota Highway 256 to junction U.S. Highway 63, thence along U.S. Highway 63 to junction U.S. Highway 52, thence along U.S. Highway 52 to junction North Dakota 3, thence along North Dakota 3 to the North Dakota-South Dakota State line, to points in Oklahoma and Texas. The purpose of this filing is to eliminate the gateways of Canton, S. Dak., and points in Kansas.

No. MC 114211 (Sub-No. E265), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Agricultural implements and machinery, tractors (except truck tractors), attachments and accessories therefor, and equipment designed for use with agricultural implements and machinery, and tractors, from the plant site and storage facilities of International Harvester Co., located at West Chicago, Ill., to points in Washington, Oregon, California, Nevada, Idaho, Utah, Wyoming, and Montana, restricted to the transportation of trucks and tractors of self-propelled vehicles designed as described in section 203(a)(13) of the Interstate Commerce Act and commodities moving in driveway service, equipment designed for use in conjunction therewith except tank semi-trailers, and parts and attachments for self-propelled vehicles and equipment designed for use in conjunction therewith. The purpose
of this filing is to eliminate the gateway of Minneapolis, Minn.

No. MC 114211 (Sub-No. E269), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant’s representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Cast iron pressure pipe and fittings and accessories therefor when moving with such pipe, from points in New York and that part of Pennsylvania on and north of a line beginning at Erie, thence along U.S. Highway 19 to junction U.S. Highway 6, thence along U.S. Highway 6 to junction U.S. Highway 11, thence along U.S. Highway 11 to junction Interstate Highway 380, thence along Interstate Highway 380 to junction Interstate Highway 80, thence along Interstate Highway 80 to the Pennsylvania-New Jersey State line, and in that part of New Jersey on and north of a line beginning at the Pennsylvania-New Jersey State line, thence along Interstate Highway 80 to junction Interstate Highway 280, thence along Interstate Highway 280, thence along U.S. Highway 90 to junction Interstate Highway 280, thence along Interstate Highway 280 to the International Boundary line, that part of Minnesota on and west of a line beginning at the Iowa-Minnesota State line, thence along U.S. Highway 59 to junction Minnesota Highway 7, thence along Minnesota Highway 7 to junction U.S. Highway 1, thence along U.S. Highway 1 to the Minnesota-South Dakota State line, that part of Texas on and west of a line beginning at the Oklahoma-Texas State line, thence along U.S. Highway 75 to junction Interstate Highway 35E, thence along Interstate Highway 35E to junction U.S. Highway 183, thence along U.S. Highway 183 to junction U.S. Highway 181, thence along U.S. Highway 181 to junction Texas Highway 72, thence along Texas Highway 72 to junction U.S. Highway 281, thence along U.S. Highway 281 to the International Boundary line between the United States and Mexico, and that part of Oklahoma on and west of a line beginning at the Kansas-Oklahoma State line, thence along U.S. Highway 75 to junction Interstate Highway 35E, thence along Interstate Highway 35E to junction U.S. Highway 183, thence along U.S. Highway 183 to junction U.S. Highway 69, thence along U.S. Highway 69 to junction U.S. Highway 75, thence along U.S. Highway 75 to the Oklahoma-Texas State line. The purpose of this filing is to eliminate the gateway of the plant site of the Griffin Pipe Co., located at or near Council Bluffs, Iowa.

No. MC 114211 (Sub-No. E270), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant’s representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Cast iron pressure pipe and fittings and accessories therefor when moving with such pipe, from points in New York and that part of Pennsylvania on and north of a line beginning at Erie, thence along U.S. Highway 19 to junction U.S. Highway 6, thence along U.S. Highway 6 to junction U.S. Highway 11, thence along U.S. Highway 11 to junction Interstate Highway 380, thence along Interstate Highway 380 to junction Interstate Highway 80, thence along Interstate Highway 80 to the Pennsylvania-New Jersey State line, and in that part of New Jersey on and north of a line beginning at the Pennsylvania-New Jersey State line, thence along Interstate Highway 80 to junction Interstate Highway 280, thence along Interstate Highway 280 to the International Boundary line, that part of Minnesota on and west of a line beginning at the Iowa-Minnesota State line, thence along U.S. Highway 59 to junction Minnesota Highway 7, thence along Minnesota Highway 7 to junction U.S. Highway 1, thence along U.S. Highway 1 to the Minnesota-South Dakota State line, that part of Texas on and west of a line beginning at the Oklahoma-Texas State line, thence along U.S. Highway 75 to junction Interstate Highway 35E, thence along Interstate Highway 35E to junction U.S. Highway 183, thence along U.S. Highway 183 to junction U.S. Highway 69, thence along U.S. Highway 69 to junction U.S. Highway 75, thence along U.S. Highway 75 to the Oklahoma-Texas State line. The purpose of this filing is to eliminate the gateway of the plant site of the Griffin Pipe Co., located at or near Council Bluffs, Iowa.

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TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant’s representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Farm tractors, road making machinery, and experimental farm tractors, between points in that part of Iowa on and east of a line beginning at the Minnesota-Iowa State line, thence along U.S. Highway 71 to junction Iowa Highway 141, thence along Iowa Highway 141 to junction Interstate Highway 90, thence along Interstate Highway 90 to junction U.S. Highway 61, thence along U.S. Highway 61 to the Missouri-Illinois State line, that part of Missouri on and east of a line beginning at the Illinois-Iowa State line, thence along U.S. Highway 67 to junction U.S. Highway 161, thence along U.S. Highway 161 to junction Oregon Highway 84, thence along U.S. Highway 84 to junction Interstate Highway 35, thence along Interstate Highway 35 to the International Boundary line between the United States and Mexico. The purpose of this filing is to eliminate the gateway of N. Dak.

TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant’s representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Farm equipment, implements, and parts thereof, excepting machinery, agricultural implements, and parts thereof, between points in that part of Iowa on and east of a line beginning at the Minnesota-Iowa State line, thence along U.S. Highway 71 to junction Iowa Highway 141, thence along Iowa Highway 141 to junction Interstate Highway 90, thence along Interstate Highway 90 to junction U.S. Highway 61, thence along U.S. Highway 61 to the Missouri-Illinois State line, that part of Missouri on and east of a line beginning at the Illinois-Iowa State line, thence along U.S. Highway 67 to junction U.S. Highway 161, thence along U.S. Highway 161 to junction Oregon Highway 84, thence along U.S. Highway 84 to junction Interstate Highway 35, thence along Interstate Highway 35 to the International Boundary line between the United States and Mexico. The purpose of this filing is to eliminate the gateway of N. Dak.
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5 to junction California Highway 99, thence along California Highway 99 to junction California Highway 58, thence along Interstate Highway 5 to junction Interstate Highway 14, thence along California Highway 14 to junction Interstate Highway 5, thence along Interstate Highway 5 to junction Interstate Highway 10, thence along California Highway 58 to junction Interstate Highway 170 to junction U.S. Highway 101, thence along U.S. Highway 101 to junction Interstate Highway 10, thence along Interstate Highway 10 to junction Interstate Highway 170 to junction U.S. Highway 101.

The purpose of this filing is to eliminate the gates of Des Moines, Iowa, and Kansas City, Mo.

No. MC 114211 (Sub-No. E284), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Agricultural shredders, agricultural sprayers, scalpers, row crop shields, corn cribs, knocked down, and attachments and parts for shredders, sprayers, scalpers, and corn cribs, when moving incidentally to and in the same vehicle with said commodities, from points in North Dakota to points in Indiana, Kentucky, Ohio, Pennsylvania, New York (except points in Kings, Queens, Nassau, and Suffolk Counties), that part of Michigan on and south of a line beginning at Lake Michigan, thence along U.S. Highway 10 to junction Michigan Highway 25, thence along Michigan Highway 25 to junction Michigan Highway 142, thence along Michigan Highway 142 to Lake Huron, and that part of Missouri on and east of U.S. Highway 65. The purpose of this filing is to eliminate the gateway of Olwein, Iowa.

No. MC 114211 (Sub-No. E285), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Agricultural shredders, agricultural sprayers, scalpers, row crop shields, corn cribs, knocked down, and attachments and parts for shredders, sprayers, scalpers, and corn cribs, when moving incidentally to and in the same vehicle with said commodities, from points in that part of Iowa on and west of U.S. Highway 59, to points in Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, Ohio, Pennsylvania, New Jersey, Delaware, Maryland, Ohio, West Virginia, Kentucky, Virginia, Tennessee, North Carolina, South Carolina, Louisiana, Mississippi, Alabama, Georgia, and Florida, and the District of Columbia, restricted to the transportation of self-propelled vehicles (except motor vehicles as defined in Section 203(a) (13) of the Interstate Commerce Act and commodities moving in driveway service), equipment designed for use in conjunction with self-propelled vehicles (except tank semitrailers), and parts and attachments therefore when moving with such pipe, from points in that part of Iowa on and west of U.S. Highway 59, to points in Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, Ohio, Pennsylvania, New Jersey, Delaware, Maryland, Ohio, West Virginia, Kentucky, Virginia, Tennessee, North Carolina, South Carolina, Louisiana, Mississippi, Alabama, Georgia, and Florida, and the District of Columbia, restricted to the transportation of self-propelled vehicles (except motor vehicles as defined in Section 203(a) (13) of the Interstate Commerce Act and commodities moving in driveway service), equipment designed for use in conjunction with self-propelled vehicles (except tank semitrailers), and parts and attachments therefore when moving with such pipe.

The purpose of this filing is to eliminate the gateway of Council Bluffs, Iowa.

No. MC 114211 (Sub-No. E288), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Agricultural shredders, agricultural sprayers, scalpers, row crop shields, corn cribs, knocked down, and attachments and parts for shredders, sprayers, scalpers, and corn cribs, when moving incidentally to and in the same vehicle with said commodities, from points in that part of the Upper Peninsula of Michigan on and south of a line beginning at the Illinois-Indiana State line, thence along Indiana Highway 32 to junction Indiana Highway 37, thence along Indiana Highway 37 to junction Indiana Highway 18, thence along Indiana Highway 18 to junction Indiana Highway 67, thence along Indiana Highway 67 to the Indiana-Ohio State line, and that part of Michigan on and south of a line beginning at the Illinois-Indiana State line, thence along Indiana Highway 32 to junction Indiana Highway 37, thence along Indiana Highway 37 to junction Indiana Highway 18, thence along Indiana Highway 18 to junction Indiana Highway 67, thence along Indiana Highway 67 to the Indiana-Ohio State line.

The purpose of this filing is to eliminate the gateway of Olwein, Iowa.

No. MC 114211 (Sub-No. E287), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Agricultural shredders, agricultural sprayers, scalpers, road crop shields, corn cribs, knocked down, and attachments and parts for said shredders, sprayers, scalpers, corn cribs, when moving incidentally to and in the same vehicle with said commodities, from points in that part of Iowa on and west of U.S. Highway 59, to points in Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, Ohio, Pennsylvania, New Jersey, Delaware, Maryland, Ohio, West Virginia, Kentucky, Virginia, Tennessee, North Carolina, South Carolina, Louisiana, Mississippi, Alabama, Georgia, and Florida, and the District of Columbia, restricted to the transportation of self-propelled vehicles (except motor vehicles as defined in Section 203(a) (13) of the Interstate Commerce Act and commodities moving in driveway service), equipment designed for use in conjunction with self-propelled vehicles (except tank semitrailers), and parts and attachments therefore when moving with such pipe, from points in that part of Iowa on and west of U.S. Highway 59, to points in Maine, Vermont, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, Ohio, Pennsylvania, New Jersey, Delaware, Maryland, Ohio, West Virginia, Kentucky, Virginia, Tennessee, North Carolina, South Carolina, Louisiana, Mississippi, Alabama, Georgia, and Florida, and the District of Columbia, restricted to the transportation of self-propelled vehicles (except motor vehicles as defined in Section 203(a) (13) of the Interstate Commerce Act and commodities moving in driveway service), equipment designed for use in conjunction with self-propelled vehicles (except tank semitrailers), and parts and attachments therefore when moving with such pipe.

The purpose of this filing is to eliminate the gateway of Olwein, Iowa.

No. MC 114211 (Sub-No. E289), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, Iowa 50704. Applicant's representative: Kenneth R. Nelson (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Agricultural shredders, agricultural sprayers, scalpers, row crop shields, corn cribs, knocked down, and attachments and parts for shredders, sprayers, scalpers, corn cribs, when moving incidentally to and in the same vehicle with said commodities, from points in that part of Iowa on and south of a line beginning at Lake Michigan, thence along U.S. Highway 10 to junction Michigan Highway 25, thence along Michigan Highway 25 to junction Michigan Highway 142, thence along Michigan Highway 142 to Lake Huron, and that part of Missouri on and east of U.S. Highway 65.
TRANSPORT, INC., P.O. Box 420, Water­
regular routes, transporting:
June 4, 1974. Applicant: WARREN
rally seeking to operate as a
No. MC 114211 (Sub-No. E288), filed
June 4, 1974. Applicant: WARREN
No. MC 114211 (Sub-No. E289), filed
June 4, 1974. Applicant: WARREN
No. MC 114211 (Sub-No. E289), filed
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TRANSPORT, INC., P.O. Box 420, Water­
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June 4, 1974. Applicant: WARREN
TRANSPORT, INC., P.O. Box 420, Water­
June 4, 1974. Applicant: TURNER
TRANSPORT, INC., P.O. Box 420, Water­
beside the points in New Mexico on and east of a line beginning at the Kansas-Nebraska State line and extending along Kansas Highway 27 to its junction with U.S. Highway 36, thence along U.S. Highway 36 to its junction with U.S. Highway 283. thence along U.S. Highway 283 to its junction with Kansas Highway 9, thence along Kansas Highway 9 to its junction with Kansas Highway 15, thence along Kansas Highway 15 to its junction with U.S. Highway 9, thence along U.S. Highway 77 to its junction with U.S. Highway 9, thence along U.S. Highway 9 to its junction with Kansas Highway 99, thence south 9 miles along Kansas Highway 99 to its junction with unnumbered highway, thence along unnumbered highway to its junction with Kansas Highway 9, thence along Kansas Highway 9 to its junction with U.S. Highway 75, thence along U.S. Highway 75 to its junction with Kansas Highway 16, thence along Kansas Highway 16 to its junction with U.S. Highway 9, thence along U.S. Highway 9 to its junction with U.S. Highway 160, thence along U.S. Highway 160 to its junction with unnumbered highway, thence along U.S. Highway 160 to its junction with U.S. Highway 83, thence along unnumbered highway to its junction with U.S. Highway 66 in and along U.S. Highway 66 in and around Oklahoma State line. The purpose of this filing is to eliminate the gateways of points in Oklahoma, Nebraska, and Missouri.

No. MC 115603 (Sub-No. E4), filed May 30, 1974. Applicant: TURNER BROS. TRUCKING CO., INC., P.O. Box 94626, Oklahoma City, Okla. 73109. Applicant's representative: Jack E. Turner (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Machinery, equipment, materials, and supplies incidental to, used in or in connection with, the discovery, development, production, refinement, manufacture, processing, storage, transmission, and distribution of natural gas and petroleum and their products and by-products, and machinery, materials, equipment, 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 (except the stringing or picking up of pipe in connection with main or trunk pipelines), between points in New Mexico, on the one hand, and, on the other, points in Arkansas. The purpose of this filing is to eliminate the gateway of points in Arkansas.

No. MC 115603 (Sub-No. E17), filed May 30, 1974. Applicant: TURNER BROS. TRUCKING CO., INC., P.O. Box 94626, Oklahoma City, Okla. 73109. Applicant's representative: Jack E. Turner (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Machinery, equipment, materials, and supplies incidental to, used in or in connection with, the discovery, development, production, refinement, manufacture, processing, storage, transmission, and distribution of natural gas and petroleum; and (2) Earth drilling machinery and equipment, and machinery, equipment, materials, and supplies incidental to, used in or in connection with (a) the transportation, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of holes or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or hole sites, and (d) the injection or removal of commodities into or from holes or wells drilled, on the one hand, and, on the other, points in New Mexico on and east of a line beginning at the New Mexico-Texas State line and extending along Interstate Highway 10 to its junction with U.S. Highway 82, thence along U.S. Highway 82 to its junction with U.S. Highway 54, thence along U.S. Highway 54 to its junction with New Mexico Highway 18, thence along New Mexico Highway 18 to its junction with U.S. Highway 87, thence along U.S. Highway 87 to the New Mexico-Colorado State line. The purpose of this filing is to eliminate the gateway of points in Oklahoma.

No. MC 115603 (Sub-No. E18), filed May 30, 1974. Applicant: TURNER BROS. TRUCKING CO., INC., P.O. Box 94626, Oklahoma City, Okla. 73109. Applicant's representative: Jack E. Turner (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Machinery, 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 (except the stringing or picking up of pipe in connection with main or trunk pipelines), between points in New Mexico, on the one hand, and, on the other, points in Oklahoma. The purpose of this filing is to eliminate the gateway of points in Oklahoma.

No. MC 115603 (Sub No. E19), filed May 30, 1974. Applicant: TURNER BROS. TRUCKING CO., INC., P.O. Box 94626, Oklahoma City, Okla. 73109. Applicant's representative: Jack E. Turner (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: (1) Machinery, equipment, materials, and supplies used in or in connection with, the discovery, development, production, refinement, manufacture, processing, storage, transmission, and distribution of natural gas and petroleum and their products and by-products, and machinery, materials, equipment, 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 (except the stringing or picking up of pipe in connection with main or trunk pipelines); (2) Machinery, equipment, materials, and supplies used in or in connection with the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, other than pipelines used for the transportation of natural gas and petroleum, their products, and by-products, water, or sewerage, restricted to the transportation of shipments moving to or from pipeline rights-of-way; and (3) Drilling machinery and equipment, and machinery, equipment, materials, supplies, and pipe incidental to, used in or in connection with (a) the transportation, installation, removal, operation, repair, servicing, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of holes or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or hole sites, and (d) the injection or removal of commodities into or from holes or wells, between points in New Mexico.
on the one hand, and, on the other, Mississippi. The purpose of this filing is to eliminate the gateway of points in Oklahoma.

No. MC 115603 (Sub-No. E20), filed May 30, 1974. Applicant: TURNER BROS. TRUCKING CO., INC., P.O. Box 94626, Oklahoma City, Okla. 73109. Applicant's representative: Jack E. Turner (same as above). Authority sought to operate as a common carrier, for the transportation of commodities into or from well or hole sites, and (d) the injection or removal of commodities into or from well or hole sites, and (c) the production, storage, transmission, and distribution of natural gas and petroleum and their products and by-products, and machinery, material, equipment, and supplies used in or in connection with the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, other than pipelines used for the transportation of shipments moving to or from pipeline rights-of-way: (3) Earth drilling machinery and equipment, and machinery, equipment, materials, and supplies used in or in connection with the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, other than pipelines used for the transportation of shipments moving to or from pipeline rights-of-way: (3) Earth drilling machinery and equipment, and machinery, equipment, materials, and supplies used in or in connection with (a) the transportation, installation, removal, operation, repair, servicing, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of wells or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or well site along wagon line beginning at Shell Beach on the Gulf of Mexico and extending along U.S. Highway 61 to its junction with Louisiana Highway 39, thence along Louisiana Highway 39 to its junction with Interstate Highway 10, thence along Interstate Highway 10 to its junction with U.S. Highway 61, thence along U.S. Highway 61 to the Louisiana-Mississippi State line. The purpose of this filing is to eliminate the gateway of points in Oklahoma and Texas.

No. MC 115603 (Sub-No. E30), filed May 30, 1974. Applicant: TURNER BROS. TRUCKING CO., INC., P.O. Box 94626, Oklahoma City, Okla. 73109. Applicant's representative: Jack E. Turner (same as above). Authority sought to operate as a common carrier, for the transportation of commodities into or from well or hole sites, and (d) the injection or removal of commodities into or from well or hole sites, and (c) the production, storage, transmission, and distribution of natural gas and petroleum and their products and by-products, and machinery, material, equipment, and supplies used in or in connection with the construction, operation, repair, servicing, maintenance, and dismantling of pipelines, other than pipelines used for the transportation of shipments moving to or from pipeline rights-of-way: (3) Earth drilling machinery and equipment, and machinery, equipment, materials, and supplies used in or in connection with (a) the transportation, installation, removal, operation, repair, servicing, maintenance, and dismantling of drilling machinery and equipment, (b) the completion of wells or wells drilled, (c) the production, storage, and transmission of commodities resulting from drilling operations at well or well site along wagon line beginning at Shell Beach on the Gulf of Mexico and extending along U.S. Highway 61 to its junction with Louisiana Highway 39, thence along Louisiana Highway 39 to its junction with Interstate Highway 10, thence along Interstate Highway 10 to its junction with U.S. Highway 61, thence along U.S. Highway 61 to the Louisiana-Mississippi State line. The purpose of this filing is to eliminate the gateway of points in Oklahoma and Texas.

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and junction Ohio Highway 30 and unnumbered Ohio Highway, thence west over unnumbered Ohio Highway through Overton to junction unnumbered Ohio Highway and Ohio Highway 539, thence north over Ohio Highway 539 to junction Ohio Highway 539 and Ohio Highway 604, thence west over Ohio Highway 604 to junction Ohio Highway 604 and Ohio Highway 302, thence west over Ohio Highway 302 to junction U.S. Highway 250, thence north over U.S. Highway 250 and Ohio Highway 262, thence west over Ohio Highway 162 to junction Ohio Highway 162 and Ohio Highway 19, thence north over Ohio Highway 162 to Green Springs and junction Ohio Highway 19 and unnumbered Ohio Highway, thence east over unnumbered Ohio Highway to junction unnumbered Ohio Highway and Ohio Highway 101, thence north over Ohio Highway 101 and Ohio Highway 269, thence north over Ohio Highway 269 to Castalia and junction Ohio Highway 269 and unnumbered Ohio Highway, thence east over unnumbered Ohio Highway to junction unnumbered Ohio Highway and Ohio Highway 4, thence over Ohio Highway 4 to Sandusky and Lake Erie. The purpose of this filing is to eliminate the gateways of Philadelphia, Hershey, Elizabethtown, and Lititz, Pa., and Dover, Del. The purpose of this correction is to correct the route description.

By the Commission.

[SEAL] Robert L. Oswald, Secretary.


LEASE AND INTERCHANGE OF VEHICLES BY MOTOR CARRIERS

DECEMBER 19, 1974.

At a session of the Interstate Commerce Commission, Motor Carrier Leasing Board, held at its office in Washington, D.C. on the 17th day of December 1974.

It appearing, that a petition has been filed by Akers Motor Lines, Inc. (MC 72464 and various subs) and Northern Freight Lines, Inc. (MC 31675 and four subs), under temporary common control, for waiver of paragraphs (a)(3) and (c) of §1057.4 of the lease and interchange of vehicles regulations (49 CFR 1057), concerning equipment leased between petitioner;

It further appearing, That petitioners have a jointly administered program applying the same standards of inspection and maintenance to equipment in accordance with the motor carrier safety regulations of the U.S. Department of Transportation;

It further appearing, That the U.S. Department of Transportation offers no objection to the petition in view of the fact that there is no significant adverse information regarding petitioners' past safety inspection and maintenance programs and the fact that the current safety program is unified and controlled, conducted, and administered by petitioner Akers;

It is ordered, That a waiver of paragraph (a)(3) and (c) of §1057.4, be, and it is hereby granted, provided that the equipment is inspected on the day it is to be leased and found to meet the requirements of the safety regulations of the U.S. Department of Transportation and that petitioners remain in satisfactory compliance with these regulations and under common control.

By the Commission, Motor Carrier Leasing Board.

[SEAL] Robert L. Oswald, Secretary.


TEMPORARY AUTHORITY TERMINATION

The temporary authorities granted in the dockets listed below have expired as a result of final action either granting or denying the issuance of a certificate on permit in a corresponding application for permanent authority, on the date indicated below:

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<td>Mobile Home Express, Inc., MC-12777 Sub-18</td>
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[SEAL] Robert L. Oswald, Secretary.

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PUBLIC INFORMATION

The Commissioner of Food and Drugs issued a notice of proposed rulemaking, published in the Federal Register, Vol. 39, No. 248 (FR 8120), on the disclosure of information to the public in conformity with Public Law 90-487, revised by Public Law 90-23, the public information law of the Administrative Procedure Act, known commonly as the "Freedom of Information Act."

The Commissioner received a total of 667 letters, 68 of which made substantive comments on one or more sections of the proposal. These letters were from individuals, consumer groups, nonprofit institutions and associations, trade associations, and representatives of companies subject to regulation under the laws administered by the Food and Drug Administration.

The bulk of the comments, mainly from individuals and trade associations, were in favor of the release of more or all information in government files to all who want to review it.

A small number of comments opposed in general any liberalization of disclosure policies on the ground that this posed a threat to free enterprise.

Most of the letters making substantive comments were concerned with various specific provisions of the regulations and contained recommendations for changes. These comments and recommendations and the Commissioner's conclusions concerning them are set out below.

The proposed regulations have been implemented since they were published except in a few minor respects. The Commissioner concluded not to issue final regulations immediately after the time for public comment on the proposal had expired, in order to gain experience under the proposal and because of pending litigation on the scope of the trade secrets exemption. Substantial experience has been gained under the proposal, and the preamble and final regulations cover all of the types of issues that have arisen in the intervening 2 years. The pending litigation, "Morgan v. FDA," 465 F.2d 173 (D.C. Cir. 1974), has been concluded. Accordingly, the Commissioner concludes that it is appropriate to issue these final regulations governing the handling of all public information requests by the Food and Drug Administration.

GENERAL POLICY AND ORGANIZATION OF THE FINAL REGULATIONS

1. When the proposed regulations were first published in May 1972, they represented a major change from prior agency policy. Whereas the agency formerly retained roughly 90 percent of the records in its files as confidential and disclosed only 10 percent, during the past 2 years it has reversed this proportion and now makes available roughly 90 percent of the records in its files.

2. The proposed regulations were divided into two different types of provisions. The general provisions relating to procedure, fees, exemptions, and some specific categories of agency records were included in Part 4 of Title 21 of the Code of Federal Regulations. Specific provisions relating to documents that are already the subject of regulations in other parts of Title 21 of the Code of Federal Regulations were incorporated directly into those other parts, such as the provisions dealing specifically with those types of documents.

3. The Commissioner has also concluded that the more general provisions in Part 4 require reorganization in order to group together the provisions that more closely relate to each other and to make these regulations more readable and understandable. Accordingly, Part 4 has been divided into six subparts, dealing with official testimony and information, general policy, procedures and fees, exemptions, limitations on exemptions, and the availability of specific types of documents for which requests are frequently made.

FREEDOM OF INFORMATION ACT AMENDMENTS

3. In October 1974 Congress passed H.R. 12471, the Freedom of Information Act amendments, to revise and add to a number of the existing provisions of the Freedom of Information Act. On October 17, 1974, the President vetoed this bill. On November 20 and 21, 1974, Congress voted to override the President's veto. The new amendments become effective 20 days after enactment, i.e., on February 19, 1975.

The Commissioner notes that, the concerns expressed by the President in his veto message are not applicable to the types of records contained in Food and Drug Administration files. Many of the provisions in the amendments reflect recommendations made earlier by the Administrative Conference of the United States. The Conference had been considering an exemption in existing case law, in the regulations of the Department of Health, Education, and Welfare, and in the proposed Food and Drug Administration regulations published in May 1972. Accordingly, the Food and Drug Administration has closely followed the legislative progress of these amendments in preparing these final regulations so that the regulations would fully implement the new amendments. The Commissioner has carefully considered the final regulations published in this order, in the light of the congressional policy established in the amendments, and concludes that they meet both the spirit and the letter of the amended law.

GENERAL COMMENTS

4. Comments contended that the open disclosure policy set out in the proposed regulations published in May 1972 would increase product liability and other litigation problems for companies.

The Commissioner advises that the question of whether this type of litigation would increase or decrease is not a factor to be considered in determining the disclosure of information to the public under the Freedom of Information Act.

5. Comments contended that many Food and Drug Administration records and documents should not be disclosed because they could be distorted, misconstrued, and quoted out of context. The Commissioner realizes that all published information contains errors and biases. This is, however, not a reason for declining to comply with the requirements of the Freedom of Information Act.

6. One comment stated that, in the scientific world, the ability to publish an article containing data that have not previously been made available is a definite advantage. It was contended that those who create the data have a right to, and the public has a right to, a prior disclosure of such data by the Food and Drug Administration. The Commissioner concludes that, once disclosable data have been submitted to the Food and Drug Administration, they will be disclosed to the public upon request. Before any voluntary submission of unpublished scientific information to the Food and Drug Administration, the agency submitting it will have the opportunity to obtain an opinion from the agency under the procedure established in 14.44 of the regulations as to whether it will be disclosed to the public or whether it will be subject to an exemption from disclosure and thus will not be available for public disclosure.
The Freedom of Information Act contains no exemption permitting the Food and Drug Administration to withhold data. In its public disclosure of the facts, the agency must consider the public's right to know, as laid out in these final regulations, it will be disclosed at once. If the matter presents a close question, the affected person may be consulted pursuant to § 4.45. The Commissioner concludes that this procedure is sufficient and will reduce the burden of the former regulatory power to an Administrative Law Judge operating out of that office. The Commissioner advises that it is in the public interest to retain the proposed new procedural regulations that will be published in the near future. As a general rule, such data and matters necessary to the same extent as they would if they had been submitted as part of a petition or application of the type involved in the proceeding.

The Commissioner advises that this matter will also be handled in the proposed new procedural regulations that will be published shortly in the FEDERAL REGISTER. A hearing will be held as to whether deletion of names of individuals who were considered for criminal prosecution but were not prosecuted from the disclosable material. The Constitution and the Freedom of Information Act protect the right of privacy only of individuals. Accordingly, § 1.6(c) does not provide for similar deletion of names of corporations.
16. Concern was expressed that the utility of the section 305 hearing, described in current Food and Drug Administration procedures, was limited by the discretionary nature of the decision (21 CFR 1.6(a), (a)(1), and (a)(4)). A determination might be made not to take regulatory action and the matter is closed. The Commissioner advises that all such records will be publicly disclosed in accordance with §1.6(c) and 4.64 after the matter is closed. Names and other information that would identify the individual will be deleted. If records are released before the hearing is completed for a specific individual are requested by name, they will also be released after deletion of identifying information.

19. There was criticism of the provision for the public accounting of witnesses obtained through promisses of confidentiality, names of individuals and other confidential information since these exemptions are not specified in the statute. It was also suggested that keeping secret the names of individuals against whom the Food and Drug Administration determines not to bring prosecutions is a misuse of the investigatory files exemption. The Court in "Frankel v. SEC," 460 F.2d 813 (2d Cir., 1972), concluded that disclosure of such factual information might well not be strictly factual since "facts" as recorded within the meaning of the Freedom of Information Act, and the Sunshine Act, all warning letters issued under these provisions of these regulations, e.g., "Rayner & Stonington, Inc. v. FDA," No. 68-1995 (E.D. Pa. 1969). The "Frankel" decision merely holds that, where an agency does assert the investigatory file exemption, it may properly so even after the matter is closed. The Commissioner believes that any individual in a section 305 citation whom "no prosecution" decisions have been made by administrative agencies, such records exemption. "Other confidential information within the meaning of the Freedom of Information Act to exempt from disclosure investigatory records compiled for law enforcement purposes, and may, under some circumstances, keep such records confidential in order to protect his privacy. The Commissioner concludes that such names will not be deleted if those individuals were included in the criminal prosecution. The name and other information that would identify any individual in a section 305 citation but not subsequently prosecuted will be deleted in order to protect his privacy.

20. It was suggested that what was determined to be disclosable "factual information" might well not be strictly factual since "facts" as recorded may reflect the opinions and subjective evaluations of the recorder. Opinions and subjective evaluations would thus be indirectly made public but the public disclosure of the investigatory records is "subject to the declaratory judgment act as a means to avoid prejudicial pretrial publicity. Accordingly, the Commissioner will only very rarely exercise his discretion to release such material before the file is closed, he concludes that this will be done only if there is clear evidence of criminal prosecution is involved. Because a section 305 hearing raises the possibility of criminal prosecution, the Food and Drug Administration, as a matter of discretion, will be in the public interest.

21. A question has also arisen as to whether the names of Food and Drug Administration employees will be deleted from section 305 hearing records. The Commissioner concludes that the names of all Food and Drug Administration employees will be disclosed, except in rare circumstances where it is concluded that disclosure of such names would be inconsistent with the other provisions of these regulations, e.g., "Wellford v. Hardin," 444 F.2d 21 (4th Cir., 1971). It was contended that the public has a right to know of and judge these kinds of decisions, particularly since strict criminal liability is involved. The Commissioner concludes that the Food and Drug Administration, as a law enforcement agency, is entitled under the Freedom of Information Act to exempt from disclosure investigatory records compiled for law enforcement purposes, and may, under some circumstances, keep such records confidential in order to protect his privacy. The Commissioner believes that the names of all government officials involved in any regulatory matter should ordinarily be a matter of public information. Section 4.32 of the final regulations states this policy.

22. Questions have also arisen as to whether the names of individuals will be deleted if those individuals were included in the criminal prosecution. The name and other information that would identify any individual in a section 305 citation but not subsequently prosecuted will be deleted in order to protect his privacy.
closed or the statute of limitations runs, and only under circumstances that demonstrate a compelling necessity.

24. Questions have been raised with respect to the exact time at which section 305 hearing records become "closed." The Commissioner advises that the Food and Drug Administration has adopted general guidelines to determine when section 305 hearing records are closed. These guidelines are set out in § 1.6(c) of the final regulations and discussed in paragraph 113 of this preamble.

25. Under the Freedom of Information Act amendments, the Investigatory records exemption has been amended to read as follows:

(7) Investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, (C) constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

The Commissioner concludes that the policy stated in § 1.6(c) fully complies with this change in the law. Section 305 hearing records deal with possible criminal matters. The Commissioner concludes that, except in rare circumstances, information should not be released from a section 305 hearing record before the record is closed, in order to avoid interference with enforcement proceedings or prejudicing a person's right to a fair trial and an impartial adjudication.

The Conference Report No. 93-1380, dated September 25, 1974, on the Freedom of Information Act amendments indicates that the purpose of this revision of the law is to narrow some of the court decisions that had tended to expand the investigative file exemption. The Commissioner notes that § 1.6(c) is considerably narrower than a number of the court decisions counsel, and that the agency has already concluded to exercise its discretion to release investigatory records when a case is closed. The information is released from such release under the final regulations to reflect within the provisions of the revised statutory exemption contained in the amendments.

OFFICIAL RECORDS AND INFORMATION

26. A number of questions have arisen as to when the Food and Drug Administration will permit an employee to testify in private litigation.

The Commissioner concludes that the primary obligation of Food and Drug Administration employees is to implement and enforce the laws subject to the agency's jurisdiction. The agency has no congressional mandate to aid private litigants. Accordingly, the Food and Drug Administration will ordinarily decline to permit agency employees to testify or otherwise participate in their official capacity in private litigation.

The Commissioner recognizes, however, that exceptions will exist to this rule. For example, the Commissioner will permit Food and Drug Administration employees to testify or participate in private litigation in instances where former Food and Drug Administration employees testify with respect to agency policy in a way that requires correction of the record to prevent an unjust result, or where private litigation is designed to achieve the same purpose that would be achieved by agency action and thereby preclude Food and Drug Administration to be in the public interest, or where the results of the private litigation may have a significant impact on Food and Drug Administration policy, or where Food and Drug Administration action resulted in the lawsuit. Section 4.1 of the regulations has been revised to state this policy, and has been divided into three sections and rewritten for editorial purposes.

GENERAL POLICY

27. A number of comments on the proposed regulations published in May 1972 related to the broad policy underlying and interspersed with the specific provisions.

The Commissioner concludes that a new Subpart B should be added to 21 CFR Part 4, to include such statements of general policy.

POLICY ON DISCLOSURE OF FOOD AND DRUG ADMINISTRATION RECORDS

28. Comments contended that the proposed regulations published in May 1972 improperly placed the burden for justifying nondisclosure on companies who have furnished information, while placing no burden upon the public to justify any compelling need or cogent reason for requesting the information.

The Commissioner advises that these comments accurately reflect the proposed and final regulations, and that those regulations in turn reflect the intent of Congress as embodied in the Freedom of Information Act. Under the law, any person is entitled to receive information unless it is subject to one of the stated exemptions. The law does not require that there be any justification whatever for such a request. Only where there is a request for discretionary release of exempt records, or for waiver of fees, does the justification for disclosure become relevant.

UNIFORM ACCESS TO RECORDS

29. In administering the Freedom of Information Act, the Food and Drug Administration has uniformly adopted the position that, if any record is available to any member of the public, it must be made available to all members of the public, with only very limited exceptions. Accordingly, a new § 4.21 has been added for that purpose.

30. Comments requested clarification of the statement to the effect that information in Food and Drug Administration files that has previously been made public "in an authorized manner" will be generally released to the public, and asked what would be considered an "unauthorized" manner.

The Commissioner advises that this phrase, and other similar language in the final regulations, is intended to exclude from agency files or otherwise disclosed in an unauthorized manner. Thus, if an internal memorandum is given to a member of the press without authorization, and private litigation may have a significant impact on Food and Drug Administration policy, or where Food and Drug Administration action resulted in the lawsuit. Section 4.1 of the regulations has been revised to state this policy, and has been divided into three sections and rewritten for editorial purposes.

The Commissioner concludes that release by Congress of material that would not be disclosed by the Food and Drug Administration, as authorized release, since Congress is authorized to release any information it wishes to release. Accordingly, any material obtained by Congress, i.e., by a committee or subcommittee, and subsequently authorized to be disclosed, automatically triggers the requirement that it be released for public disclosure by the Food and Drug Administration to any person who requests it.

31. Some comments indicated that it would be acceptable to have scientific information contained in Food and Drug Administration files furnished to scientists and scholars, but that it should not be furnished to the news media or others who might distort it.

The Commissioner advises that such a distinction is untenable under the Freedom of Information Act. If any such information is made available to one member of the public, it must be made available to all.

PARTIAL DISCLOSURE OF RECORDS

32. The Freedom of Information Act amendments specify that any reasonable partial disclosure of a record shall be provided to any person requesting such record after deletion of the portions which are exempt under the Freedom of Information Act.

The Commissioner regards this new provision as a statement of existing Food and Drug Administration policy under the proposed regulations, and existing case law. See "EPA v. Mink," 410 U.S. 73
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(1973). Accordingly, § 4.22 has been added to state this general policy.

The Commissioner concludes that, as a general rule, when a document contains some material that is disclosable and other material that is nondisclosable, it will be released with the nondisclosable material deleted unless the two types of material are so inextricably linked that it is not reasonably possible to separate them. In instances of this type, the Commissioner may also exercise his discretion pursuant to § 4.62 of the regulations to release the entire document, or to make only a minimum number of deletions, e.g., the names of individuals, in order to avoid release of a document that would not be meaningful or useful to the public.

REQUEST FOR EXISTING RECORDS

33. Questions have been raised as to what constitutes a request for records under the Freedom of Information Act.

The Commissioner advises that pamphlets, speeches, and other materials routinely prepared for public distribution are distributed free of cost to the public. Such materials that fall under the Freedom of Information Act and these regulations. It is the policy of the Food and Drug Administration to regard any request for records not routinely prepared for public distribution as a request for new computer programs, or similar work, except where such work would benefit the public generally and fit within the priorities and objectives of the agency. Any decision to undertake such work is subject within the discretion of the Commissioner.

RETROACTIVE APPLICATION OF REGULATIONS

36. Comments contended that the Freedom of Information Act may not properly be applied on a retroactive basis to data and information supplied to the Food and Drug Administration prior to the enactment date of the statute.

The Commissioner concludes that the Freedom of Information Act applies to all data and information in Food and Drug Administration files, regardless of whether said data and information were acquired by the Commissioner or obtained prior to the enactment date of the statute.

INDEXES OF CERTAIN AGENCY RECORDS

37. The Freedom of Information Act amendments of 1967 provide for the maintenance and distribution of current indexes identifying information with respect to final opinions by an agency made in the adjudication of cases. New § 4.22 of the regulations did not provide for the preparation of indexes, not published in the Federal Register, and administrative staff manuals and instructions to staff that affect members of the public.

The Commissioner has ordered preparation of appropriate indexes of this type. New § 4.26 has been added to the regulations stating that such indexes shall be available at cost upon request from the Food and Drug Administration Public Records and Documents Center (HFC-18), Rm. 4-82, 5600 Fishers Lane, Rockville, MD 20852.

Since each of the agency opinions in the adjudication of administrative cases are published in the Federal Register, an index will contain a citation to each. Such matters include only adjudicatory decisions on the denial or revocation of new drug applications and new animal drug applications, and not decisions in rule making proceedings such as food standards and antibiotic regulations. Furthermore, the index will not include all statements of policy and interpretation adopted by the agency since enactment of the various laws subject to the jurisdiction of the agency, not published in the Federal Register, and still in force.

Finally, an index will cover all administrative staff manuals and instructions that contain directives that affect a member of the public, except those that are subject to the maintenance and distribution of current indexes. New § 4.24 of the regulations reflects this policy.

35. In the past 2 years, several requests have been received which would involve compiling statistics, researching citations to Federal Register notices, and similar work by the Food and Drug Administration.

The Commissioner advises that the Food and Drug Administration will not undertake the compilation of new statistical reports or legal research, or preparation of new computer programs, or similar work, except where such work would benefit the public generally and fit within the priorities and objectives of the agency. Any decision to undertake such work is subject within the discretion of the Commissioner.

PROHIBITION ON WITHDRAWAL OF RECORDS FROM FOOD AND DRUG ADMINISTRATION FILES

40. Situations have frequently arisen within the past 2 years in which persons who have voluntarily submitted information without a written pledge of confidentiality by the Food and Drug Administration have objected to release of the documents involved or have requested that the disputed documents be returned to them.

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The Commissioner notes that new § 4.44 makes it clear that any information voluntarily submitted without a written pledge of confidentiality pursuant to the procedures contained in that provision may be disclosed to the public unless the Commissioner concludes that it falls within any of the exemptions set out in the Freedom of Information Act and these implementing regulations and that he should not exercise his discretion to release the information involved. Under no circumstances will the Food and Drug Administration return any document submitted to it. The only circumstances under which any document will not be retained by the Food and Drug Administration is where, pursuant to new § 4.44, there is a presumptive review, the Food and Drug Administration concludes that the information will not be accepted as confidential, and the person declines to submit the information on that basis and requests that it be returned to him instead. New § 4.29 makes this policy clear.

Food and Drug Administration Public Records and Documents Center

41. The Freedom of Information Act amendments embody a congressional mandate for greater agency accountability for compliance with the provisions of the Freedom of Information Act.

The Commissioner has established a Public Records and Documents Center to be responsible for the agency's compliance with the provisions of the Freedom of Information Act. All requests for records will be submitted to this Center, and all responses will be coordinated by it. Section 4.30 of the final regulations so provides.

Permanent File of Requests for Food and Drug Administration Records

42. In order to permit public review of Information Act appeals, the Food and Drug Administration maintains a permanent file of all requests and responses. This file is available for public review during working hours.

The Commissioner concludes that a new § 4.31 should be added to the final regulations stating this policy.

Disclosure of Food and Drug Administration Employee Names

43. Questions frequently arise as to whether the names of Food and Drug Administration employees contained in various agency records will be deleted prior to disclosure of such records.

The Commissioner concludes that, except in extraordinary circumstances, the names of agency officials involved in any regulatory matter are properly disclosed to the public. New § 4.32 states this policy. Only in unusual circumstances, such as where the identity of a confidential source would be disclosed if the name of the agency employee involved in the matter were also disclosed, will the name of the agency employee be deleted before the requested records are made available for public disclosure.

Rules and Regulations

PROCEDURES AND FEES

44. The Freedom of Information Act amendments contain a number of provisions pertaining to procedures and fees. In addition, the proposed regulations published in May 1972 contained several provisions relating to procedures and fees, and the Commissioner concludes that they should be set out in one place for ready reference.

Accordingly, the Commissioner is adding a new Subpart C to 21 CFR Part 4, relating to procedures and fees.

Filing a Request for Records

45. The Freedom of Information Act amendments state that, upon any request for records which reasonably describes the records involved, the Food and Drug Administration shall determine whether the requested records shall be made promptly available.

The Commissioner concludes that this policy should be clearly stated in a new § 4.90, along with directions on where to file a request for any Food and Drug Administration record.

Time Limitations

46. The publication of rules stating the time, place, fees (if any) and procedures to be followed by the public in requesting records pursuant to the Freedom of Information Act is essential for the proper implementation of that law.

The Commissioner concludes that all requests for Food and Drug Administration documents shall be made in writing to the Public Records and Documents Center (HFC-18), Rm. 4-62, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. Such requests will be logged in at the time, and in the order, they are received. The time at which a written request is logged in at that office shall determine the beginning of any time requirements. Oral requests for documents will not trigger any time requirements. Written requests sent elsewhere within the agency will not trigger any time requirements until they are redirected to the Public Records and Documents Center. This is the only way in which an accounting of all public information requests can accurately be made.

47. The recommendations of the Administrative Conference of the United States, the regulations of the Department of Health, Education, and Welfare, and the Freedom of Information Act amendments all provide that the agency determine within 10 days, excepting Saturdays, Sundays, and legal public holidays, after the receipt of any request whether or not to comply with that request, and, if not immediately notify the person making the request of such determination, the reasons therefor, and the right of such person to appeal any adverse determination. The Freedom of Information Act amendments provide for an extension of the 10-day time period in "unusual circumstances," and define that phrase.

The Commissioner has included in § 4.41 of the final regulations, provisions implementing this concept. Within 10 days of receipt, a determination will be made whether, or to what extent, the information involved will be disclosed under extraordinary circumstances. As soon as possible after that determination is made and any required prepayment is furnished, the disclosed material will be forwarded on or made available to the person requesting it.

The Commissioner anticipates that in most instances the specific provisions of those final regulations, together with the explanatory discussion in this preamble, will clearly determine whether the material is disclosable.

48. A number of comments on the proposed regulations asked for clarification of the procedures under which responses are made and persons are required to furnish payment before receiving the requested records.

The Commissioner agrees that a specific procedure should be included in the regulations and a new provision in § 4.41 has been added for this purpose.

Within the 10 days required for response to a Freedom of Information Act request, an estimate will be made of the cost of providing the requested records that are available and the response will contain that estimate. If the cost can be determined accurately ahead of time and is greater than $25, the response will state that the records will be sent or made available upon receipt of the amount of money specified or estimated. If the person requesting the information wishes to proceed and sends the prepayment, the material will be obtained and forwarded as quickly as possible.

The Commissioner concludes that records should not be furnished until the money is actually received, since otherwise there would be no way to guarantee that fees will in fact be paid. Situations have arisen during the past 2 years where the Food and Drug Administration has gathered documents at agency expense in response to a request under the Freedom of Information Act and has been informed that the expense involved was too high.

Fees

49. The proposed regulations published in May 1972 contained uniform standard charges for requests made or answered by the mail, or below the cost of the activity to the Food and Drug Administration. It also provided for waiver of fees on the basis of indigence. Criticism of the fee schedule was made by several groups in comments filed on the proposal. One comment indicated that copies should cost no more than the few cents per page they cost the agency. The $3.00 fee for certification of authenticity was thought to be out of line and it was suggested that the charge be 50 cents, the amount charged for that service by the United States District Court for the District of Columbia. It was contended that there should be a threshold fee, below which there is no charge. It was suggested that the fees, as proposed, would act as a deterrent to legitimate requests for disclosure.

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Upon reconsideration, the Commissioner has modified the fee schedule in some respects. The fees charged by the Department of Justice (16 CFR 16.9) and the Department of Health, Education, and Welfare (45 CFR 5.61) have been used as a model. The charges, as modified, are slightly less than the actual cost to the agency. Under the Federal User Charges Act (31 U.S.C. 483a), and in accordance with the policy of the Federal government, these costs must be passed along to those who seek services from the agency. This system should not act as a deterrent to legitimate requests for disclosure.

50. Comments requested that the fees for copying be reduced to five cents per page. The Commissioner advises that the fees to the government for copying is in excess of 10 cents per page. Accordingly, the Commissioner concludes that a fee of 10 cents per page is reasonable.

51. Numerous comments have been received with respect to the fee required for a computer printout of information that is available in this form. The Commissioner advises that fees for copying shall be assessed at actual cost. No standard fee can be calculated, because of the different factors that must be considered with respect to each request. Section 4.42(a) (9) states the procedure.

52. Comments also urged that the hourly fee for search not be charged for administrative time spent in deciding whether to release information. The Commissioner concludes that this be explicitly stated in the regulations.

The Commissioner advises that the hourly fee is to be charged exclusively for actual time spent in determining whether to release information, and that this be explicitly stated in the regulations.

53. Questions have been raised as to how a check or money order for documents should be made payable, and to whom it shall be sent within the Food and Drug Administration.

The Commissioner advises that all checks or money orders should be made payable to the "Food and Drug Administration." The term "United States" or the initials "U.S." should not be included.

54. Many different circumstances have been brought to the Commissioner's attention to justify a waiver of fees.

As a general principle, the Commissioner concludes that waiver or reduction of fees should not be granted except under circumstances of Indigence, or where it will benefit the public broadly, or where it involves another component of the federal government or a state government. Thus, information furnished to a congressional committee, a federal agency, a state or local agency, a court, or a foreign government, will ordinarily be furnished without cost.

The Commissioner has also determined that the cost of obtaining payment for a small number of records of a government time and effort involved, exceeds the revenue obtained from this effort. Accordingly, the final regulations provide that no fee will be charged for a computer printout of information unless it is slight less than the actual cost.

55. Comments stated that the regulations should include a definition of "indigence" and "strong public interest necessary to justify a waiver of fees." It was suggested that the customary definition of indigence, "unable to afford a reduced charge where the agency makes a discretionary determination that waiver or reduction of the fee is in the public interest because furnishing the information can be considered primarily as benefiting the general public.

The Commissioner advises that a new paragraph (e) has been added to § 4.43 of the final regulations to implement this provision.

The Food and Drug Administration has in the past received a substantial number of open-ended requests for documents, from individuals and organizations purporting to represent the consumer and general public, from other charitable and non-profit and citizens' groups. The following test was suggested:

1. The requester purports to represent the consuming public or a broad public interest.

2. The requester is a nonprofit organization exempted from payment of Federal income taxes by the Internal Revenue Service.

3. It generates no profits and, except in connection with its charitable activities, sells no goods or services.

4. It receives its funds solely from one or more of the following sources: Membership dues, contributions from the general public and from other charitable organizations, and grants and contracts with government agencies.

5. It has no uncommitted funds available at the time of the request for payment of the fees from which it seeks relief by waiver.

The Commissioner notes that the Federal User Charges Act (31 U.S.C. 483a) and the Food and Drug Administration's authority to encourage requests for information can be considered primarily as benefiting the public generally. Narrow and specific requests for documents will be far more likely to satisfy this standard than will broad fishing expeditions requesting large numbers of vaguely described documents covering a wide range of issues. In making a determination of the public interest involved, the Commissioner will weigh the agency resources involved against the likely benefit to the public.

56. The Commissioner wishes to assist any inquiry that will genuinely advance the public interest. If this is to be done, however, many of the documents available in the Food and Drug Administration for this purpose must be devoted to those requests that demonstrate the greatest likelihood of useful public service. The Commissioner intends to utilize this authority to encourage requests for information that will broadly promote the public interest.

57. Questions have arisen as to whether fees will be assessed when the records requested are not found or are withheld from public disclosure.

The Commissioner advises that no fees will be assessed under these circumstances. This policy is stated in new § 4.49 (d).

PRESUMPTION REVIEW OF REQUEST FOR CONFIDENTIALITY OF VOLUNTARILY SUBMITTED DATA OR INFORMATION

58. Section 4.26 of the proposed regulations contained a provision permitting...
any person who wishes to submit information voluntarily to the Food and Drug Administration to request an initial determination of confidentiality. The final regulations provide that such information may be accepted only if it is confidence only. It is relevant to and important for agency activity, and only if the Assistant Commissioner for Public Affairs signs a letter pertaining to the decision to permit the commencement of an appeal process.

The Commissioner concludes that any person who believes he would be disclosed to the public in the future. The proper remedy for an person to pursue, in the event that he has submitted information as confidential, is to bring a declaratory judgment action contesting the validity of the regulations. Unless these regulations are successfully challenged in the courts, the Food and Drug Administration will continue to implement them. Thus, all persons who have previously submitted records to the Food and Drug Administration are hereby put on public notice that the information they submitted in the past which he believes to be confidential but which, under the final regulations, is included within a category not otherwise exempt from disclosure, promptly be disclosed upon request.

61. Many comments indicated the need for a "meaningful" appeal procedure that would go to the highest level within the agency. In an effort to provide for a stay of disclosure to permit the commencement of an appeal process.

The Commissioner agrees that an appeal procedure and a stay of disclosure pending appeal reason, where the issue presents a close question. Appropriate procedures have been incorporated in §§ 4.44 through 4.46 for this purpose.

SITUATIONS IN WHICH CONFIDENTIALITY IS UNCERTAIN

63. Proposed § 4.43 stated that, where disclosure is uncertain, the Food and Drug Administration will consult with the person who submitted the information in making a determination whether it will be disclosed. This proposed provision has been included in the final regulations as § 4.45.

Comments stated that industry should be notified in all instances, not just in situations where the Food and Drug Administration is uncertain about disclosure. This section was also criticized because it does not make clear who decides when disclosure of data is uncertain, and whether such an uncertain status is based on with regard to previously submitted material or whether it also applies to newly submitted material.

The Commissioner concludes that the Food and Drug Administration will notify the submitting person only when it determines that there is some question as to the status of the material. There are many circumstances in which the material is clearly disclosable under the law and these implementing regulations, and it would be burdensome and wasteful to contact the person who had submitted it under such circumstances. A decision as to whether or not the status of the data is "uncertain" and therefore subject to § 4.45 will be made by those administratively responsible for making disclosures. Such a decision will be made, if necessary, with the assistance of legal counsel.

Uncertainty about the status of information voluntarily submitted on which preclusion review is requested is the subject of separate provisions in new § 4.44.

63. Comments suggested that a company should be advised whenever any record is to be released for public disclosure pursuant to the Freedom of Information Act if that record was either submitted by the company or refers to the company.

The Commissioner rejects this suggestion. Any such procedure would severely hinder implementation of the Freedom of Information Act, Section 4.46 of the final regulations provides for consultation with affected persons wherever a close issue arises, and § 4.46 permits an affected person to seek court review in such instances.

Regarding disclosure, comments advises that the final regulations adequately state the basis on which disclosure will be made to the public in the future. The proper remedy for an person to pursue, in the event that he has submitted information as confidential in the past which he believes to be confidential but which, under the final regulations, is included within a category not otherwise exempt from disclosure, promptly be disclosed upon request.

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be adversely affected by disclosure of informa-
tion to institute suit in a United States District court to enjoin such dis-
closure. The Commissioner has stated that, if any such suit is instituted, no
disclosure will be undertaken until all court appeals are exhausted. The Com-
missoner believes that this procedure adequately balances the right of the pub-
clic to obtain information against the right of a person to protect the confi-
cidentiality of material that he believes should not be disclosed. Accord-
gingly, new § 4.46 of the final regulations includes this procedure.

The Commissioner cautions that this does not mean that the Food and Drug
Administration must in every instance advise persons who might be affected by
a disclosure of information that such information has been requested by a mem-
ber of the public. The Food and Drug Administration will exercise its judgment
in determining when close issues exist that may give rise to this procedure. The Commissioner believes that experience during the past 2 years has demonstrated that proper judgment in these matters can readily be exercised.

**DENIAL OF A REQUEST FOR RECORDS**

66. The Commissioner concludes that specific provisions should be made in the
final regulations for the procedure to be followed upon denial of any request for
records. The Freedom of Information Act amendments provide that the names and
titles or positions of each person responsible for the denial of a request for in-
formation shall be set forth in the letter denying the request.

Accordingly, new § 4.47 has been added to the regulations to accomplish these
purposes.

**NONSPECIFIC AND OVERLY BURDENSOME REQUESTS**

67. Section 4.38 of the proposed regu-
lations, which deals with nonspecific and overbroad requests, has been redesignated as § 4.48 in the final regulations.

A few comments were concerned that the proposed regulations were not suf-
cient to prevent “fishing expeditions.” It was emphasized that the Freedom of
Information Act, as well as the Attorney General’s Memorandum Interpreting it,
makes information available only in re-
response to a request for identifiable rec-
ords. It was noted that the courts have upheld the requirement that those seek-
ing disclosure under the act provide a reasonable description of the records to enable government employees to locate the documents, citing “Irons v. Schuy-

The Commissioner notes that many cases, as well as the Freedom of Informa-
tion Act amendments, require only that documents be described, not that they be specifically identified. For example, a request for all of the documents in a particular cate-
gory is a broad, nonspecific request, yet such records would be easily identified. If a request is so vague that it is diffi-
cult, if not impossible, to determine which records the request seeks, the agency will seek clarification.

68. A concern was also raised to do this
 provision on the ground that the Freedom of
Information Act provides for no such balancing of public interest against ad-
ministrative efficiency, and contended that there is no justification for any pro-

The Commissioner advises that this provision is intended to emphasize the need for specific requests, rather than general requests for large numbers of documents that are often not relevant to the Freedom of Information Act. A person making the request, and to point out that responding to requests for large numbers of documents may require a substantial period of time. The Commissioner notes that the Freedom of Information Act amendments provide only that the person making a request be informed within 10 days whether part or all of the docu-
ments requested have been located. No statutory time limit is established, but there is a general expectation that the documents may require a substantial period of time.

This indicates recognition by Congress that government employees cannot be expected to drop all other duties in order to respond to requests for information. There is no indication, in short, that Congress intends the Food and Drug Administration to handle freedom of information requests on a higher priority basis than its important law enforcement duties.

On the other hand, the Commissioner does not find that requests under the Freedom of Information Act must receive a low priority or simply be ignored. They will be handled as expeditiously as is feasible. Sections 4.41 and 4.48 of the final regulations so provide.

**REFERRAL TO PRIMARY SOURCE OF RECORDS**

69. Comments on the proposed regulations asked what documents will be dis-
tributed without charge pursuant to the regulations. In particular, questions were
raised about the status of documents such as the Code of Federal Regulations
(CFR), Federal Register, United States Pharmacopeia (U.S.P.), and National Formulary (N.F.).

The Commissioner notes that there are a wide variety of materials, including press releases and educational materials, which are held by the Food and Drug Administration for distribution to the public. These will continue to be re-
leased and distributed without charge.

It is the policy of the Food and Drug Administration that anyone is charged for a document, all must be charged unless the fee is waived pursuant to these regulations. Conversely, if a document is routinely given free of charge, then all must receive it free of charge.

Two of the documents referred to in this comment, i.e., CFR and the Fed-
eral Register, are available from the Government Printing Office. The other two, U.S.P. and N.P., are available from the organizations that publish them.

Shall scientific literature, drug Administration materials and all are readily available elsewhere at a price lower than it would cost the Food and Drug Administration to reproduce them, it is the policy of the Food and Drug Administration to refer anyone who re-
quests them to those places where they are available, pursuant to § 4.49 of the final regulations.

**AVAILABILITY OF RECORDS AT NATIONAL TECHNICAL INFORMATION SERVICE**

70. In a number of instances, the Food and Drug Administration has been asked that reports or information generated or received by the agency will receive widespread interest. The Department of Commerce has established a National Technical Information Service (NTIS) at 5250 Port Royal Road, Springfield, VA 22152, to serve as a clearinghouse for such information. The Food and Drug Administration is, for example, sending all general requests for raw data, and final reports of the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology to NTIS. The reproduction and distribution to the public, as set forth in the final

The Commissioner concludes that, when documents are furnished to NTIS, a single copy will be available for public review at the Food and Drug Administration. All requests for copies of such documents will be handled by referring the person requesting the copies to NTIS. The Commissioner concludes that this approach fully satisfies the requirements of the Freedom of Information Act. Section 4.49 of the final regulations states this policy.

**USE OF PRIVATE CONTRACTOR FOR COPYING**

71. A comment suggested that, rather than charge for copying or sending infor-
mation to an independent contractor for copying, information in Food and
Drug Administration files that is available for public disclosure should be loaned to the person who is requesting it, who can then copy it himself.

The Commissioner concludes that lending material for copying usually will not be permitted. The Food and Drug Administration has had difficulty with loss of materials from files in the office of the Adirondack Clerk. The Food and Drug Administration would have to determine whether materials loaned to individuals would be returned intact. Only where materials requested are con-
tained in bound volumes and their safe return can be assured would this possibly be feasible. The Commissioner concludes
that no change in the final regulations is warranted to handle these situations.

REQUEST FOR REVIEW WITHOUT COYING

72. Numerous requests have been received by the Food and Drug Administration during the past 2 years for an opportunity to review specific documents without the necessity of copying them. Such requests have pointed out that copying is expensive and that on occasion only a few, if any, of the requests might be met by the person's needs. Copies would then be requested only of those documents which, after a personal review, are determined to be relevant.

The Commissioner advises that this procedure is entirely acceptable and endorsed by the Food and Drug Administration except where a record involved contains both disclosable and nondisclosable material. Under those circumstances, the only feasible way to make the record available for inspection is to copy it with the nondisclosable material blocked out. Accord ingly, § 4.62 is added to the final regulations to state this policy.

INDEXING TRADE SECRET AND CONFIDENTIAL COMMERICAL OR FINANCIAL DATA AND INFORMATION

73. In recent court decisions, it has been suggested that, upon judicial review of an agency decision to deny documents or portions thereof, the agency be required to itemize and index the disputed material in order to permit adequate judicial consideration of the issue.

The Commissioner concludes that, where records or portions thereof are denied on the basis of the exemption for trade secrets and confidential commercial or financial data and information, the matter is subsequently contested in the courts, and the court orders such itemization and indexing, the Food and Drug Administration will require that this be undertaken by the person affected. If the matter is submitted to the Food and Drug Administration, it will also request that the person affected intervene to defend the trade secret status of the disputed documents. The failure of the affected person to itemize and index such disputed documents and to defend their status will constitute a waiver of any trade secret defense, and the Food and Drug Administration will promptly make them available for public disclosure. Section 4.63 states this policy.

The Commissioner concludes that the burden of defending the trade secret status of any disclosed document is properly placed upon the affected person, because this status inures only to the benefit of that person. The Commissioner concludes that it should not be incumbent upon the government to itemize and index every right of a person in such a manner, and that, in any event, the person affected is in the best position to present a trade secret defense to the court.

EXEMPTIONS

74. The Freedom of Information Act provides that all government records and documents shall be made available to the public upon request, except for the following nine specific types of information:

1. (A) Specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense or foreign policy and (B) are in fact properly classified pursuant to such Executive order.

2. Material which has been requested by the requesting person in an internal personnel rules and practices of an agency.

3. Specifically exempted from disclosure by statute.

4. Trade secrets and commercial or financial information obtained from a person and privileged or confidential.

5. Interagency or intra-agency memorandums or letters which would not be available by law to a person outside an agency in litigation with the agency.

6. Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

7. Investigatory records compiled for law enforcement purposes, but only to the extent that the production of such records would (A) interfere with enforcement proceedings, (B) disclose the identity of a confidential source, (C) endanger an individual's life or physical safety of law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (D) disclose investigative or procedural techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel.

8. Contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions.

9. Geological and geophysical information and data, including maps, concerning wells.

Of these nine exemptions, the four relating to trade secrets, internal memora nda, personal privacy, and investigatory files are of particular importance to the Food and Drug Administration.

In the proposed regulations published in May 1974 relating to § 4.53 of the rules and regulations, these four exemptions were interspersed with a number of other sections relating to other matters. The Commissioner concludes that, for purposes of clarity, the provisions of the final regulations relating to these exemptions should be separated from the other sections and placed in a separate new Subpart D of Part 4.

Questions have arisen as to whether documents that are not available from the Food and Drug Administration because of the applicability of one of the exemptions, e.g., trade secrets, may be obtained directly from the company or other person who has submitted them.

The Commissioner advises that this procedure is entirely acceptable, and encourages companies and other persons submitting material for review by the Food and Drug Administration to make such exempt material available.

APPLICABILITY OF EXEMPTIONS

76. Numerous comments on the proposed regulations suggested that each of the available exemptions should be repeated as possibly applicable in every particular section dealing with the status of particular types of documents, e.g., correspondence and written summaries of oral discussions.

The Commissioner notes that § 4.36 of the proposal provided that nondisclosable portions of documents will be deleted from otherwise disclosable material before it is made public, if it is apparent, however, that this provision was not clearly understood by many who reviewed the proposal. Accordingly, the Commissioner is placing this provision in new § 4.60, the first section in Subpart D of Part 4 dealing with exemptions, and has revised it more clearly to state the policy that each exemption is to be considered in determining whether all or any part of otherwise disclosable records should be deleted before making the records available to the public.

77. It was suggested in comments on the proposed regulations that, if deletions of confidential trade secrets and financial information are to be made, only the company is capable of making all necessary deletions. Frequently, it was stated, just the association of a product with a certain composition may be a breach of confidentiality. In many records a complete rewriting would be necessary rather than a simple deletion because confidentiality may be interwoven with nonconfidential material.

The Commissioner advises that, where there is some uncertainty as to the confidential status of the material, the person submitting it under § 4.45, have the opportunity to indicate which portions of a record he believes should be exempt. However, the person who submits material does not under any circumstances have the right to say on what will and will not be deleted.

TRADE SECRETS AND COMMERCIAL OR FINANCIAL INFORMATION THAT IS PRIVILEGED OR CONFIDENTIAL

78. By far the most extensive comment on the proposed regulations related to the definitions of "trade secret" and "commercial or financial information." In proposed § 4.26, and the proposed definition of these definitions with respect to particular information received in petitions and applications as reflected in the proposed amendments to Parts 8, 121, 130, 136, and 146.

Numerous comments pointed out that the regulations must reflect the interaction of three statutes: The general Federal confidentiality statute, 18 U.S.C. 1905; the confidentiality provisions in section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)); and the exemption under the Freedom of Information Act for "trade secrets and commercial or financial information that is privileged or confidential" (5 U.S.C. 552(b)(4)). The Commissioner notes that the preamble to the proposed regulations referred to all three statutes, and that the proposal was intended to reflect the congressional policy embodied in them.
The general Federal confidentiality statute, 18 U.S.C. 1905, provides that:

Whoever, being an officer or employee of the United States or of any department or agency thereof, publishes, divulges, discloses, or makes known in any manner or to any extent or for any purpose the information acquired under authority of any statute (other than the Freedom of Information Act) by law any information coming to him in the course of his employment or official duties or by reason of any examination or investigation made by, or preliminary or declaratory order made thereunder, or by reason of any right of privacy or trade secret or confidential information contained in the two mandatory Federal confidentiality statutes.

The Food and Drug Administration has on one occasion testified before Congress that current statutory provisions do not allow even if the Commissioner wished as a matter of discretion to release such material, such disclosure cannot be lawful under the Freedom of Information Act.

The Commissioner concludes that the Freedom of Information Act trade secrets exemption is as broad as, and is perhaps somewhat broader than, the confidentiality provisions of the other two statutes. The major difference between them is that, whereas the Freedom of Information Act exemption is discretionary, the other two statutes embody mandatory requirements. Disclosure of information prohibited by either of the other two statutes constitutes a criminal offense. Accordingly, to the extent that the other two confidentiality statutes apply, disclosure of trade secrets and confidential commercial or financial information by the Food and Drug Administration is wholly prohibited by Federal law. Even if such disclosure would be in the public interest, in order to protect the public health, and even if the Commissioner wishes as a matter of discretion to release such material, such disclosure cannot be lawful under the Freedom of Information Act.

The Commissioner concludes that it is not feasible or practical to determine the differences, if any, between the confidentiality provisions in 18 U.S.C. 1905 and 21 U.S.C. 331(j), and in the Freedom of Information Act. If there are any differences, they are extremely subtle and small. Accordingly, the Commissioner intends, for practical reasons of daily administration of the law, to regard the provisions of these statutes as identical. This will have the effect of prohibiting any discretionary release of documents that fall within the trade secrets and confidential commercial information exemption to the Freedom of Information Act. The Commissioner concludes that to do otherwise would invite confusion, invite arbitrary decision, and raise the possibility of violation of the criminal sanctions contained in the two mandatory Federal confidentiality statutes.

The Food and Drug Administration has on one occasion testified before Congress that current statutory provisions do not allow disclosure of information contained in the agency's files, particularly, data relating to the safety or effectiveness of drugs. The Food and Drug Administration cannot change the law, and thus is bound by the present provisions until Congress acts.

79. One comment discussed at length the Commissioner's citation of 18 U.S.C. 1905, the general Federal confidentiality statute, contending that this statutory provision was intended by Congress to be soley a "remedial provision" and does not represent substantive law. It argued that 18 U.S.C. 1905 has no application when such disclosure is specifically prohibited by another statute, and to read 18 U.S.C. 1905 as an exemption to the Freedom of Information Act would, in effect, nullify the act and such could not have been the intent of Congress.

The Commissioner believes that this issue is moot, in view of the fact that the confidentiality provisions in 21 U.S.C. 331(j) and the trade secret exemption from the Freedom of Information Act cover the same type of information. The Commissioner also adds, however, that he does not concur with the legal interpretation provided by the comment. The comment did not cite any other confidentiality provision in Federal law that does not carry with it a sanction against release of the confidentiality information. Accordingly, if 18 U.S.C. 1905 were read solely as a remedial statute, to provide sanctions for disclosure of information that is prohibited by other sections of the law, it would be wholly meaningless. The only way to give this provision the true meaning is to read it as a general Federal prohibition against disclosure of trade secret information. This is the interpretation adopted by the Attorney General's Memorandum of March 23, 1973, "Sloane v. SEC," 336 F. Supp. 675 (S.D.N.Y. 1971); "Phelps v. SEC," 339 F. Supp. 467 (D.D.C. 1972). It was suggested that 18 U.S.C. 1905 may properly be read to provide for criminal penalties for disclosure of information only when such disclosure is specifically prohibited by another statute, and to read 18 U.S.C. 1905 as an exemption to the Freedom of Information Act would, in effect, nullify the act and such could not have been the intent of Congress.

80. A large number of comments questioned the use of the definition of a trade secret in section 757 of the Restatement of Torts. The comments argued that this definition was intended for purposes of litigation involving commercial damages, and thus is an inappropriate definition for harmonizing the competing values of an "open society" with adequate protection of trade secrets. The comments stated that the definition should be sensitive to a "right of privacy" of a manufacturer and should recognize that information furnished by industry to the Food and Drug Administration is wholly protected. Under the approach suggested in these comments, the key to a question of confidentiality would be whether the company intended the information to be confidential and whether it had, in fact, so treated the information, not whether there is a competitive use for the information.

The Commissioner concludes, upon review of the comments and the relevant case law, that the Restatement definition of a trade secret should remain the basic guideline for application of this exemption from the Freedom of Information Act. The Commissioner noted that the Restatement definition of a trade secret is "widely relied-upon," "Kewanee Oil Co. v. Bicron Corp.," 94 S. Ct. 2947 (1974). The Commissioner can find no reason why it should be modified for determining commercial damages but not for purposes of the Freedom of Information Act.

The Commissioner agrees that there is a property right reflected by the trade secrets exemption from the Freedom of Information Act. He concludes that new § 8.61 adequately reflects that right.

The Commissioner does not agree that the intent of the person who submits documents to the Food and Drug Administration controls, or is even relevant to, the question whether those documents may be released to the public upon request under the Freedom of Information Act. The Freedom of Information Act does not establish specific exemptions, which are to be applied by objective criteria. The subjective standard proposed in the comments would be in little or no disclosure of information to the public, contrary to the clear Intent of Congress.

81. Comments suggested that the official Restatement Comment on the definition of trade secrets be included as part of the Food and Drug Administration regulations. Comment (b) to section 757 of the Restatement of Torts states that:

An exact definition of a trade secret is not possible. Some factors to be considered in determining whether information is a trade secret are: (1) the extent to which the information is known outside his business; (2) the extent to which the information is known to and obtained from employees and others involved in his business; (3) the extent of measures taken by him to guard the secrecy of the information; (4) the value of the information to the public; and to his competitors; (5) the amount of effort or money expended by him in developing or improving the information; (6) the extent of any public disclosure by him of the information with which the information could be properly acquired or duplicated by others.
The Commissioner agrees that the official Comment on the Restatement definition is helpful in understanding the intent behind the definition. This Comment neither broadens nor narrows the definition itself, but simply elucidates the various factors encompassed within that definition. The Commissioner concludes that it is unnecessary to include this Comment as part of the definition in the final regulations, but advises that these factors will be considered in applying the definition set out in the regulations.

83. The definition of a trade secret as set forth in the proposed Uniform Trade Secret Protection Act was suggested as a possible alternative definition by several comments.

Any formula, pattern, device or compilation of scientific, technical, or commercial information which the trade secret owner has taken reasonable precautions to maintain in secrecy so that except by the use of improper means there would be difficulty in acquiring it, and which gives said owner an opportunity to obtain an advantage over others who do not know or use it * * * Matter which otherwise constitutes a trade secret may lose its status as such if it is disclosed in a lawful manner to any member of the public. Accordingly, no modifications in the definition in the final regulations is warranted.

85. Several comments took the position that, while the Restatement definition indicates that the information must give an individual an opportunity to obtain an advantage over competitors, the language of the second paragraph 5 of the preamble to the proposal seemingly excluded any information which is not currently providing a manufacturer with a competitive advantage and thus narrowed further what was already a narrow definition of trade secrets.

The Commissioner concludes that information which provided a manufacturer with a competitive advantage in the past, but is not currently providing a competitive advantage and will not, in all likelihood, do so in the future, is not covered by the Restatement definition and does not qualify as a trade secret.

86. Several comments took the position that, while the Restatement definition indicates that the information must give an individual an opportunity to obtain an advantage over competitors, the language in the second paragraph 5 of the preamble to the proposal seemingly excluded any information which is not currently providing a manufacturer with a competitive advantage and thus narrowed further what was already a narrow definition of trade secrets.

The Commissioner concludes that information which provided a manufacturer with a competitive advantage in the past, but is not currently providing a competitive advantage and will not, in all likelihood, do so in the future, is not covered by the Restatement definition and does not qualify as a trade secret.

87. Several comments pointed out that the statutory exemption for trade secrets in connection with the release of information should be the one noted in “Consumers Union v. Veterans Administration,” 301 F. Supp. 796, 801 (S.D.N.Y. 1969), appeal dismissed, 436 F.2d 1393 (2d Cir. 1971):

This is not an unpatented, secret, commercially valuable plan, appliance, formula or process, which is used for the making, preparing, compounding, treating, or processing of articles or materials which are trade commodities.

Information contained in a new drug application concerning animal and clinical testing, it was asserted, would not be a trade secret under this definition.

The Commissioner notes that the court in the “Consumers Union” case did not attempt an all-inclusive definition of a trade secret for purposes of all Federal law. It used a judicial description found in a 1925 case (alluded to in the preamble section 18 U.S.C. 1905. There is no reason to consider that definition controlling for purposes of the Freedom of Information Act. Moreover, even this definition does not exclude all personal data, but it seems likely that such data can properly be considered as part of a “plan” or a “process”.

85. Comments stated that the Restatement definition of trade secret is inadequate because it does not include a crucial element required in the common law of trade secrets in order to prove damages, i.e., the requirement that improper means be employed in obtaining the information.

The Commissioner concludes that the common law requirement that improper means be employed to obtain a trade secret in order to prove damage is comparable to the requirement included in the proposed and final regulations that information cannot be regarded as a trade secret if it has been obtained by improper means. This is reflected in the separate definitions for each given in 4.61 (a) and (b) of the final regulations. If information fails to satisfy either part of this definition, it will be considered exempt. However, it should be noted that the matter of competitive advantage is often significant in determining whether commercial information is considered a trade secret under the Freedom of Information Act. The Commissioner concludes that, under the relevant statutes, trade secrets and confidential commercial or financial information are two separate categories of exempt information, and that there was no exemption for confidential information that does not rely upon the concept of competitive advantage.

Other comments emphasized that there was no exemption for confidential information per se and that the exemption applies only to confidential information that is commercial or financial in nature.

The Commissioner states that, under the relevant statutes, trade secrets and confidential commercial or financial information are two separate categories of exempt information, and that there was no exemption for confidential information that does not rely upon the concept of competitive advantage.

88. Several comments pointed out that the statutory exemption for confidential information per se that is privileged or confidential. Some argued that this would include all information which a company regards as confidential and uses in the course of its business, and others contended that it should apply only to such clear financial information as relating to profits and the like.

The Commissioner has reviewed the legislative history of the Freedom of Information Act and has concluded that this phrase is properly interpreted on a narrow basis. If it were interpreted broadly, as suggested by some comments, it would make the trade secrets exemption irrelevant, and indeed would largely undermine the philosophy of the Freedom of Information Act. The legislative history indicates that this portion of the exemption was intended to apply to information customarily held in strict confidence, such as business sales statistics, inventories, customer lists, manufacturing processes, and financial data submitted to obtain a loan, as well as to information customarily subject to the doctor-patient and lawyer-client privileges. The Commissioner believes that the provisions of 18 U.S.C. 1905 and 21 U.S.C. 331(j) are properly interpreted in the same way. Accordingly, the Commissioner has revised the final regulations to reflect this approach to the matter.
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89. There was objection to the dependence of a confidential status upon whether or not the information was of a type customarily held in strict confidence or regarded as privileged. The issue, it was asserted, was whether a particular record or document was, in fact, held in confidence.

The Commissioner does not agree with this comment. If the confidential status of commercial information depended solely upon the way that each individual manufacturer handles information in his own business, decisions under the Freedom of Information Act would be highly inconsistent and would require the Food and Drug Administration to conduct an ad hoc inquiry into the way that each manufacturer handles documents submitted to the agency. Such an approach is neither practicable nor contemplated by the law.

The Commissioner notes that the legislative history shows that Congress intended that commercial and financial information submitted to the government would be handled according to the conditions established in the industry rather than according to the way that any particular firm regards it. Thus, it is customary to expect that the doctor-patient and lawyer-client privilege, whereas many other forms of commercial information are not customarily held in confidence.

In this respect, the criteria for a trade secret and for confidential commercial information are substantially different. The former depends entirely upon the competitive advantage attributable to the specific information involved, whereas the latter may be applicable even if there is no specific competitive advantage involved if such information is generally held in strict confidence according to usual industry practice. In both instances, of course, lawful prior publication or the information automatically destroys the confidential status of the information.

90. Comments asserted that the need for the public disclosure of safety and effectiveness data required the need for some great degree of assurance that the confidentiality of trade secret or confidential commercial status was sufficient to withhold such information.

The Commissioner concludes that it is Congress which weighs the need for the release of certain information against the need for retaining it as confidential. With regard to trade secrets, Congress has concluded that the need to withhold such information outweighs the need to release it. The Freedom of Information Act expressly makes an exemption for this type of information and other statutes are used for criminal penalties for releasing it.

91. Comments suggested that language covering manufacturing and quality control procedures be added to this provision in the final regulations even though it is specifically dealt with in other provisions.

The Commissioner advises that § 4.61 is intended to be as broad as possible, to cover all information that may have trade secret status. The fact that it does not mention a particular type of information does not mean that information is not a trade secret.

92. One comment contended that the fact that more than one manufacturer in an industry may know of and use an ingredient does not lessen the competitive advantage that accrues to those manufacturers who know and use the ingredient and who are manufacturers in the industry. The Commissioner also argued that it is frequently impossible for any manufacturer to know whether any of his competitors has become aware of his use of a particular ingredient.

The Commissioner concludes that use of an ingredient by more than one manufacturer for the same purpose is not, in itself, sufficient to justify a conclusion that such use is not a trade secret. The Commissioner recognizes that whether the use of an ingredient constitutes a trade secret will depend upon a number of factors, and primarily whether it has previously been disclosed to the public as defined in § 4.81 of the regulations. A representation by a company that, to the best of its knowledge and belief, the ingredient has not previously been disclosed to any member of the public, will be sufficient to create a prima facie case of confidentiality, which may be rebutted only by the Food and Drug Administration if it determines that the ingredient has in fact become public knowledge.

93. Comments asserted that the release of information under the proposed regulations would result in claims against the government based on "Padbloc v. United States," 161 Ct. Cl. 369 (1963) and "Bofors v. United States," 153 F. Supp. 397 (Ct. Cl. 1957).

The Commissioner concludes that, since the Freedom of Information Act requires release of information not specifically exempted, and no contract is involved, the release of the information does not make the government under the "Padbloc" case. The Commissioner notes that the "Padbloc" and "Bofors" cases involved a breach of contract in a commercial venture between the government and thus are not relevant here.

94. Comments suggested that a manufacturer's assertion that specified information is either a trade secret or confidential commercial information not be overruled unless "clearly erroneous." It was also suggested that a final determination be subject to judicial review on the basis of the evidence as a whole, since otherwise there would be too severe a burden of persuasion for the company in court to overturn an incorrect determination by the Food and Drug Administration.

The Commissioner concludes that the Freedom of Information Act does not permit the Food and Drug Administration to accept a manufacturer's assertions of confidential status without careful and full scrutiny of each claim. Moreover, under the Freedom of Information Act the courts are obligated to "determine the matter de novo" and the burden is on the agency to sustain any denial of records.

95. A question has arisen as to whether information that has been made public through a patent can nevertheless be classified as a trade secret.

The Commissioner concludes that all information made public through a patent will be available for public disclosure, and that the trade secrets exemption will apply only if circumstances are applicable to any such information as part of the marketing process.

96. A comment contended that information which may fall within the trade secrets protection cannot be divulged without notice, hearing, and judicial review. The Commissioner concludes that information which may fall within the trade secrets protection cannot be divulged without notice, hearing, and judicial review.

97. Section 4.27 of the proposed regulations, which dealt with the internal memorandum exemption from the Freedom of Information Act, is redesignated as § 4.62 in the final regulations.

Comments stated that the term "memoranda" is unclear. Questions were asked whether it refers to all written communications within the agency, or whether an investigator's report, or a report described as "memorandum." It was suggested that the preamble should state the criteria for determining whether or not a document is a "memorandum."

The Commissioner advises that the term "memoranda" refers to all written communications and not just to those documents bearing the title "memorandum." The legislative history of the Freedom of Information Act reveals that this was the intended congressional meaning of the term. Section 4.62 has been revised accordingly.

88. One comment contended that if the explanatory portions of an internal agency memorandum are deleted and the remainder is disclosed, the "factual" information may be reported out of context. It was suggested that, because of this consideration, the remaining parts of an agency memorandum should be excised. It was also suggested that, since it is frequently difficult to distinguish between "fact" and
"conclusion," some clarification of the term "factual information" would be helpful. It was noted that, while "factual information" should be defined to include factual analysis and materials which can be considered surveys and studies.

The Commissioner notes that the intra-agency memorandum exemption applies only to opinions, recommendations, or policy discussions within the deliberative processes of an agency. The courts have held that an entire agency memorandum that includes both factual information and opinions is not exempt from disclosure unless fact is so interwoven with opinion that the two cannot be separated. The Commissioner intends to make liberal use of his discretion to disclose internal memoranda reflecting policy discussions, with deletion only of trade secret data and material relating to personal privacy, wherever this can be done without disrupting the agency's activities. In all other instances the agency will do its best to distinguish between "fact" and "opinion" to ensure that it is neither necessary nor practical to define the term "factual information." The dividing line between fact and opinion must be made on a review of the specific case.

99. Comments contended that the agency, by not disclosing agency memoranda while at the same time disclosing written communications from private external sources, creates the possibility of presenting a distorted view. For example, damaging communications from and to a firm could be disclosed while data contained in intra-agency memoranda relevant to a full understanding of the situation would be withheld.

The Commissioner advises that he intends, wherever feasible, to exercise his discretion to release internal agency memoranda in order to avoid the possibility of preventing the public from reading the factual information that may be disclosable, they also contain conclusions and recommendations relating to policy that are not disclosable.

The Commissioner concludes that such summaries are internal memoranda that ordinarily will not be made available for public disclosure. Such summaries usually combine both factual information and conclusions and policy recommendations. The underlying documents on which the summary is based are all available for public disclosure. The courts have recently ruled that such summaries are therefore exempt from disclosure pursuant to the internal memorandum exemption.

100. In a number of instances, requests have been received by the Food and Drug Administration for disclosure of internal memoranda analyzing data or information submitted to the Food and Drug Administration. Such memoranda invariably contain both factual information and opinions and recommendations, and the two very seldom are or can be separated. Moreover, even the way that the factual information is presented may well reflect the internal opinions and views of the Food and Drug Administration staff.

The Commissioner concludes that, as a general rule, such internal summaries of data and information will not ordinarily be disclosed if the underlying data and information are available for public disclosure.

Thus, an analysis of food additive safety data contained in intra-agency memorandum that includes both factual information and opinions should be made available for public disclosure, usually will not be made public. Where the underlying data and information are not available for public disclosure, however, the Commissioner either will exercise his discretion to release the entire analysis with deletion only of the limited type mentioned above, since the underlying safety and effectiveness data are themselves not publicly available. This general approach to the handling of internal agency summaries has recently received judicial approval in "Montrose Chemical Corp. v. Train," 491 F.2d 63 (D.C. Cir. 1974).

101. It is frequent practice for the Food and Drug Administration to prepare a summary of comments received on proposed regulations or objections received on final regulations, for purposes of internal decisionmaking. Requests have been made for copies of such summaries.

The Commissioner concludes that such summaries are internal memoranda that ordinarily will not be made available for public disclosure. Such summaries usually combine both factual information and conclusions and policy recommendations. The underlying documents on which the summary is based are all available for public disclosure. The courts have recently ruled that such summaries are therefore exempt from disclosure pursuant to the internal memorandum exemption.

"Montrose Chemical Corp. v. Train," 491 F.2d 63 (D.C. Cir. 1974).

102. Weekly reports are prepared by the Food and Drug Administration field offices for submission to the Executive Director for Regional Operations in Washington. Requests have been made for such reports.

The Commissioner advises that such reports are internal memoranda that are explicitly exempt from disclosure under the Freedom of Information Act. Although they contain some factual information that may be disclosable, they also contain conclusions and recommendations relating to policy that are not disclosable.

The Commissioner advises that, in order to promote free and open discussion between field personnel and headquarters, it is not feasible to make such reports available for public disclosure on a routine basis. The factual information contained in any specific report may well be available for public disclosure if it does not otherwise fall within an exemption from the Freedom of Information Act, and the Commissioner tries to consider release of any specific report on a discretionary basis if good cause is shown for such release.

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CLEARLY UNWARRANTED INVASIONS OF PERSONAL PRIVACY

103. A comment wanted to know the exemption to the Freedom of Information Act from the disclosure of names of persons from the records of the agency. The comment stated that names or identifying characteristics may be deleted from "personnel and medical files" only if disclosure would provide a clearly unwarranted invasion of privacy. Whether or not an invasion of privacy is clearly unwarranted must be decided on a case-by-case basis. "Geiman v. NLUB," 450 F.2d 674 (D.C. Cir. 1971) was cited for the proposition that an agency must "balance the right of privacy of affected individuals against the right of the public to be informed, and the statutory language 'clearly unwarranted' instructs (an agency) to tilt the balance in favor of disclosure," 450 F.2d at 674.

The Commissioner advises that he has deleted the names of persons in intramural memoranda that are internal memoranda exempt under the Freedom of Information Act and general principles pertaining to the right to privacy under common law and the Constitution. The Freedom of Information Act exempts from public disclosure trade secret data and personnel files, and similar files the disclosure of which is a clearly unwarranted invasion of personal privacy.

The agency has concluded that the release of any names contained in a medical file is clearly unwarranted, except in extraordinary circumstances. A possible exception to this general conclusion might arise if an issue of fraud were to be involved. Similarly, names of individuals involved in criminal investigations will be deleted if no criminal charges are brought, in order to prevent unfair accusation.

104. Many questions have been asked about the relationship between proposed § 4.31 and the related provisions in proposed § 4.26(f). It was contended that a provision allowing for a leakage of personal files, and all similar files the disclosure of which is clearly unwarranted invasion of personal privacy, will be deleted if no criminal charges are brought, in order to prevent unfair accusation.

The Commissioner agrees that these two provisions require clarification, and appropriate modifications have been made in the final regulations. The Commissioner advises that, pursuant to §4111(c)(3)(i) of the final regulations, all consumer letters and other communications received from lay persons, which relate to their own personal complaints, will be made public after deletion of names and other identifying information, in order to protect their privacy.

With respect to complaints received voluntarily from third parties, usually health professionals, i.e., doctors, nurses, pharmacists, and so forth, relating to patients, to the extent the Commissioner has observed, and which thus relate to complaints made on behalf of other persons, the Commissioner concludes on the

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basis of the longstanding experience of the Food and Drug Administration that it is essential to pledge that all identifying information will be deleted prior to public disclosure, and § 4.111(e)(3)(ii) so provides. If the pledge is not made, the possibility of persuading medical professionals voluntarily to submit important adverse reaction information on marketed products to the Food and Drug Administration is substantially diminished, and indeed perhaps wholly destroyed. Such information is important to the Food and Drug Administration and to the public, since it may well lead to action by the Food and Drug Administration designed to protect the public health. Accordingly, the Commissioner concludes that deletion of all such identifying information from such reports prior to release to the public is fully within the intent of the personal privacy and confidential commercial information exemptions.

The comments stated that, even though a specific request for confidentiality may not be made, consumer complaint letters may contain documents which are per se confidential. Some complaints and records were obtained by a patient's written request to doctors or hospitals. Such medical records may be confidential or such medical release may imply the confidence of the patient. Release of medical records of complainants may violate the doctor-patient relationship of confidentiality. The comments pointed out the provisions of the Freedom of Information Act exempting medical files of government employees from disclosure, and urged that this same privilege be extended to all letters containing such material which are submitted to the Food and Drug Administration.

The Commissioner advises that such medical records are seldom enclosed with a consumer complaint. However, if the Food and Drug Administration does receive medical records of a complainant, they will be held as confidential even if the complainant makes no specific request for confidentiality, except that they may be released in the public interest.

106. Comments on various provisions in the proposed regulations contended that manufacturer and product names should be accorded the same treatment as individual names. It was urged that corporations be permitted to require the Food and Drug Administration to keep their identity confidential if they submitted a particular piece of information voluntarily. The Commissioner agrees that this is implied in § 4.63(b) of the final regulations.

107. Comments stated that, if the name of the investigator is a test or research project should be deleted where the report of the test or project is otherwise disclosable, in order to prevent a clearly unwarranted invasion of his personal privacy.

The Commissioner concludes that the final regulations properly provide for a showing in a particular instance that a manufacturer or product name constitutes confidential commercial information and thus, under § 4.61, is properly deleted from a record before it is made available for public disclosure.

108. A comment asserts that the disclosure of personal privacy or confidential commercial information is warranted invasion of personal privacy. A "fishing expedition" of this type will not be permitted. In the event that a specific record relating to a specifically named individual, without that individual's consent.

109. Comments stated that § 4.31(b) of the proposed regulations, which stated that the identity of patients should not be disclosed in IND and NDA submissions, more properly belongs in other portions of the Food and Drug Administration regulations.

110. The proposed § 4.32, dealing with investigatory records, has been redesignated as § 4.111(c) of the final regulations.

The Commissioner concurs that this provision should be added to other Food and Drug Administration regulations, but believes that the principle should also be stated in Part 4. Accordingly, § 4.65(b) of the final regulations states this policy in general terms.

111. Numerous questions have been raised with respect to specific documents that will or will not be made available pursuant to the investigatory records exemption in detail by the Commissioner in light of the exemption for Investigatory records. The proposed regulations published in May 1973 took a very open disclosure policy, and provided for disclosure even where the law permitted retention of records as confidential. Implementation of that proposal during the test and study of investigatory records is customarily published in the scientific literature with a summary of their work, and an investigator's curriculum vitae may be part of the related projects in which he has participated. Accordingly, the Commissioner concludes that disclosure of the name of the investigator on a particular project is neither a clearly unwarranted invasion of personal privacy nor confidential commercial information.

112. Questions have arisen as to whether the Food and Drug Administration will divulge all agency records relating to a specifically named individual, without that individual's consent. The Commissioner advises that any such request is regarded as a clearly unwarranted invasion of personal privacy. A "fishing expedition" of this type will not be permitted. In the event that a specific record relating to a specifically named individual, without that individual's consent, A "fishing expedition" of this type will not be permitted. In the event that a specific record relating to a specifically named individual, without that individual's consent, the Commissioner concludes that this provision should be added to other Food and Drug Administration regulations.

The Commissioner concludes that the final regulations properly provide for a showing in a particular instance that a manufacturer or product name constitutes confidential commercial information and thus, under § 4.61, is properly deleted from a record before it is made available for public disclosure.
there will be no adverse impact whatever on the right to fair trial and impartial adjudication.

The Commissioner has also considered these matters in light of the revision of the investigatory records exemption contained in the Freedom of Information Act amendments. It is the Commissioner's conclusion that the final regulations fully meet the standards set out in that revision and thus that the regulations do not require further change.

112. Comments contended that the release of investigatory records after a matter is closed is directly contrary to the Food and Drug Administration's prior position as expressed in Mamana, "FDA's Obligations Under The 1966 Public Information Act," FDA Papers, Sept. 1967 at page 18:

"It is also reasonable to conclude that the indiscriminate distribution of FDA investigatory files to the public would result in a carte blanche interpretation of the facts contained in such files. This would not be in keeping with the principles of fair play and justice to those regulated."

The Commissioner advises that, since the publication of that article, there has been a reevaluation of the release of information to the public. Whether or not to claim a particular exemption is discretionary and, in this instance, the agency has exercised its discretion in favor of greater disclosure. Experience during the past 2 years has demonstrated that this will not jeopardize the agency's law enforcement efforts. The Commissioner therefore concludes that disclosure of this material is entirely proper.

113. A comment contended that, in order to justify the use of the investigatory records exemption, there must be a concrete prospect of enforcement proceedings. It was urged that, after an inspection has been made, the Food and Drug Administration should within 3 months to determine whether or not to institute proceedings.

If a decision is made not to institute proceedings or if no decision is made within 3 months, the files should be opened. The comment concluded that 3 years of such limitations would destroy all attempts to examine or understand Food and Drug Administration compliance activities within the last 3 years, which is clearly not the intent of the Freedom of Information Act.

The Commissioner concludes that it is appropriate to establish internal guidelines in determining when a matter is "closed." No arbitrary time period can properly be established. In very few, if any, instances will disclosure of investigatory records be delayed until the statute of limitations runs. A decision on action is normally made within the Food and Drug Administration within a relatively short period of time. Only where a decision is made to take legal action and the action is in protecting prosecution or litigation will the matter normally remain open for any lengthy period of time.

The Commissioner advises that investigatory records will be available as soon as the decision is made not to take action on the specific matter involved in that record. To make this intent clearer, § 4.64 has been revised to replace the word "file" with the word "record." This is consistent with the Freedom of Information Act amendments, which make the same change in the statutory language. Thus, although a Food and Drug Administration file remains open on a continuous basis, and records on which no action has been taken in the past may well be the subject of future action where there is a continuing problem, individual records will be released at the earliest possible moment.

The Commissioner advises that, except in unusual circumstances, a record will be considered closed following:

1. Inspection, when:
   a. The report, as endorsed by the supervisor, shows either no action is indicated (NAI), or in compliance (IC), and there are no samples in the process of being analyzed which are related to the inspection. If samples are being analyzed, the file remains open until the samples are determined to be not actionable (NAD).
   b. The report is endorsed as voluntary action indicated (VAI), and a subsequent decision is made by higher review authority that no action will be taken (NAI).

Note: The issuance of a letter to the company has no bearing on the status of the matter.

2. Sample collection, when:
   a. The district office concludes the sample is not actionable (NAI), or not the sample was analyzed.
   b. A decision is made by higher review authority that the sample is not actionable (NAI), based on the sample results.
   c. Any legal action involving the sample is completed.

Note: Results of analyses or worksheets shall be given to a firm on request and thus are available to the public on request.

3. Regulatory letter, when:
   a. A response has been received which has been verified to show the violations were corrected, and no further action is contemplated.

Note: The regulatory letter itself and any correspondence relating to it or documents given to the company are available to the public as soon as they are issued.

4. Seizure, when:
   a. A decision is made not to forward the case to a United States attorney (PA).
   b. A final decision is made by the Department of Justice not to file the case.
   c. The case is adjudicated and time for appeal is past.

Note: Court papers filed in connection with litigation are available to the public when filed, unless directed otherwise by the court.

5. Injunction, when:
   a. A decision is made not to forward the case to a United States attorney (PA).
   b. A final decision is made by the Department of Justice not to file the case.
   c. The case is adjudicated and time for appeal is past.

Note: Court papers filed in connection with an injunction are available to the public when filed, unless directed otherwise by the court.

6. Recall, when:
   a. A decision has been made not to pursue criminal or civil action, based on the recall. This may be some time after the recall is completed, or shortly after it begins. The point is reached whenever the decision is made.

Note: Information on each recall is immediately released. The recall releases may be issued on certain recalls, and all correspondence with the firm is available to the public upon request.

7. Imports, when:
   a. A refusal of entry has been issued. The fact of detention is public information as soon as the detention is made, but the file does not become available until after there is an opportunity for an informal hearing, a final refusal of admission is made, and all litigation is concluded.
   b. The product has been released into commerce.

LIMITATIONS ON EXEMPTIONS

114. A number of the regulations in the May 1972 proposal relate to limitations on the exemptions from the Freedom of Information Act, i.e., exceptions to the usual rules of nondisclosure. The Commissioner concludes that these limitations should properly be grouped together in a separate new Subpart E of Part 4, for purposes of clarity.
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APPLICABILITY OF LIMITATIONS ON EXEMPTIONS

115. Comments requested clarification on the extent to which a record that is ordinarily exempt from public disclosure could nonetheless be disclosed by the Food and Drug Administration to limited categories of persons without breaking the rule that a record must be available to all members of the public if it is available to anyone.

The Commissioner advises that the Freedom of Information Act specifically recognizes certain categories of persons and situations where a record may be disclosed without making it generally available to all members of the public. A number of comments were focused on the circumstances where disclosure of a record will and will not require general disclosure to the public. For example, when the Commissioner concludes to exercise his discretion pursuant to § 4.82 to disclose an internal memorandum that he would otherwise be authorized to withhold from disclosure, that record must be available to any member of the public who requests it. If the Commissioner discloses that internal memorandum to Congress or to another Federal agency, however, disclosure to the public is not required.

DATA AND INFORMATION PREVIOUSLY DISCLOSED TO THE PUBLIC

116. Section 4.28 of the proposed regulations, which provided that data and information previously made available to the public will not be regarded as confidential by the Food and Drug Administration, has been redesignated as § 4.81 in the final regulation.

A number of comments stated that the proposal was too restrictive and indicated that there may be situations in which trade secret information is furnished in confidence to individuals other than employees or paid consultants, e.g., confidential disclosures to clinical investigators or to potential or actual licensees, or during discovery, or to other government agencies, or to health authorities outside the United States. It was suggested that the applicant himself may have received the information under contract from a third party. It was further suggested that the provision be revised to contain the following language:

For purposes of these regulations, such data and information will not be deemed to have been disclosed to the public if it is disclosed by the owner thereof on a confidential basis and with appropriate restrictions on its disclosure or use.

The Commissioner agrees that there may be other legal arrangements between business associates under which such disclosure of trade secrets is entirely appropriate and would not destroy the confidentiality of the information involved.

Section 4.81 of the final regulation provides. Disclosure to a limited number of unpaid consultants solely for purposes of the consultation involved is specifically permitted.

117. Comments stated that the mechanism for determining whether there has been prior public disclosure of a submission is unclear. It was suggested that a statement be required, subject to the False Reports to the Government Act (18 U.S.C. 1001), for all information previously submitted.

The Commissioner concludes that a statement with respect to prior disclosure will be requested only when the Food and Drug Administration concludes that the issue is relevant to a question of disclosure. It would not be feasible to require such a statement for all information previously submitted to the agency, and any requirement would be wasteful because much of the previously submitted information is unlikely ever to be requested.

118. A comment contended that the policy as stated in the preamble seems more restrictive than as stated in the proposed regulation, i.e., the preamble refers to disclosure by the manufacturer, while the proposed regulation refers to disclosure by the Commissioner. The Commissioner advises that lawful disclosure to the public by any person is sufficient to destroy the confidentiality of the information. Disclosure of material in any unlawful way, e.g., stolen material, will not destroy its confidentiality.

119. A question was raised as to what was meant by “public disclosure.” It was suggested that the disclosure in a scientific article of the product formula should not be equated with the manufacturing process information and quantitative formula as required by the Food and Drug Administration. Refinement of a manufacturing process to the point where it produces a drug of high quality is a process more costly and exacting than required to prepare new components which are described in scientific literature.

The Commissioner advises that public disclosure is any lawful disclosure outside of the company and its consultants. Any information that has appeared in a published article has been publicly disclosed. However, such publication constitutes the publication of the information that appears in the article. If only the product formula appears, only the product formula has been disclosed.

120. Questions have been raised as to whether disclosure in litigation is sufficient to break the trade secret status of data and information.

The Commissioner concludes that such disclosure would break the trade secret status of the material unless it were disclosed to the court in camera or pursuant to a protective order or only to defense counsel.

121. Questions were raised in comments as to whether the confidential status of a trade secret will be broken if the information involved has been given to licensees, to Federal or State agencies, to foreign governments for regulatory purposes, or to business associates under contract.

The Commissioner advises that, under all the situations described above, the confidentiality of the information will be retained. It is only when the information is given to a member of the public without any arrangement of this type that confidentiality can no longer be claimed.

The Commissioner specifically rejects the suggestion that trade secret material should not lose its confidential status if it was conveyed to any member of the public pursuant to any type of "confidentiality agreement." This loose wording would permit, for example, a manufacturer to disseminate any information he wished on a widespread basis, simply through stating in his letters that receipt of the information constitutes agreement that it will be retained as confidential. The Commissioner concludes that the trade secret laws cannot properly be construed this broadly.

122. A comment asked whether, in a situation where the composition of a new packaging material and process has been published in a patent, the patent does not reveal the detailed commercial process, the Food and Drug Administration would conclude that the detailed commercial process has been disclosed, and thus would release it to the public.

The Commissioner advises that the Food and Drug Administration must find a previous disclosure of information only to the extent that such information has actually been disclosed. In the instance cited in the comment, if the commercial process was not described in the patent or elsewhere, there has not been prior disclosure and the Food and Drug Administration will not release the information.

123. In one instance during the past 2 years, the Food and Drug Administration denied a consumer's request for release of the identity of the color used in a drug when the company affected informed the agency that it had not previously made such information available to the public. Shortly thereafter, when a physician requested the same information from the manufacturer, the latter refused to give it to him. The Food and Drug Administration then released the information to the consumer who had originally requested it.

The Commissioner concludes that it is important to emphasize to companies who request trade secret status of data or information submitted to the Food and Drug Administration that any statements made with respect to the lack of prior release to the public are subject to the False Reports to the Government Act. Accordingly, all communications with firms with respect to this type of issue in the future will contain a statement to that effect.

DISCRETIONARY DISCLOSURE BY THE COMMISSIONER

124. The exemptions from public disclosure under the Freedom of Information Act are discretionary, not mandatory. Numerous occasions have arisen in the past 2 years where the Commissioner has made available, in the absence of public disclosure under the Freedom of Information Act should nonetheless be made available to the public.

Accordingly, the Commissioner has concluded that new § 4.82 should be
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added to the final regulations to authorize the discretionary release of documents which could lawfully be held as confidential under the Freedom of Information Act, where the Commissioner concludes that such release would be in the public interest, and where such release is not otherwise prohibited by law. The Commissioner concludes that the purpose of the Freedom of Information Act was to make the operations of Federal agencies more available to public scrutiny, but to subject information derived from private sources to unwarranted disclosure. Comments argued that the proposed regulations published in May 1972 released most information shielded by statutory or internal Food and Drug Administration memoranda.

The Commissioner advises that the congressional intent was to permit greater public scrutiny of Federal agency operations and the data and information on which those agencies base their decisions. Even though internal agency memoranda are explicitly excluded by the law, the final regulations provide for discretionary release of such information whenever the Commissioner concludes that it will not hinder agency operations and is in the public interest.

126. Questions have arisen as to whether the Commissioner may, in his discretion, release trade secret information. The Commissioner advises, for the reasons set out elsewhere in this preamble, that he has no discretion to release trade secret information. All records subject to such an exemption from public disclosure pursuant to 18 U.S.C. 1905 and 21 U.S.C. 331(j) do not require disclosure of all similar documents. Such a conclusion would be counter-productive, because it would require rigid adherence to the statutory exemptions, and less disclosure of information to the public, contrary to the intent of the Freedom of Information Act. A new provision has been added to §4.82 of the final regulations to state this policy.

DISCLOSURE PURSUANT TO COURT ORDER

130. Comments pointed out that the Food and Drug Administration cannot guarantee confidentiality for any record, since a court may conclude that the information is subject to disclosure.

The Commissioner concurs with this comment. Accordingly, new §4.83 states that a determination of confidentiality by the Food and Drug Administration pursuant to §4.4, or indeed pursuant to any provision in these final regulations which states that a particular record is exempt from public disclosure, means that the Food and Drug Administration will make the record available for public disclosure only if ordered by a court.

DISCLOSURE TO CONSULTANTS, ADVISORY COMMITTEES, STATE AND LOCAL GOVERNMENT OFFICIALS COMMISSIONED PURSUANT TO 21 U.S.C. 372(a), AND OTHER SPECIAL GOVERNMENT EMPLOYEES

131. Section 4.30 of the proposed regulations published in May 1972, which states that confidential documents may be disclosed to special government employees without disclosing them to all members of the public, is redesignated as §4.84 in the final regulations.

A comment stated that disclosure to consultants and advisory committees should be made pursuant to a ‘‘confidentiality agreement’’ to insure that the data must be treated on a confidential basis.

The Commissioner agrees with this comment. Sections 4.80(c) and 4.84 of the regulations provide that all governmental employees and special government employees to whom such records are disclosed shall be subject to the same restrictions as Food and Drug Administration employees with respect to their disclosure.

132. In preparing for court cases, the Food and Drug Administration often consults with potential witnesses and, in the course of such discussion, may disclose internal information not previously disclosed to the general public. Questions have arisen as to whether such disclosure triggers the requirement that such information also be made available for public disclosure to any other person who requests it.

The Commissioner concludes that consultation with potential witnesses in preparation for litigation, whether it be in any court or at any place of hearing, does not fall within the rule that disclosure to one member of the public requires disclosure to all. Although these potential witnesses are not always special government employees, they are government consultants for purposes of the litigation, and thus such consultation falls within the exception established in §4.46 of the regulations for records of law enforcement purposes.

133. Comments stated that the Food and Drug Administration should clarify the conditions under which correspondences and summaries of meetings with special government employees are not disclosable. The Commissioner advised that there be disclosure unless the communication relates only and specifically to matters (a) upon which government employees are consulting or advising (b) which are encompassed within the scope of their duties as special government employees.

The Commissioner agrees with this comment, and §4.84 has been revised accordingly. The Commissioner concludes that, since these records are not special government employees, they stand in the same position as any other member of the public and are not subject to the provisions in §4.46 of the final regulations.

DISCLOSURE TO OTHER FEDERAL GOVERNMENT DEPARTMENTS AND AGENCIES

135. Questions have arisen about the disclosure of information contained in Food and Drug Administration files to other Federal government departments and agencies.

The Commissioner concludes that, since most records are not special government employees, they stand in the same position as any other member of the public and are not subject to the provisions in §4.46 of the final regulations.

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informed of new developments and can prepare for any appropriate action prior to release to the public of the full results in a final report.

Section 703 (d) explicitly provides that the material it covers may only be disclosed within the Department of Health, Education, and Welfare, or to the courts when relevant in any judicial proceeding. This provision is in accordance with the provisions of § 4.85. Where another Federal government agency has concurrent jurisdiction over a matter, however, and thus also has legal authority to review new material covered by section 301 (c), the Food and Drug Administration may share such material directly with that other agency rather than requiring the other agency to obtain it from the original source. This situation occurs, for example, as a result of the joint jurisdiction of the Food and Drug Administration and the Environmental Protection Agency over pesticides that are also new animal drugs.

136. Concern has been expressed that, if the Food and Drug Administration makes available to other government agencies information that is exempt from public disclosure, those other agencies may disclose the information contrary to a pledge of confidentiality given by the Food and Drug Administration in writing or in regulations.

The Commissioner advises that any data or information furnished to other government agencies that is not disclosable to the general public will be furnished only pursuant to an agreement that the information will be held in confidence. If no such assurance can be given, the data or information will not be furnished. Section 4.85 of the final regulations so provides.

DISCLOSURE IN ADMINISTRATIVE OR COURT PROCEEDINGS

137. No comments were received on the provision in the proposed regulations which stated that data and information exempt from public disclosure may nevertheless be revealed in administrative or court proceedings.

The Commissioner concludes that this provision should be retained in the final regulations under § 4.86. The Food and Drug Administration will, where some disclosure is necessary, take whatever action is reasonable to reduce such disclosure to the minimum necessary under the circumstances.

DISCLOSURE TO CONGRESS

138. The Freedom of Information Act explicitly provides that the exemptions are "not authority to withhold information from Congress." Section 301 (c) and thus is not subject to the exemptions from disclosure. A request for records from an individual member of Congress, on his own behalf or on behalf of any constituent, is subject to all the requirements applicable to a request for records by a member of the public, including the usual exemptions and fees.

See "EPA v. National. 410 U.S. 75 (1973)" and "Aspen v. Department of Defense." 491 F.2d 24 (D.C. Cir. 1978). A new § 4.87 has been added to the final regulations to state that the exemption from Congress" (5 U.S.C. 552(c)).

139. A question has arisen as to whether the General Accounting Office is within the provision contained in 5 U.S.C. 552(c) which states that the exemptions from disclosure under the Freedom of Information Act do not apply to "Congress." The Commissioner concludes that, since GAO was established by an act of Congress with powers to investigate agencies of the executive branch, it is within the exception set out in 5 U.S.C. 552(c) and thus stands on the same footing as congressional committees and subcommittees.

140. Concern has been expressed that information exempt from public disclosure pursuant to the Freedom of Information Act should not be disclosed to Congress, and that there is no statutory provision prohibiting Congress from disclosing such information. In particular, it has been pointed out that some years ago a committee obtained from the Food and Drug Administration adverse reaction information which it subsequently published as part of a record of a hearing without the consent of the physician or other identifying information. As a result, physicians have expressed reluctance to supply such information to the Food and Drug Administration. The Commissioner concludes that the law presently does not prohibit release by Congress of confidential information obtained from the Food and Drug Administration which is otherwise exempt from public disclosure. However, the Commissioner knows of no instance other than the one mentioned above in which this has happened. In that specific instance, no record of the hearing was obtained from the disclosure. In discussions with congressional staff members, the Food and Drug Administration has been advised that the single incident mentioned above was an aberration that will be guarded against in the future. The Commissioner therefore concludes that disclosures of this type are extremely unlikely.

COMMUNICATIONS WITH STATE AND LOCAL GOVERNMENT OFFICIALS

141. Section 702(a) of the act (21 U.S.C. 372(a)) authorizes the Food and Drug Administration to commission any health, food, or drug officers or employee of any State, Territory, or political subdivision to act as an officer of the Food and Drug Administration in conducting examinations and investigations for purposes of enforcement of the act. Pursuant to this provision, the Food and Drug Administration has commissioned a number of State and local officials to help enforce the law. In addition, sections 301 and 311 of the Public Health Service Act (42 U.S.C. 241 and 243) encourage cooperative efforts between State and local officials and the Food and Drug Administration in regulatory activities. Indeed, the effectiveness of the Food and Drug Administration is frequently dependent upon the cooperation of such State and local officials.

The Commissioner concludes that all information exchanged between the Food and Drug Administration and a State or local official is protected by Section 702(a) of the act, whether the official is a State or local official or a State or local official under contract with the Food and Drug Administration to conduct law enforcement work is exempt from disclosure under the Freedom of Information Act pursuant to the intra-agency memorandum and investigatory records exemption. Such information will be subject to discretionary release by the Commissioner, however, pursuant to the principles established in these new regulations, after consultation with the State or local official involved.

142. A number of comments raised questions about the status of foreign government officials. Specific instances have arisen in which a counterpart agency in a foreign country has offered data or information to the Food and Drug Administration on a confidential basis, or the Food and Drug Administration has wished to make

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The Commissioner concludes that the Food and Drug Administration has authority to withhold only information specifically exempt from disclosure under the Freedom of Information Act. The Commissioner believes that § 4.69 reflects the current law in this regard and will permit the agency to retain in confidence all trade secret information or investigatory files.

145. Questions have arisen about the status of papers prepared for or by international organizations. In particular, the Food and Agriculture Organization and the World Health Organization.

The Commissioner notes that 22 U.S.C. 288a(c) provides that "The archives of international organizations shall be inviolable." The Commissioner interprets this to mean that the United States government and the public may not obtain information from such organizations, i.e., the Freedom of Information Act does not apply to such organizations. This does not mean, however, that communications from such organizations, or materials prepared by the Food and Drug Administration for such organizations, are not subject to public disclosure under the Freedom of Information Act. The Commissioner concludes that Congress has not granted special immunity to such records. Accordingly, communications to and from such organizations will have the same status as documents to and from any other organization.

146. In particular, a question has been raised about the availability for public disclosure of working papers prepared by an employee of the Food and Drug Administration for the World Health Organization.

The Commissioner notes that when such working papers are prepared by an employee of a representative of the Food and Drug Administration, and not in an individual capacity, all such documents are properly available for public disclosure in accordance with the rules that apply to all records contained in agency files. However, when such records are not prepared during working hours, using the facilities of the Food and Drug Administration, and are included on Food and Drug Administration files, they are not available for public disclosure.

147. No comments were received on the provisions contained in the proposed regulations stating that any data or information obtained by the Food and Drug Administration, by any means whatever, may be used as the basis for taking any appropriate administrative or court enforcement action within its jurisdiction.

The Commissioner concludes that this provision should be retained in the final regulations as § 4.90 Data and information generated by the Food and Drug Administration routinely discloses commercial information about recalled products that is relevant to the recall but that would not otherwise be disclosed. The Commissioner concludes that, when enforcement action of this type occurs, such information is customarily revealed and thus that the exemption for confidential commercial information is no longer applicable.

**AVAILABILITY OF SPECIFIC CATEGORIES OF DOCUMENTS**

148. Many of the sections in the proposed regulations published in May 1972 related to the availability of specific categories of documents. Some of these categories of documents are the subject of specific regulations established by the Food and Drug Administration, e.g., food additive petitions and new drug applications, and the detailed rules on the availability of documents not dealt with elsewhere in Food and Drug Administration, by any means whatsoever, may be used as the basis for taking any appropriate administrative or court enforcement action within its jurisdiction.

The Commissioner concludes that this provision should be retained in the final regulations as § 4.90 Data and information generated by the Food and Drug Administration routinely discloses commercial information about recalled products that is relevant to the recall but that would not otherwise be disclosed. The Commissioner concludes that, when enforcement action of this type occurs, such information is customarily revealed and thus that the exemption for confidential commercial information is no longer applicable.

**APPLICATION**

149. Numerous comments on the proposed regulations published in May 1972 expressed concern that some of the provisions relating to specific categories of documents not dealt with elsewhere in Food and Drug Administration regulations, for example, § 4.60 and § 4.100(c) is also included to cross-reference all other sections in the act relating to the availability of documents not specifically dealt with in Subpart F of Part 4.
For ready reference, new § 4.100(e) lists all of the other Food and Drug Administration regulations relating to public disclosure of records. Additions to this list will be made when new procedures relating to public disclosure are published. When other regulations are published by the Food and Drug Administration setting out rules on the availability of specific records for public disclosure.

ADMINISTRATIVE ENFORCEMENT RECORDS

A Rule 4.21 of the proposed regulations, which made available for public disclosure records of all informal administrative enforcement action, has been redesignated as § 4.101 in the final regulations.

As with § 16(c), a number of comments expressed concern about "trial by newspaper" as a result of release of informal enforcement action records. It was stated that there was a great potential for an imbalanced and distorted view since not all information bearing on an alleged violation would necessarily be in the files, e.g., information concerning the severity of the violation and the extent of its occurrence. A Food and Drug Administration employee's report might be incorrect, and the discovery of the extent of the possible violations, should be given the opportunity to review the file and explain it before it is released to the public. It was argued that a rebuttal after the item had hit the newspapers was too late. A denial after disclosure could not repair the damage already done to the business reputation. It was also suggested that if the agency disclosed warning letters and other requests for corrective action, it should also make public a balanced presentation of the facts, including the fact, if such is the case, that an alleged violation is purely technical.

The Commissioner concludes that these comments are not persuasive, and that all records of administrative enforcement action disclosed to any person, as well as all administrative actions. The Commissioner concludes that these comments are not persuasive, and that all records of administrative enforcement action disclosed to any person, as well as all administrative actions.

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The Commissioner concludes that these comments are not persuasive, and that all records of administrative enforcement action disclosed to any person, as well as all administrative actions.
have been observed during a factory inspection and reported in an EIR.

In accordance with the Commissioner’s conclusion, this correspondence with any person outside the Federal government is properly made public, all such postinspection correspondence will be made publicly available upon request. Such letters, under the heading of warnings pursuant to section 306 of the act, and may well be in lieu of seizure. See “Wellford v. Hardin,” 444 F.2d 21 (4th Cir. 1971). Such letters have been released publicly for the past 2 years without disruption of the activities of the agency.

In many instances, the Food and Drug Administration issues a formal regulatory letter pursuant to section 306 of the act, stating that appropriate court action will be undertaken if specified violations of the act are not corrected.

The Commissioner concludes that all regulatory letters, and all followup correspondence relating to such letters, will be made publicly available upon their issuance. These letters constitute administrative enforcement records of the agency and should be subject to the same disclosure principles as court enforcement action.

The Commissioner concludes that a copy of each regulatory letter will be filed in the Food and Drug Administration Public Records and Documents Center, for public review. Additional correspondence and memoranda relating to such letters and followup correspondence shall also be made available. Thus, regulatory letters will be handled in the same way as court actions filed by the agency. All regulatory letters issued by the agency during the past 2 years have been made publicly available upon request without any adverse consequences.

The Commissioner concludes that all administrative enforcement records require administrative enforcement records be public upon request, for the same reasons that regulatory letters and other administrative enforcement records are the subject of public disclosure. The Commissioner believes that all regulatory action taken by the agency, whether of an administrative or of a court nature, must be subject to public scrutiny and public accountability. In releasing records on recall, however, the Commissioner will delete any confidential commercial information that may be included. For example, a list of customers of a particular regulated product and sales demographics are considered confidential commercial information, and will not be disclosed to the public.

A number of comments noted the absence of such an exemption for trade secret or confidential information, and indicated that such an exemption should be added.

4.100(a) makes clear, each exemption from the Freedom of Information Act, including the exemption for trade secret and confidential commercial information, applies to all records released by the agency. The Commissioner concludes that it is impractical to mention each exemption in each section of the regulations.

162. Comments suggested that some of the information covered by this section would be included in the investigatory records exemption.

The Commissioner concludes that there is no overlap between these sections. The investigatory records exemption in § 4.100 is explicitly limited only to data and information obtained by the Food and Drug Administration, retained solely in its files, and not shown to anyone outside the agency. Thus, communications with an affected person or company, such as the observations left by a Food and Drug Administration employee or product analyses furnished to a company, Section 4.64 covers only the Food and Drug Administration’s own investigatory reports which are not made available outside the agency, such as an EIR or any other internal report, as well as the information obtained by the FDA after hearing records and other investigatory reports relating to an active and current criminal investigation. The provisions of §§ 4.64 and 4.101 have been revised to clarify this point.

163. A number of requests have been made for “action levels” used by the agency in determining when it will institute administrative or court enforcement action against a product for violation of the law.

The Commissioner advises that all such action levels have, to the best of his knowledge, now been made public. The action levels naturally are unavoidable defects in food are the subject of § 128.10 (21 CFR 128.10). Paragraph 7 of the preamble to the final order promulgating that regulation, published in the Federal Register of November 14, 1973 (38 FR 3854), stated that, when finally revised, all such action levels will be published in the Federal Register for comment, and that, in the absence of comment, such action levels will be made available to the public upon request from the office of the Assistant Commissioner for Public Affairs, Food and Drug Administration, Rm. 15B-42, 5600 Fishers Lane, Rockville, MD 20852. Such action levels are also available at the Food and Drug Administration Public Records and Documents Center.

The Commissioner has recently proposed a revision of Part 123 of the regulations (21 CFR Part 123), published in the Federal Register of December 6, 1974 (39 FR 42738), to provide for publication of all action levels for food products not included within § 128.10. Although the Commissioner recognizes that this project will require a significant amount of resources and cannot be completed in a short period of time, and that legal action can in any event be taken for violation of the law without publication of action levels or enforcement criteria, it is the Commissioner’s intent in the future to publish all action levels in the Federal Register with time for comment, in order to codify them in regulations.

In the past, the Food and Drug Administration utilized a “tolerance on a tolerance” under some limited circumstances. In these instances, legal action would not be undertaken against a product which exceeded a specified level. In many instances, these tolerances may properly be retained by an agency as confidential. Nevertheless, the Food and Drug Administration concluded some years ago that all such unannounced tolerances should be abolished, and none remains in existence today.

A determination that a product violates an action level must, of course, be made on the basis of specified analytical methodology and equipment. In many instances, such methodology yields variable results, and thus is accurate only within a specified variance. In many instances, this variability is widely known within the scientific profession. The Food and Drug Administration will make available to the public upon request the amount of variability in the methodology the agency in considering enforcement action based upon analytical results.

Finally, the Food and Drug Administration has established levels above which its field offices may request legal action directly to the office of the General Counsel, rather than through the Bureau compliance offices. Findings below these levels, but above the action level, must be sent to the Bureau compliance office and then forwarded to the office of General Counsel. The Commissioner concludes that these “direct reference levels” need not be held in confidence and may properly be made available for disclosure to the public.

COURT ENFORCEMENT RECORDS

164. The Food and Drug Administration institutes many formal legal actions in the courts every year. These include seizures, injunctions, and criminal prosecutions. The Commissioner concludes that a new § 4.102 should be added to the final regulations concerning the availability of documents relating to these matters.

All legal documents filed in the courts are public information. In order to make certain that accurate copies are obtained, copies of any such documents must be requested directly from the court involved. The Commissioner concludes, however, that the Food and Drug Administration will make available copies of such documents when it has a copy that can be determined to be in the form actually filed in the court.

165. In some instances, legal actions requested by the Food and Drug Administration are not filed by a United States attorney. Requests have been made for copies of such records, regardless whether the action was or was not filed.

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The Commissioner advises that the correspondence with the United States attorney and the recommendations to which the correspondence is related are available for public disclosure upon request in accordance with the provisions of § 4.64 Investigatory records containing executive or judicial chambers.

The Commissioner concludes that there is no such communication between the Food and Drug Administration and industry because of a reluctance of industry to discuss sensitive issues in a public forum. It was asserted that the public interest would be better served by open communication between the Food and Drug Administration and the regulated industries.

The Commissioner concludes that there is no reason to believe that public disclosure of correspondence would hinder the flow of communications in any way. Experience under this provision during the past 2 years has shown no difficulty whatever. Correspondence between the agency and nongovernmental groups and individuals outside the agency is clearly not exempt under the Freedom of Information Act, except to the extent that portions may fall within the specific exemptions under the law.

The Commissioner advises that the exemption for trade secrets and confidential commercial information was not included in this provision, since correspondence might well include such information.

The Commissioner advises that the exemption for trade secrets and confidential commercial information applies to all agencies. Any exemption will be deleted before correspondence is disclosed. Sections 4.60 and 4.100 emphasize that fact.

The Commissioner advised that any correspondence with the agency's decision will be subject to full disclosure, e.g., correspondence with appli-
were cited for that proposition, "Grum-
man Aircraft Corporation v. Nego-
tiation Board," 425 F.2d 578 (D.C. Cir.
1970).

The Commissioner agrees with this
comment and advises that §§ 4.22 and
4.60 make this policy clear.

174. Comments asked whether the
summaries to which this provision applies
were intended to be a contemporaneous
record or a record prepared in response
to a request for information.

As stated in § 4.24 of the final regula-
tions, the Freedom of Information Act
does not require the preparation of docu-
ments in response to requests for infor-
mation. Any summary of oral discussions
to be disclosed pursuant to § 4.104 will be
an existing contemporaneous record. If
no such summary exists, none need be
prepared. The Commissioner will shortly
be issuing comprehensive new pro-
cedural regulations that will state the
circumstances under which Food and Drug
Administration employees will be
required to prepare a summary of an oral
discussion.

175. One comment advanced the propo-
sition that summaries of telephone calls
or meetings containing a clearly identifi-
able active file should carry the level of
confidentiality of the parent file. An-
other indicated that confidentiality
should be maintained if the disclosure
was necessary in the public interest or for
an assumption of confidential treatment of
the information. Still another drew a paral-
el to the disclosure of the sum-
maries and wiretapping and commented
that such disclosure of this nature is un-
permissible in a court of law, there was a
serious question as to whether it should
be made available to the public.

The Commissioner concludes that
the proposals of the Freedom of Information
Act apply only to specific records, not to
total bodies of documents. Accordingly,
it is improper to label any particular file as "confiden-
tial" and thus any summary subject to § 4.16 will not be releasable to determine whether, on its own merits, it is dis-
closable in part or in full.

The Commissioner advises that disclo-
sure of information on the basis of a grant
of confidentiality will be subject to the
specific procedures set out in new
§ 4.44 of the final regulations. No other
form of confidentiality will be granted
except in the form of explicit provisions
relating to particular types of documents
in the final regulations.

The Commissioner concludes that there
is no parallel whatever between prepara-
tion of a summary of telephone conver-
tation and disclosure of such conversa-
tions. The public should be aware that
such summaries are routinely maintained. In
any event, these regulations and the new
provisions on confidentiality constitute public
notice that such summaries are being
preparing.

176. A number of comments were con-
cerned with the possibility that govern-
ment-composed summaries of telephone
calls and meetings might contain mis-
quotes, inaccurate transcriptions, and
one-sided interpretations. It was sug-
gested that the problem of misinterpre-
tation could be dealt with by furnishing
a copy of the summary to the nongovern-
ment party. The nongovernment person
would then be given an opportunity to
reply in writing and any written reply would be included when
disclosure was made.

The Commissioner is aware that a summary
prepared by one party to an oral discus-
sion and that summary is not otherwise
disclosed would be disclosed under the
Freedom of Information Act for any such
summary, both summaries (or indeed as many as
exist) will be disclosed at the same time
pursuant to § 4.104(c).

177. Many comments cited this section as
inhibiting frank and open communi-
cation between the Food and Drug
Administration and industry. One letter
suggested, on the strength of "Israel v.
Baxter Laboratories," 406 F. 2d 372 (D.C.
Cir. 1970), that reports of violations by
Trust litigants may properly request a
copy of the summary in order to verify
its contents. The new procedural regu-
lations will explicitly provide that any
summary prepared by the Food and Drug
Administration in the event that a re-
quest is made under the Freedom of In-
formation Act for any such summary,
will be disclosed under the Freedom of
Information Act for any such summary,
both summaries (or indeed as many as
exist) will be disclosed at the same time
pursuant to § 4.104(c).

178. A number of comments referred to
the lack of a specific exemption in § 4.24
(b) for trade secrets and confidential in-
formation and expressed the fear that
there would be disclosure without the
editing out of such exempt information.
Comments noted that confidential in-
formation is frequently subject to disclo-
sure under the Freedom of Informa-
tion Act. The exemption covers only
"commercial or financial information"
that is "privileged or confidential". It was
argued that reference to confidential information in this provision was in ef-
flect broadening the exemption as it ap-
pears in the statute.

The Commissioner concludes that re-
vised § 4.61 makes this clear.

The Commissioner agrees that "confidential" information is not per se exempt from disclosure under the Freedom of Information Act, and § 4.61 makes this clear.

The Commissioner concludes that it is often not feas-
able to distinguish between regulatory and nonregulatory testing and research, and that, in any event, there is no sound public policy reason for not disclosing both types of testing and research.

The intent of the proposal was to retain as
cochaerent the regulatory testing and
research that is part of investigatory
activities for law enforcement purposes.

The Commissioner concludes, however,
that he should exercise his discretion to
release this part of investigatory records
in order to make as full a disclosure of agency activities as possible
without disrupting enforcement proceed-
ings. All such testing and research would be disclosed in the course of law enforcement proceedings, and in its earlier disclosure should not have
any adverse impact on agency activities.

Moreover, there are strong public pol-
icy reasons for disclosing all regulatory
testing and research when it is com-
pleted and a final report is available or it
is otherwise disclosed to any member of
the public. The Food and Drug Ad-
mistration is an agency of the govern-
ment and the only way to determine the
basis for the request.

The proposed regulation provided that
a list of nonregulatory testing and
research being conducted by other funds
provided by the Food and Drug
Administration, together with any re-
search contract, would be available for
public disclosure.

In seeking to implement this proposed
provision, the Commissioner has dis-
covered that, as already noted, it is not
feasible to divide testing and research into
regulatory and nonregulatory pur-
poses nor is it practical to maintain a
list of all testing and research being
carried out. All research contracts are of
course available for public disclosure,
and any internal listing of ongoing testing or
research is also available upon request.

The Commissioner therefore concludes
that § 4.105(a) should be revised to delete
the requirement for preparation and main-
tenance of a comprehensive list of all agency testing and research, but to
retain the provision stating that any list
of agency testing and research that is
prepared will be available upon request.
181. Comments requested clarification of the term "final report." If some form of agency approval is necessary before the results of such research can be characterized as "final," the public should be informed whether or not this would mean an effective agency method for al- lowing disclosure of testing and research the agency deems ill-advised to release, i.e., by simply never characterizing a report as "final." The comments cited "Con- sumers Union v. Veterans Administration," 301 F. Supp. 796 (S.D.N.Y. 1969), in which the court ordered the Veterans Administration to release raw test data on hearing aids, for the proposition that raw data in a tabular form must be released.

The Commissioner concludes that, un- til a report is completed and accepted by the Veterans Administration official, it represents an intra- agency document that is not available for public disclosure. The Freedom of Infor- mation Act does not require pre- mises by the agency in a manner other than as provided in Subpart E of Part 4 of this chapter whether or not a final report has not yet been prepared. Authorized dissemination of any data or information to persons other than as provided in Subpart E of Part 4 of this chapter breaks the internal memorandum ex- emption and requires disclosure of such data or information to any person who requests it.

184. Questions have been raised as to whether preliminary data obtained from agency testing or research is disclosable if it forms the basis for a talk or other public presentation prior to preparation of a final report.

The Commissioner advises that, once such information is disclosed publicly by the Food and Drug Administration in any way, whether in a formal or in a private conversation or in a public talk, all of such information reasonably related to the material disclosed must be made publicly available at that time even though a final report has not yet been prepared. Authorized dissemination of any data or information to persons other than as provided in Subpart E of Part 4 of this chapter breaks the internal memorandum ex- emption and requires disclosure of such data or information to any person who requests it.

185. One comment expressed uncer- tainty as to whether testing done on marketed drugs would be disclosed to the public. If so, it was argued that the manufacturer should be given the op- portunity to review the results and com- ment on them before the report was made available to the public. Another comment suggested that a summary of the research should be prepared so that the study might be properly understood by the lay public.

The Commissioner concludes that all testing on marketed drugs, whether for regulatory or nonregulatory purposes, will be available for public disclosure. Comment was made that the release of test results is not feasible or required by the law. The preparation of summaries of this research, as sug- gested, is not contemplated by the Free- dom of Information Act, nor can the agency justify the expenditure of man- power which would be required to create such documents.

186. The Food and Drug Administra- tion obtains different types of product samples in the course of its regula- tory activities. A Food and Drug Administra- tion employee will often obtain a sample during a factory inspection. The Food and Drug Administration employee must make a receipt for such a sample, and a copy of the results of the analyses are required by law to be furnished promptly to the person from whom the sample was obtained. Where a sample is obtained other than through a factory inspection, and it results in a release, the Food and Drug Administra- tion is required under section 304(c) of the Federal Food, Drug, and Cosmetic Act to furnish the results of any analysis to any party to the inspection.

There is no legal requirement that the Food and Drug Administration fur- nish the results of any other analyses to any person who might be affected by them.

The Commissioner concludes that, regardless of the origin of any sample obtained by the Food and Drug Administra- tion, the results of any analysis of a sample will be made available upon re- quest to any interested person, whether or not that person is directly affected by the results of the analysis. As a matter of policy, any affected person should immediately be given the results upon re- quest in order to take appropriate action. In accordance with the general principle that any information available to one member of the public must be available to everyone, the Commissioner concludes that all analyses of this type should be made generally available to the public upon request.

187. Several comments noted the pos- sibility that agency research might rely, in part, on manufacturer-generated or government-funded research results. If information utilized in such studies which had been supplied by nongovernment sources.

The Commissioner advises that § 4.61 of the regulations applies to disclosure of trade secrets and confidential com- mercial information in any agency docu- ments, and §§ 4.60 and 4.100 of the final regulations make this clear. The Com- missioner concludes that trade secret in- formation may not be disclosed. This does not mean, however, that agency re- search or regulatory requirements can be based on trade secret informa- tion. For example, bioavailability data on a drug submitted by a manufacturer may constitute trade secret information that is not disclosable to the public. This secret status for such information would not prevent the Food and Drug Administration from conduct- ing and disclosing its own similar re- search, however, or from imposing by regulation new requirements for the data involved in order to protect the public health.

188. A comment pointed out that in its performance tests and analyses, the Food and Drug Administration may include trade secrets or other confidential commercial data in test protocols or re- cords of the testing.

The Commissioner advises that any trade secrets or confidential commercial information involved in testing or re- search will be deleted before the results are made available for public disclosure.

189. Questions have arisen as to what Internal Food and Drug Administration

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reports and studies are available for public disclosure.

The Commissioner has reviewed the various categories of reports and studies conducted by the Food and Drug Administration, and has set out in new § 4.106 those types that will be disclosed and those that will be retained as confidential under the internal memorandum exemption. The Commissioner recognizes that a number of these reports may be partially or fully exempt under the internal memorandum exemption, but has concluded that it is in the public interest to release as many of them as feasible when they are prepared in final form. In general, the following types of reports and studies will be reviewed upon their acceptance by the responsible agency official: Quarterly and annual reports of the agency; broad reviews of outside sources for purposes of establishing internal priorities and programs; compilations, and summaries of industry surveys of consumers or industry and other similar studies undertaken to determine the need for or content of proposed new regulations or compliance programs; studies undertaken to determine the performance of the regulated industry or the products it produces, such as contamination of foods or the sanitation status of a particular type of food product; for example. As a general rule, the following types of studies will not ordinarily be disclosed to the public: Internal audits of agency performance to determine the possible need for personnel changes or other action to strengthen agency performance; the records relating to the internal planning and budget process; and legislative proposals or comments unless, as yet, they are submitted to Congress.

190. In particular, questions have been raised about the availability of the results of special drug surveys, and FORDS studies (Formulator Oriented Rx Drug Study).

The Commissioner advises that all such analyses and surveys are available for public disclosure without deletion of the brand name or lot number involved. The Bureau of Drugs of the Food and Drug Administration presently publishes the results of such analyses and surveys on a periodic basis.

191. Questions have been raised about the public availability of Food and Drug Administration compliance programs, which are sent to field offices to direct specific regulatory activities.

The Commissioner advises that all such compliance programs are available for public disclosure upon request, with any names of specific firms, the location of specific activity, and details about sampling numbers or sizes deleted in order to preclude disclosure of regulatory activity.

192. Questions have been raised about the availability of final agency work plans prepared by bureaus, field offices, and other agency components, as well as the yearly and other agency plans prepared by the office of the Commissioner for the entire agency.

The Commissioner advises that all such plans are available for public disclosure after they have been reviewed and approved by the responsible agency official in their final form, with any information about specific regulatory activities deleted.

FOOD AND DRUG ADMINISTRATION MANUALS

193. Questions have arisen about the status of various manuals maintained by the Food and Drug Administration, such as the Regulatory Procedures Manual, the Administrative Guidelines Manual, and similar material.

The Commissioner advises that all such manuals have been reviewed to delete confidential internal directives, and are available for public review in the Food and Drug Administration Public Records and Documents Center. Copies of these manuals may also be purchased at cost, but the Food and Drug Administration does not maintain a mailing list for small orders. Further, the cost of these manuals because of the prohibitive expense involved. A complete index of all such manuals is being prepared and will be available from the Food and Drug Administration Public Records and Documents Center pursuant to § 4.26. A partial list of these manuals is as follows:

Administrative Guidelines Manual
Bacteriological Analytical Manual
Drug Additives Manual
Food Additives Manual
Inspector Operations Manual
Instrument Operations Manual
Laboratory Information Bulletins
Laboratory Operations Manual
Microanalytical Manual
Pesticide Analytical Manual
Regulatory Procedures Manual

194. A comment contended that all agency operating manuals must be made available under the Freedom of Information Act, and that the exemptions from disclosure do not apply to any portion of them.

The Commissioner disagrees with this comment. Nothing in the administrative history of the Freedom of Information Act indicates that otherwise nondisclosable information must be made available through agency operating manuals. Accordingly, the Commissioner has reviewed all such manuals and deleted from them information that falls within any of the exemptions from disclosure. All of those manuals, as so revised, are now available for public review and purchase.

AGREEMENTS BETWEEN THE FOOD AND DRUG ADMINISTRATION AND OTHER DEPARTMENTS, AGENCIES, AND ORGANIZATIONS

195. Requests have been made for copies of agreements entered into by the Food and Drug Administration with State and Federal agencies and with private organizations.

The Commissioner has recently issued a notice, published in the Federal Register of October 5, 1974 (39 FR 35697), stating that all such agreements are on file in the office of the Food and Drug Administration Public Records and Documents Center, and that all future agreements will be published in the Federal Register. A new § 4.108 has been added to state this policy.

DATA AND INFORMATION OBTAINED BY CONTRACT

196. Various questions have been raised about the availability for public disclosure of data and information furnished to the Food and Drug Administration pursuant to contracts with outside organizations. In particular, the question has been raised whether information can be purchased from the Food and Drug Administration by contract, with a clause which precludes public dissemination. Some private organizations, for example, undertake market research surveys and then sell the results to purchasers who must agree not to distribute the information further. This type of contract is used so that one person to whom information is disclosed cannot distribute it to a second person. There has been concern that the Freedom of Information Act would preclude the Food and Drug Administration from purchasing such information pursuant to a contract of this type.

The Commissioner concludes that the Freedom of Information Act does not permit the Food and Drug Administration to purchase information under a contract that prohibits its further public distribution, unless the information is otherwise exempt from disclosure. All information obtained by the Food and Drug Administration is available for public disclosure unless it falls within a specific exemption established in Subpart D of Part 4 of the regulations.

The Commissioner notes that, on occasion, the Food and Drug Administration has also entered into contracts which permit representatives of the agency to review and obtain copies of such material. Under these circumstances, since the Food and Drug Administration does not have copies of the documents in its files, the Freedom of Information Act is inapplicable.

197. A question has arisen as to whether the progress reports on contracts, which are usually submitted to the Food and Drug Administration quarterly, are available for public disclosure.

The Commissioner advises that the Freedom of Information Act requires disclosure of information generated under contract. Including progress reports, is available for public disclosure when received by the Food and Drug Administration, except to the extent that it contains material otherwise exempt from public disclosure under these regulations.

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198. Questions have arisen as to what information is available about Food and Drug Administration employees. The Commissioner advises that the name, title, grade, position description, salary, and work address and telephone number for every Food and Drug Administration employee is available for public disclosure. The home address and telephone number of such employees are not available because they fall within the personal privacy exemption. A new § 4.110 has been added to the regulations to state this policy.

199. The Food and Drug Administration has received a number of requests with respect to prior employment experience of present agency employees, and present employment of past agency employees. Although no such lists had been kept in the past, the Commissioner concluded that one such list should be undertaken in order to respond adequately to inquiries of this type.

The Commissioner advises that the statistics obtained from this research are not available for public disclosure at the Food and Drug Administration Public Records and Documents Center. They will be kept up to date on a periodic basis. Pursuant to the exemption for personal privacy, the data are not available for public disclosure.

DATA AND INFORMATION SUBMITTED VOLUNTARILY TO THE FOOD AND DRUG ADMINISTRATION

200. Section 4.26 of the proposed regulations published in May 1972, dealing with data and information submitted voluntarily, has been redesignated as § 4.111 in its present form.

Several comments objected to the concept of permitting information to be withheld as confidential simply because the agency would refuse to submit it unless it was so held. It was argued that the Freedom of Information Act makes no such distinction and that such an approach flatly obstructs the purpose of the act. However, § 4.26 permits the agency to require, in every instance of voluntary submission of data and information, a pledge of confidentiality. Consumer complaints are exempt from disclosure to the extent set out in § 4.111(c) (3) (v) of the final regulations, i.e., they will be released only as part of a blind compilation. Consumer complaints, adverse reaction information, and confidential commercial information exemptions justify these rules.

203. Comments contended that the Food and Drug Administration should not distinguish between information submitted voluntarily and involuntarily, and suggested that the agency should reject all "voluntary" information in order to impress upon Congress the need for new legislation to compel submission of such data and information.

The Commissioner rejects this contention. As the agency is not designated by Congress to protect against distribution of adulterated or misbranded food, drugs, cosmetics, devices, and electronic products, the Food and Drug Administration is obligated to obtain all data and information, from any source, that will assist it in these important regulatory efforts. The Food and Drug Administration will also continue to request appropriate legislation from Congress to provide important new investigatory and enforcement tools.

204. Questions have arisen about the status of records of adverse reactions to products, where such information is submitted voluntarily by the manufacturer, i.e., not pursuant to the requirements of the new drug or prescription drug factory inspection sections of the law or pursuant to a procurement contract. The law presently does not authorize the Food and Drug Administration to require that reports of such adverse reactions be furnished, unless the personal privacy and confidential commercial information exemptions are satisfied.

The Commissioner advises that such adverse reaction reports are subject to the following disclosure rules, depending upon the source of the information and any request for confidentiality submitted with it. If the report is received in a consumer complaint letter, it will be made public after deletion of any information that could identify the individual involved. If it is made by a physician or other health professional, it will be made public after all identifying information relating to the patient, physician, and product has been deleted, with the identification of the product will be revealed. If the reaction is reported by a manufacturer, public disclosure of the report will be made only in the form of a blinded compilation.

205. Experience during the past 2 years has shown that manufacturers and physicians are uniformly unwilling to divulge consumer complaint or adverse reaction information, or other materials of this type, voluntarily except on a selective basis.

Accordingly, the Commissioner concludes that it serves no useful purpose to require, in every instance of voluntary disclosure of this type, that the manufacturer or physician be requested to state whether the information will be disclosed without such a pledge of confidentiality. Adherence to such a provision would simply increase administrative red tape and serve no public interest. Section 4.111(e) (3) (ii) and (iii) of the final regulations therefore provides for appropriate deletions of information where it is provided by a physician, and provides that reports submitted by a manufacturer may be released only as part of a blind compilation that will not reveal the name of the manufacturer or the brand name of the product involved except when regulatory action is involved.
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reporting to the agency, upon the pay-
ment of a standard fee, adverse reac-
tions and other medical information re-
lated to products subject to the agency's
jurisdiction.

The Commissioner advises that the re-
ports obtained pursuant to such con-
tracts are not submitted voluntarily, and
that the identity of the reporting
institution will be disclosed. The name of
any physician or other health profes-
sionals will also be disclosed if any
such name is included in the agency,
but the contracts involved do not re-
quire the reporting of any such names.

207. One comment suggested that the
provisions which permit names of those
submitting adverse reaction data to re-
main confidential “applies the sniper”
and that if an individual is unwilling to
be identified he should not be heard to
be heard.

The Commissioner concludes that
there are valid reasons why an indi-
vidual might wish to submit informa-
tion without disclosure. It should be
noted that if an individual is not identi-
fied and the complaint cannot be followed
up, this may affect the weight accorded
the complaint by those to whom it is
disclosed.

208. Comments contended that the
Freedom of Information Act does not
allow the Food and Drug Administra-
tion to distinguish between the handling of
adverse reactions to products for which
reports must be submitted to the agency,
and adverse reactions to products for
which the agency presently cannot re-
quire such reports.

The Commissioner disagrees with this
comment. Until new legislation is en-
acted authorizing the Food and Drug Adminis-
tration to obtain adverse reaction reports
from manufacturers on all products
subject to its jurisdiction, the
agency is dependent upon the voluntary
submission of such information for all
products except new drugs and prescrip-
tion drugs. Adverse reaction information
is often of critical importance in deter-
mining the safety, or lack thereof, of a
marketed product. Without such infor-
mation, the Food and Drug Adminis-
tration’s efforts to prevent the continued
marketing of an unsafe product would be
substantially hindered.

Nothing in the legislative history of
the Freedom of Information Act indi-
cates that the agency intended to be
applied in a way that would hinder reg-
ulatory activity or prevent an agency from
taking action to protect the pub-
lic health.

The Commissioner believes that it is en-
thusiasm to require disclosure of any
adverse reaction reports that are not
required to be submitted to the Food
and Drug Administration, and which
the manufacturer will not otherwise
submit, fall within the exemptions for
confidential commercial information,
Voluntary Product Defect Reports

216. The Food and Drug Administration has entered into a program with the United States Pharmacopeia (U.S.P.) under which reports on drug product defects are furnished to the agency for use in formulating regulatory action. The information obtained in this manner will be deleted prior to public disclosure of any report. Similar programs are being pursued with other organizations.

The Commissioner advises that all commitments with respect to confidentiality of identifying information of this type will be honored, under the personal privacy, confidential commercial information, and investigatory records exemptions. A new § 4.113 has been added to the final regulations to state this policy.

217. A request was received for a compilation of all the defect reports received for one particular drug pursuant to the program undertaken by the United States Pharmacopeia and the Food and Drug Administration. The Commissioner advises that specific reports will be disclosed after deletion of information that would identify any individual. A compilation of reports showing the number of reports for each drug, by generic name or by brand name, is also available for public disclosure. The Commissioner realizes that the Food and Drug Administration does not necessarily investigate each defect report, and therefore their accuracy cannot be verified. Where this is the situation, release of such reports may be accomplished with an explanatory statement to that effect.

Data and Information Submitted Pursuant to Cooperative Quality Assurance Agreements

218. The Food and Drug Administration has entered into a number of cooperative quality assurance agreements with members of the food and drug industry. These agreements provide that the company will disclose to the Food and Drug Administration pertinent internal records and documents which are not required by law to be disclosed, and which the company regards as confidential trade secret and commercial information.

The Commissioner advises that all records and documents of this nature which are voluntarily disclosed pursuant to a cooperative quality assurance agreement will be retained by the Food and Drug Administration as confidential in accordance with section 4.111. In order to clarify this matter, a new § 4.114 has been added to the regulations to state this policy.

219. Questions have been raised as to whether the Better Salmon Control Plan entered into between the National Canners Association and the Food and Drug Administration, and any records obtained from companies pursuant to this plan, will be available for public disclosure under the Freedom of Information Act.

The Commissioner advises that the plan is available for public review in the Office of the Food and Drug Administration Public Records and Documents Center. All company records obtained pursuant to the plan will be handled in accordance with §§ 4.111 and 4.114 of these final regulations for information voluntarily submitted to the Food and Drug Administration relating to quality assurance. No records relating to manufacturing procedures and quality control will be available for public disclosure.

Product Codes for Manufacturing or Sales Dates

220. Requests have been made for the keys to the codes used by manufacturers to identify the actual date of manufacture of a drug. Final regulations at 21 CFR 1022.10(b) and 1010.3(a) (2) were published in the Federal Register of May 8, 1974 (39 FR 16227), requiring that, in the future, the date of actual manufacture must be stated on the product in understandable terms rather than in code.

The Commissioner concludes that coded information with respect to a date of manufacture, a date by which the product should be sold, or a date by which the product must be withdrawn and the date the Food and Drug Administration was notified that marketing of the product was discontinued.

Drug Listing Information

221. The Drug Listing Act of 1972 (Public Law 92-387, 86 Stat. 559), which amended section 510 of the Federal Food, Drug, and Cosmetic Act in 1938, requires drug manufacturers to submit specific information to the Food and Drug Administration with respect to marketed drugs. This provision of the law contains its own confidentiality requirements, and there is extensive legislative history interpreting them.

The Commissioner has previously promulgated regulations in the Federal Register of March 7, 1973 (38 FR 6238), establishing Part 132 of the regulations (21 CFR Part 132) implementing these provisions of the law. All requests for information obtained by the Food and Drug Administration pursuant to section 510 of the act will be handled in accordance with the provisions of Part 132. Accordingly, new § 4.116 cross-references the confidentiality provisions of these regulations.

New Drug Information

222. The Food and Drug Administration Bureau of Drugs has computerized a large amount of information relating to investigational new drug notices and new drug applications, extending back to the enactment of the Federal Food, Drug, and Cosmetic Act in 1938. Questions have arisen as to what information will be made available for public disclosure, and in what form, from this computer bank of information.

The Commissioner concludes that certain basic information on previously approved new drug applications should be readily available to any member of the public who wishes to review it, without cost. Accordingly, the following two computer printouts have been placed on public display in the Office of the Food and Drug Administration Public Records and Documents Center, where they may be reviewed during working hours:

a. A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938, showing the NDA number, the trade name, the applicant, the approval date, and, where applicable, the date approval was withdrawn and the date the Food and Drug Administration was notified that marketing of the product was discontinued.

b. A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938 which are still approved. This printout shows the same information as the first printout, except that it does not show a withdrawal date.

c. Printouts of these printouts may be ordered, at cost. Orders will be filled in accordance with the priorities established for use of the Food and Drug Administration computer.

In addition to the computer printouts that will be permanently available for public review, the following examples of information may be obtained in printout form upon special request:

An alphabetical list by trade name of the approved new drug applications and abbreviated new drug applications held by specific applicants.

An alphabetical list of the trade names of drugs subject to approved new drug applications showing either the NDA number or the applicant or both.

d. An alphabetical list of generic drugs showing approved new drug applications and abbreviated new drug applications held by applicants.

e. An alphabetical list of commercial sponsors who have filed investigational new drug notices.

Orders for such printouts will also be filled as rapidly as possible, subject to other priorities for the Food and Drug Administration computer.

The Commissioner concludes that a list of all drugs subject to investigational new drug notices constitutes trade secret information that may not be disclosed to the public.

223. The Food and Drug Administration has received requests for a list of the names and addresses of all investigators who have ever worked on investigational new drugs, without designating the specific drugs they investigated.
similar request has been received for a
list of the names and addresses of all drug
manufacturers. The Commissioners who have
ever filed an investigational new drug no-
tice (IND) or a new drug application (NDA), without designating the specific drugs involved.

The Commissioner advises that such lists are available for public disclosure to the extent that they already exist in documentary form or can be obtained from computer printouts by existing programs.

ADVISORY COMMITTEES

224. One comment contended that the proposed regulations relating to advisory committees "perpetuates the secrecy that has characterized the deliberations of FDA advisory committees" and proposed that the following items be required and available for disclosure:

a. The transcript of each advisory committee meeting where the same had been stenographically reported, or a complete summary of the meeting, in lieu of the stenographic report. The transcript or summary shall contain a record of the person present with their affiliation, a description of the matters discussed and the conclusions reached, and copies of reports and background information on the advisory activities as approved by the advisory committee. The accuracy of a summary shall be certified to by the chairman of the advisory committee. Participants shall be given an opportunity to review and make corrections before a summary is certified.

b. A complete and accurate summary of each meeting, telephone call or activity relating to an advisory committee, in whole or in part, to advisory committee business which was conducted at a time or in a place other than an actual meeting of an advisory committee only or advisory committee members and strangers. In case a stranger is involved, his affiliation will be disclosed.

c. A copy of each directive or guideline given to the advisory committee by the Food and Drug Administration.

d. A copy of the agenda of each meeting of an advisory committee.

e. A list of the names of all the corporations, companies, firms, state or local organizations, research organizations, and educational or other institutions in which an advisory committee member is serving as an employee, officer, member, owner, director, trustee, advisor or consultant.

The Commissioner concludes that the provisions governing whether the meeting or telephone conversation involved advisory committee members only or advisory committee members and strangers. In case a stranger is involved, his affiliation will be disclosed.

The Commissioner advises that data and file information contained in a master file and have the same status that they would have in a petition or application. The fact that they are maintained in a master file rather than directly in a petition or application is of no relevance.

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COLOR ADDITIVE, FOOD ADDITIVE, ANTIBIOTIC, NEW DRUG, AND NEW ANIMAL DRUG PETITIONS, APPLICATIONS, AND FORMS

225. The proposed regulations published in May 1972 contained specific amendments to existing regulations dealing with color additives, food additives, new animal drugs, and new drugs. The Commissioner determined that the provisions present issues that are common to some or all of these regulations, as well as to the provisions in § 4.111 Data and Information submitted voluntarily to the Food and Drug Administration. For example, the handling of requests for disclosure of test protocols, assay, and reaction reports, source of the products and methods must be the same for all of these various types of documents.

Accordingly, the Commissioner has grouped together all of the comments relating to the status of test protocols, assay, and adverse reaction reports, source of the products and methods. All of these comments have been revised to reflect this policy.

226. Questions have been raised with respect to the status of data and information submitted to the Food and Drug Administration in the form of a master file, which are subsequently used to support individual petitions or applications. It was suggested in comments that all master file material should remain confidential.

The Commissioner advises that data and file information contained in a master file and have the same status that they would have in a petition or application. The fact that they are maintained in a master file rather than directly in a petition or application is of no relevance.

227. Several comments questioned the Commissioner's reference to § 4.111 Data and Information submitted voluntarily to the Food and Drug Administration. For example, the handling of requests for disclosure of test protocols, assay, and adverse reaction reports, source of the products and methods must be the same for all of these various types of documents.

Accordingly, the Commissioner has grouped together all of the comments relating to the status of test protocols, assay, and adverse reaction reports, source of the products and methods. All of these comments have been revised to reflect this policy.

228. A number of comments requested clarification of the intended scope of "safety, effectiveness, and functionality data" under the regulations.

The Commissioner advises that this phrase encompasses all data from animal and human tests designed to show safety, effectiveness, and all studies and tests conducted to establish the basic safety, stability, purity, potency, bioavailability, performance, and usefulness of the product. It does not include quality control tests conducted on manufacturing process and a product to be marketed.

The Commissioner advises that this phrase encompasses all data from animal and human tests designed to show safety, effectiveness, and all studies and tests conducted to establish the basic safety, stability, purity, potency, bioavailability, performance, and usefulness of the product. It does not include quality control tests conducted on manufacturing process and a product to be marketed.

229. Requests have been made for safety, effectiveness, and functionality data and information contained in letter format concerning commercial and noncommercial data or new or new animal drug status of products or ingredients.

The Commissioner advises that these matters will be handled as follows:

a. If the request relates to the status of a food or feed ingredient, the safety and functionality information will be made available to the public immediately.

b. If the request relates to the status of a drug or animal drug under the act, a decision as to what information is discloseable must await the response of the Food and Drug Administration to the request. If it is decided that the drug or animal drug does not require a new drug application or new animal drug application, the safety and effectiveness data will be made available for public disclosure. If the decision is that the new drug application or new animal drug application is required, such data and information will remain exempt from disclosure as trade secrets except to the extent that any of the data is in possession of the person; and it has previously been made public. This is the procedure presently being followed under the OTC drug review pursuant to § 330.10(a)(2) of the regulations (21 C.F.R. § 330.10(a)).

SAFETY, EFFECTIVENESS, AND FUNCTIONALITY DATA AND INFORMATION CONTAINED IN COLOR ADDITIVE, FOOD ADDITIVE, AND ANTIBIOTIC DRUG PETITIONS AND FORMS

230. The proposed regulations published in May 1972 established the same rules for release of safety, effectiveness, and functionality data contained in color additive, food additive, antibiotic drug petitions and forms. Under the Federal Food, Drug, and Cosmetic Act, these three types of petitions and forms result in public regulations rather than private licenses, although antibiotic drugs are subject to the IND provisions of the law.

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prior to approval for marketing. Accordingly, it was concluded that the safety, functionality, and effectiveness data do not fall within the trade secrets and confidential commercial information exemption and thus are properly made available for public disclosure regardless of whether the petitioner has previously made this information public.

All of the comments received with respect to the handling of these matters have been grouped together for purposes of analysis and discussion in this preamble.

It was pointed out in some comments that this was a direct about-face from the previous position of the Food and Drug Administration. It was urged that data contained in food and color additive petitions and antibiotic drug forms be disclosed only to Food and Drug Administration consultants, advisory committees, and special government employees not to the public.

The Commissioner notes that there was no clear policy on this matter in the past, and that in any event the policy of the Food and Drug Administration prior to enactment of the Freedom of Information Act was uncertain as to whether data produced with respect to proper implementation of the Freedom of Information Act at the present time. The Commissioner concludes that the safety, functionality, and effectiveness data contained in food and color additive petitions and antibiotic drug forms have no trade secret value and, since they are often published in scientific journals or given to customers or scientists or disclosed to the public in other ways, are not customarily regarded as privileged. Accordingly, this type of material does not qualify as confidential either under the trade secret portion of the exemption or under the confidential commercial and financial data portion of the exemption. This is in contrast to other information, such as manufacturing processes, which are customarily so disclosed or made public.

Several comments objected to the statement in paragraph 5 of the preamble to the proposed regulations published May 1972, to the effect that research data for food additives and color additives are "not the type of commercial information customarily regarded as privileged."

The Commissioner disagrees with this comment and affirms the statement made in the preamble to the proposed regulations. A number of comments filed by food ingredient manufacturers did not object to the type of safety and functionality data for food additives and color additives. In the intervening 2 years, all such data have been made available to the public. Although affected manufacturers may be legally entitled to keep data secret, the Commissioner concludes that the legitimate desire of industry to maintain the confidentiality of its data until the final decision on the petition or approval is usually not in the public interest, particularly in light of the potential for competitive advantage and for unfair competitive advantage that would otherwise be enjoyed by competitors. The Commissioner disagrees with the proposed regulations as written in this paragraph.

The Commissioner agrees with the substance of this comment. Accordingly, the final regulations provide that the safety and functionality data contained in color additive and food additive petitions will be made available for public disclosure when the notice of filing of the petition is published in the Federal Register. Where such notice of filing is substantially delayed, because the petition does not contain all information that must be furnished and further testing is required, the safety and functionality data submitted will be available for public disclosure after the review of the submission by the Food and Drug Administration is complete and the petitioner has been informed of the deficiencies. Similarly, the safety and effectiveness data contained in an antibiotic drug form will be available for public disclosure when the Food and Drug Administration issues an approval letter to the manufacturer. This usually occurs a substantial time before an antibiotic drug monograph is published in the Federal Register.

The Commissioner believes that this approach adequately accommodates any legitimate desire of industry to maintain the confidentiality of its data until a reasonable time before approval, the need for the Food and Drug Administration for review and evaluation of the submission before it is released to the public, and the right of the public for access to the data and information submitted in order to make meaningful comments on it within the time period provided.

Comments suggested that, if food and color additive petitions and antibiotic drug forms are not customarily privileged, manufacturers should not be able to show "extraordinary circumstances" to justify nondisclosure. It was emphasized that no "extraordinary circumstances" may be created by a manufacturer's plea where the Freedom of Information Act exemptions do not apply.

The Commissioner advises that the provision permitting a manufacturer to show "extraordinary circumstances" to justify nondisclosure is useful in the event that, on rare occasions, circumstances may arise that cannot be foreseen at this time which would require, in fairness, that information not be released to the public. The Commissioner anticipates that this will happen on very few occasions, and that in almost all instances this type of information will promptly be released to the public. In order to show "extraordinary circumstances," the manufacturer must demonstrate that release of the information will destroy a competitive advantage that he would otherwise enjoy, that he will be harmed financially as a result, and thus that it would be unlawful or unfair to release the information involved. The mere fact that the information may be embarrassing to the manufacturer or may disclose adverse reactions, or may be of interest to others, or that there is some remote future possibility of competitive advantage, or that others might conduct duplicative research which would be obviated by release of the information, or similar arguments, will be insufficient to justify nondisclosure.
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237. Following publication of the proposed regulations in May 1972, some food additive petitions were submitted to the agency marked "confidential" or accompanied by letters stating the opinion that the information contained therein was confidential.

In each of these instances, the Food and Drug Administration responded stating that the petition was being filed without any pledge of confidentiality. In order to clarify this matter, the Commissioner is including in new § 4.27 of the final regulations a statement that any such gratuitous designation by a person submitting a petition or application is of no legal effect, and that the only pledges of confidentiality that will be made by the Food and Drug Administration are contained in these final regulations themselves and through the procedure established in new § 4.44 of the regulations.

SAFETY AND EFFECTIVENESS DATA FOR NEW DRUGS AND NEW ANIMAL DRUGS

238. The proposed regulations published in May 1972 established the same rules for release of safety and effectiveness data contained in new drug and new animal drug applications. Under the Federal Food, Drug, and Cosmetic Act, these applications, and the notices relating to investigational use of new drugs, result in private licenses rather than in public regulations. Accordingly, it was concluded that the safety and effectiveness data for new drugs and new animal drugs, including antibiotic drugs for veterinary use, fall within the trade secrets exemption and thus are not available for public disclosure unless the applicant has previously made the information public or the drug has been approved or withdrawn from the market or the drug has reached the stage where it may be marketed without submission of such data to the agency for approval.

All of the comments received with respect to the handling of these matters have been grouped together for purposes of analysis and discussion in this preamble.

239. Comments suggested that the provision in the proposed regulations, that the existence of an IND will not be disclosed unless it has previously been "acknowledged" by the sponsor, is too vague, and that the term "publicly disclosed" should be substituted for "acknowledged."

The Commissioner concurs in part with this comment, and uses the phrase "publicly disclosed or acknowledged" in the final regulations. Private acknowledgment of the existence of an IND to a consultant is insufficient to constitute public disclosure. Discussion with other scientists who are not paid consultants, however, provides similar advantages in acknowledging the existence of an IND to any such person, is sufficient to break the confidentiality of the existence of an IND. The Commissioner notes that the existence of an IND is often common knowledge within the industry and the scientific world, and that confidentiality of such information is becoming more and more unusual.

240. Questions have arisen as to whether the existence of an IND notice can be regarded as confidential commercial information if the drug is marketed abroad or if published literature exists on the drug.

The Commissioner concludes that the existence of an IND notice under these circumstances will not be regarded as confidential. The marketing of a drug abroad or the publication of information about the drug constitutes public notice of the existence of the drug entity and the probability that the company will be considering marketing it. In particular, scientific discussion of the drug in the United States, in the literature or in meetings, clearly discloses the existence of an IND.

241. Requests have been received for the names and addresses of all investigators who have submitted an investigational new drug where the existence of the IND notice has been publicly disclosed or acknowledged.

The Commissioner concludes that a list of all such investigators is confidential commercial information. If such a list were disclosed, there would be a good possibility that competitors could determine from the list the identity of that investigators would seek out the investigators to determine whether they might also receive the investigational drug, or that the value of the study could be destroyed. If publicly known to be an investigator for a particular new drug. The Commissioner concludes that a curriculum vitae of a specific person who is publicly known to be an investigator for a particular new drug.

242. A request was received for the curriculum vitae of an individual who has previously been "approved" by the sponsor, and that the term "publicly disclosed" should be substituted for "acknowledged."

The Commissioner concludes that a curriculum vitae is properly available for public disclosure under these circumstances. Information contained in a curriculum vitae is properly distributed in a public fashion, and accordingly such release does not constitute an unwarranted invasion of privacy.

243. A comment contended that all IND information should likewise be disclosed, whether or not the IND has been terminated, for the protection of the human subjects involved in the drug experiments. The Commissioner concludes that the existence of an IND is full disclosure of all information, in particular, the adverse effects and more unusual.

244. Comments contended that once an IND is terminated, there is no public benefit to be obtained from the disclosure of information in it.

The Commissioner concludes that "public benefit" is not a criterion for determining whether information shall be disclosed to the public under the Freedom of Information Act. Moreover, in many instances there will be a definite public benefit from such disclosure.

245. Comments stated that even the irrevocable and final termination of an IND in this country should not result in disclosure of the safety and effectiveness information contained in it if the same drugs is being marketed elsewhere in the world.

The Commissioner does not agree with this comment. Even the pharmaceutical industry's competitors generally agreed that a summary of safety and effectiveness information can properly be disclosed to the public without violating the trade secrets and confidential commercial information contained in it if the same drugs is being marketed elsewhere in the world.

Moreover, none of the comments submitted for the Commissioner generally agreed that the full reports of such information, as contrasted with summaries, are required under foreign law in order to justify marketing abroad. The Commissioner concludes that the possibility of competitive advantage is too conjectural and remote to justify invoking the trade secrets exemption of the Freedom of Information Act. Should a specific instance arise in which a competitive advantage can be demonstrated in concrete terms, a manufacturer is permitted to seek nondisclosure of such information under the "extraordinary circumstances" exemption provided in the final regulations.

246. In at least two instances, manufacturers have requested that an IND be made non-dispositive because of the irrevocable and final termination, in and of itself, would result in the disclosure of the information in the IND becoming available for public disclosure.

The Commissioner advises that the termination of an IND is not dispositive. In the testing of a new drug, information about the drug from the drug company involved. Current Food and Drug Administration regulations require such disclosure, and the individual to be tested also also has the option of not participating in the test unless there is full disclosure of all information, including, in particular, the adverse effects on other test subjects. Proposed regulations on the follow-up of test subjects, and in some cases, the testing of animal tests before human tests, are presently under active consideration.
247. In one instance, a request was made for information contained in an IND file that is otherwise confidential. The Commissioner concludes that, under these circumstances, safety and effectiveness information contained in an IND file that is otherwise confidential will remain confidential. An IND is terminated or abandoned only after all human and animal work with respect to the drug has been discontinued. Accordingly, upon the filing and information contained in an IND that are otherwise confidential will not be disclosed to the public as long as the matter remains open and active. Where it is in doubt, the Food and Drug Administration will require submission of further information from the person who submitted the IND. Any statement relating to the future termination or abandonment with respect to the IND will be subject to the False Reports to the Government Act, 18 U.S.C. 1001.

248. One comment suggested that the IND filing be clarified to state that approval of an NDA, which technically results in termination or discontinuance of an IND, does not require release of all the confidential information contained in the IND. The Commissioner advises that the IND and NDA are regarded as one continuous process. Indeed, the NDA incorporates the IND. Accordingly, upon the filing or approval of an NDA the material in the IND has the same status as the material in the NDA. The final regulations make this clear.

249. The proposed regulations published in May 1972 provided that a list of pending new drug applications would be available for public inspection. The Commissioner has concluded that such a list should be made available only for new drug applications for which the applicant has been advised that the NDA is "approvable," and not for all pending new drug applications. The existence of a pending NDA constitutes confidential commercial information where the existence of clinical testing has not previously been publicly disclosed or acknowledged. Accordingly, the final regulations have been revised to state that the list will include only those new drug applications where the Commissioner has concluded that the Food and Drug Administration that the NDA is approvable.

250. Comments stated that the fact that a company has filed an IND or is engaged in particular pharmaceutical research may well be a trade secret. The Commissioner concludes that such information, although not a trade secret, is properly regarded as confidential commercial information that will not be disclosed to the public by the Food and Drug Administration unless it has previously been disclosed or acknowledged to any member of the public.

251. Comments asserted that knowledge of a pending IND will allow a potential competitor an advantage because he will then be in a position to adjust his marketing strategy in anticipation of a competing product.

252. Undoubtedly the most persistent issue raised in the comments relates to the disclosure of safety and effectiveness data in IND and NDA files. Comments requesting disclosure of all such information quite properly pointed out that it is important to scientists and physicians. The Commissioner agrees that the fact that an NDA or NADA is pending is confidential commercial information that will not be disclosed if it has not previously been publicly acknowledged or disclosed. The trade press often reports that an NDA has been submitted or is pending for a particular drug. Consequently, a company will make such information public in its reports to stockholders.

253. Undoubtedly the most persistent issue raised in the comments relates to the disclosure of safety and effectiveness data in IND and NDA files. Comments requesting disclosure of all such information quite properly pointed out that it is of enormous economic value. The Commissioner concludes that there can be no question, under present law, about the economic value of the full reports of the safety and effectiveness data contained in an IND, NDA, INAD, or NADA. Such information is the product of millions of dollars of tests and the work of thousands of scientists. Release of such information would allow a competitor to obtain approval from the Food and Drug Administration for the marketing of the identical product, at a mere fraction of the cost. Present law contains no provision that would permit the Food and Drug Administration to refuse to approve a "me-too" product on the basis of information obtained from the first manufacturer, once that information from the first manufacturer is disclosed.

254. The Commissioner recognizes the important public policy interest that would be raised by disclosure of such trade secret data. The public is dependent upon private pharmaceutical manufacturers for development of drugs. In some instances, millions of dollars to obtain. Release of such information would allow a competitor to obtain approval from the Food and Drug Administration for the marketing of the identical product, at a fraction of the cost. Present law contains no provision that would permit the Food and Drug Administration to refuse to approve a "me-too" product on the basis of information obtained from the first manufacturer, once that information from the first manufacturer is disclosed.

255. Comments questioned whether animal and human data on safety and effectiveness can be considered a "method or process which as a trade secret is entitled to protection", within the meaning of section 301(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301(j)). The Commissioner advises that, since 1938, it has been the consistent administrative interpretation that this statutory provision can be applied to the animal and human data, although the agency did not previously have a clear policy as to whether such data could or did not represent trade
new drug license system results in "super-

lies that the Department of Justice and it is well recognized that a person who

utes by cross-licensing.

cross-licensing agreements within the legal authority to prevent any collusive

the Federal Trade Commission have full authority to institute such a system the

Congress, not the Food and Drug Admin-

Statistics recommended in 1971 that all such data and information, should be released. It was pointed out that such records will include internal re-

sare insufficient to afford adequate

owing to convey this information, because this

A The Commissioner recognizes the difficulty involved in implementing this
decision for previously approved NDA's and NADA's. It is not administratively feasible to do so at this time for all such prior approvals. Accordingly, for such prior approvals the Commissioner has concluded that internal agency records that describe such data and information and which will be made available for public disclosure upon re-

quest, it is not possible to state exactly which internal records will be adequate to
coupy such information, because this

may vary depending upon the bureau involved, the administrative procedures being followed at the time the approval was granted, and various other factors. Such summaries will include internal reviews of the data and information, ac-
tion memoranda, a summary of the basis for approval, or other internal memo-
randa sufficient to describe the safety and effectiveness data and information for the drug involved.

The Commissioner also recognizes that

many of these old memorandum were pre-

pared solely for internal consideration, and may contain information that is not proper for public disclosure. For example, some memoranda may mention the names of patients in an IND study. Some of these memoranda also contain criticism of investigations to which the investigators have never had an op-
portunity to respond and other inappropri-
ate gratuitous comments unnecessary to an objective presentation of the data and information. If these memoranda had been prepared for public dissemination, such information and comments would not have been included. Accordingly, the Commissioner believes that public discussion of these matters is better served by disclosure of all of the conclusions and recommenda-
tions set out in the memoranda, with only the minimal deletions mentioned above. In some instances, this will dis-

close recommendations which the Food and Drug Administration decisions are not to follow at the time, or decisions which have subsequently been reversed. The Commissioner believes that such disclosure will not harm the regulatory efforts of the agency, but will serve to foster better public understanding of the internal discussion about scientific and medical issues that must always charac-
terize an open and responsive regulatory agency.

b. For NDA's and NADA's approved in the future, the Commissioner concludes that somewhat different rules should apply. Rather than disclosing internal discussion memoranda, the Commissioner concludes that they should be prepared in one of two alternative ways. First, the relevant bureau may re-

quest the applicant to prepare a summary of all of the data and information contained in the file. Alternatively, the Commissioner may consider a request for release of an objective presentation of the data and information. If these memoranda had been prepared for public dissemination, such information and comments would not have been included. Accordingly, the Commissioner concludes that public discussion of these matters is better served by disclosure of all of the conclusions and recommenda-
tions set out in the memoranda, with only the minimal deletions mentioned above. In some instances, this will dis-

close recommendations which the Food and Drug Administration decisions are not to follow at the time, or decisions which have subsequently been reversed. The Commissioner believes that such disclosure will not harm the regulatory efforts of the agency, but will serve to foster better public understanding of the internal discussion about scientific and medical issues that must always charac-
terize an open and responsive regulatory agency.

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this summary be submitted with the NDA or NADA. Rather, where this alternative is utilized, the bureau will request submission of such a summary at an appropriate time near approval of the application, when it is likely that the full administrative record of the data and information will have been submitted and fully considered.

The second alternative way for preparing such a summary will be for the bureau to prepare its own summary, without requesting the applicant to submit a summary for this purpose. The Commissioner concludes that this approach may well be appropriate where the application and internal memoranda already contain various summaries and the bureau decides that submission of another summary is unnecessary.

Once the requirement for an institutional summary was removed on July 1, 1975, it will no longer be necessary or appropriate for the Food and Drug Administration to release other internal discussion memoranda relating to approved NDA's and NADA's. This institutional summary will collate and distill all of the numerous internal memoranda relating to these matters, and thus will set forth in a comprehensive way the administration to release other internal memoranda relating to approved NDA's and NADA's as well as to original NDA's and NADA's. On the other hand, not every supplemental or abbreviated NDA or NADA is sufficiently different to justify a new summary. Accordingly, it will be left to the judgment of the bureau to determine whether the original summary for an NDA or NADA will require revision or supplementation to reflect changes made by approval of a supplemental NDA or NADA. Where a new use or substantially different dosage is approved such revision would undoubtedly be required, but where only such matters as manufacturing controls or ingredient sources are involved no change would be warranted.

259. A number of comments from the pharmaceutical industry agreed with the concept of making public a summary of the information on safety and effectiveness in approved new drug applications. Some comments agreed with the proposal that this should be a specially prepared summary, and some suggested that it should be the summary already provided in the NDA.

The Commissioner concludes that the rules for preparation and disclosure of summaries set out in the final regulations are adequate to provide for information to the public on the safety and effectiveness data on the basis of which an NDA or NADA is approved. Such summaries are intended to be an indispensable tool of the practicing physician, and the scientific community. A "detailed" summary, it was indicated, would ease the burden of a subsequent new drug applicant in this country and might encourage manufacturers to market in other countries with little or no testing. It was also indicated that a detailed summary might well constitute prior disclosure under the patent laws of one or more foreign countries and therefore prevent the original NDA holder from obtaining patent protection in those countries. It was also suggested that a detailed summary, and otherwise confidential nature of the underlying data involved, that the manufacturer should have the final say on the content of any such summary, and that no summary be made without the consent of the manufacturer.

The Commissioner concludes that the summaries to be released pursuant to the final regulations will not ease the burden on a subsequent new drug applicant in this country since such an applicant would nonetheless be responsible for running the required tests. The Commissioner also concludes that the possibility of competitive advantage abroad is speculative and remote. Although in some instances the bureau may wish to confer with others, including the applicant, in preparing the institutional summary, this is not required and under no circumstances will the applicant have the final say on its contents.

261. One comment suggested whether submission of a summary is required each time a supplemental NDA is filed. This, it was indicated, would be an unnecessary duplication since the supplement is often directed entirely toward a change in the labeling of the product with no relevance to the previously submitted safety and effectiveness data.

The Commissioner advises that, under the final regulations, a summary will be released for a supplemental NDA or NADA where the supplemental application contains a significant change in safety or effectiveness. It is unnecessary specifically to mention supplemental applications in the regulations because a supplemental application becomes part of the original application. The consideration of revision or supplementation of a summary is required whenever a supplemental application is approved.

262. Comments complained that disclosure of summaries of safety and effectiveness data does not serve the purpose of the Freedom of Information Act since outside scientists need the raw data in order to determine whether the agency has acted wisely in a given instance. It was contended that release of a summary would serve only as a "public relations stunt" for the industry.

The Commissioner concludes that the present law provides the Food and Drug Administration a choice between release of a summary or release of the raw safety and effectiveness information, and release of the complete data would constitute disclosure of a trade secret prohibited by 21 U.S.C. 331(j) and 18 U.S.C. 1905. The release of a summary is preferable to no disclosure of information on safety and effectiveness data on a selective basis, in a way that will not reveal the full administrative record. Such a situation usually occurs when the matter is under consideration by a Food and Drug Administration advisory committee. This policy is reflected in 314.14(d) of the final regulations.

263. Questions have arisen as to whether the Food and Drug Administration may release adverse safety data submitted by a manufacturer as part of an IND file or a pending NDA.

The Commissioner concludes that the IND or pending NDA file may not properly be released, but that a summary of such data may be released. If the existence of the IND or pending NDA is itself confidential, if the existence of the IND or pending NDA is itself confidential, release of a summary of adverse safety data would not be permitted.

Because the Commissioner concludes that the full administrative record of an IND or pending NDA represents confidential commercial information prior to approval of an NDA, a summary of safety or effectiveness data in an IND or pending NDA shall be made public only on a selective basis, in a way that will not reveal the full administrative record. Such a situation usually occurs when the matter is considered by a Food and Drug Administration advisory committee. This policy is reflected in 314.14(d) of the final regulations.

264. Foreign governments have discussed with the Food and Drug Administration the possibility of exchanging data and information on the safety and effectiveness of investigational and marketed drugs.

The Commissioner concludes that the same rules will apply with respect to disclosure of such information to foreign governments as to disclosure to the public. This will permit the Food and Drug Administration to provide full summaries of all safety and effectiveness data for all approved NDA's, and selected summaries for IND's and pending NDA's.
for which the existence of an IND has been publicly disclosed or acknowledged. The Commissioner concludes that this will adequately satisfy the need for internal exchange, or of important regulatory information of this type.

265. Comments were received that adverse safety and effectiveness information, which might lead to a reduction in use of a drug, would be essential to withdrawal of the drug from the market, is properly regarded as confidential commercial information because it can adversely affect the sales of the product. Other comments, however, did not distinguish between adverse information and favorable information, and concluded that the Food and Drug Administration could properly release summaries of all material relating to safety and effectiveness.

The Commissioner concludes that a summary of adverse safety and effectiveness information may properly be made available for public disclosure. As already discussed, such information is commonly published in the scientific literature and distributed to the scientific community. Accordingly, it cannot be said to be confidential.

266. A comment stated that, for an NDA which is not approved, a summary of the basis of the refusal should be released.

The Commissioner advises that the disapproval letter and all data from an NDA which has received final agency disapproval will be available for disclosure after all options for legal action have been exhausted. However, such records will be released only where the agency disapproval is final, and not where there is merely an intermediate determination of insufficient data for approval and the applicant continues the work needed to obtain approval.

267. Comments contended that all data and information explained in an NDA are properly held in confidence forever by the Food and Drug Administration, and thus cannot be disclosed when the drug is withdrawn or becomes an old drug. The Commissioner found that Congress, by (1) the legislative history of 21 U.S.C. 331(j) indicates that all such information was to be regarded as trade secrets, (2) the Food and Drug Administration has in any event obligated itself to maintain the confidence of this information by promises made to industry since 1938, and (3) the agency is precluded from changing its consistent administrative interpretation of the law under the doctrine of "Udall v. Tallman," 380 U.S. 1 (1965).

The Commissioner concludes that the legislative history of 21 U.S.C. 331(j) sheds no light on whether information may be conveyed by contract. In the Udall case, the court noted that the plaintiff had not specifically alleged an express contract, and stated that the mere fact that a company is not using a particular product at a particular time does not prevent it from being a trade secret. The final regulations make it clear that termination or disapproval of an IND or NDA refer to final termination or disapproval, not to some intermediate step. As is discussed elsewhere in the preamble, continued pursuit of the IND or NDA will be sufficient to justify the continued confidence of the safety and effectiveness data involved.

In the "Ferroline" case, the company had conveyed by contract the right to the trade secret to another party, and then later regained the rights to that trade secret and attempted unsuccessfully to re-enter the field. The claims of the plaintiff that the misappropriation of the trade secret by the defendant precluded successful reentry. The court held that the plaintiff was entitled to bring the suit notwithstanding the fact that it currently was not utilizing the trade secret in question. The Commissioner concludes that the circumstances of this case are totally different from any of those involved in the final regulations, and thus that this case is of little, if any, relevance. The final regulations do recognize that a property right in a trade secret may be conveyed by contract. In the "Ferroline" case, however, the non-use of the trade secret was caused by the alleged breach of confidentiality, whereas in the final regulations promulgated by the Commissioner there can be no authorized release until the product is not currently being marketed or has been withdrawn from the market.

268. The major argument advanced in comments objecting to the disclosure of IND and NDA safety and effectiveness data after disapproval of the product is that the events upon which disclosure hinges, e.g., termination, discontinuance, approval, etc., are actually irrelevant to the issue of whether or not the information is a trade secret. It was contended that a number of competitive advantages continue to exist or later accrue after such events, and contended that simply knowing a process does or does not work is worth hundreds of thousands of dollars and years of research to a competitor. Further, such information could not be protected in marketing and sales literature and provides a definite advantage to its owner in obtaining foreign product registrations. The advantage was thought to be equivalent to a strong wrinkle to marketing in countries where there is little or no patent protection. The advantage in the foreign market situation could, it was suggested, be so great as to create a further imbalance against the United States in foreign trade. It was indicated that a discontinued or terminated IND or NDA may be reviewed and reactivated if there is a change in scientific knowledge or if the drugs subject to termination may simply be the result of a determination at that point in time to use research money on another drug. The data in an investigational file may later become essential when related drugs are being investigated. Such data could form the basis of cooperative agreements with other drug companies or universities on renewed trials of a drug. Comments contended that the termination of one IND or NDA and disclosure of trade secrets relating to it may affect another IND or NDA which has not been terminated. It was also pointed out that investigations voluntarily terminated here may be continued abroad.

The Commissioner concludes that termination, in order to trigger disclosure, must be final. If there is some legitimate
The Commissioner notes that, upon appeal in that case, the Supreme Court held that the Food and Drug Administration has primary jurisdiction to decide the new drug/old drug status of a drug. "Weinberger v. Benton Pharmaceuticals, Inc.," 412 U.S. 645 (1973). Since the agency will be in a position to settle this issue with administrative finality, subject only to judicial review, there should no longer be any confusion with respect to the time at which safety and effectiveness data become available for public disclosure.

273. Comments argued that information concerning a drug on which a patent is pending should be considered prima facie confidential.

The Commissioner notes that a patent application may or may not be granted. A patent which has been granted may run out before the new drug status of a product is terminated. The Freedom of Information Act provides for a special status for patented products, not for the Federal Food, Drug, and Cosmetic Act. For these reasons, the patent status of a product cannot be relied upon by the Food and Drug Administration as determinative or indicative of whether information or data on that product should be released to the public.

274. Requests have been received for safety and effectiveness information with respect to a new drug for which an NDA is currently subject to the drug efficacy study implementation (DESI) review program. Some of these data have been submitted after publication of an initial DIS review notice but prior to a notice of opportunity for hearing, and some have been submitted in response to a notice of opportunity for hearing in order to justify a request for a hearing.

The Commissioner concludes that such data and information have the same status as any other data and information on safety and effectiveness contained in the NDA. Therefore, when an NDA requests for data and information will be handled in the same way as requests relating to any other approved NDA. If the NDA is withdrawn, after all appeals are exhausted and the data and information will be disclosed in the same way that data and information are disclosed for all other NDA's for which approval is denied or withdrawn.

275. Questions have arisen as to whether an approval of an antibiotic drug for animal use is a private license or a public regulation, and thus whether the safety and effectiveness data are or are not subject to disclosure. The Animal Drug Amendments of 1968 (Pub. L. 90-399, 82 Stat. 342), which amended the Federal Food, Drug, and Cosmetic Act as are antibiotic drugs for human use, i.e., a public regulation, the Animal Drug Amendments of 1968 (Pub. L. 90-399, 82 Stat. 342), which added section 512 to the act (21 U.S.C. 360b), changed this. Under section 512, all new animal drugs, including antibiotics, require an approved NADA, i.e., a private license. Therefore, they may lawfully be marketed. Accordingly, § 146.16 of the final regulations states the same disclosure rules for new antibiotic animal drugs as for any other new animal drugs.

276. Comments stated that, prior to the development of Form FD-1800, feed manufacturers had to submit essentially the same information as the animal drug manufacturer, in order to obtain approval for use of a new animal drug. It was the previous understanding that confidentiality of feed manufacturers' applications and related files would be honored by the Food and Drug Administration. The Food and Drug Administration should honor this previous understanding.

The Commissioner advises that the Food and Drug Administration will honor the confidentiality of such applications insofar as the information contained in them is exempt under the Freedom of Information Act. In accordance with the provisions of § 4.48, any request for information contained in such files will be discussed with the manufacturer if a close question is raised. The manufacturer will be given the opportunity to assert and justify confidential status for the material requested, and may appeal to the courts in the event the Food and Drug Administration determines that the material is disclosable.

277. Questions have been raised as to whether food additive and antibiotic petitions and forms for veterinary drugs submitted prior to the effective date of the Animal Drug Amendments of 1968 (Pub. L. 90-399, 82 Stat. 342) are subject to the disclosure rules established for new animal drug applications in §§ 135.33a and 146.16. The Animal Drug Amendments changed the law by requiring approval of an individual new animal drug application for every new animal drug product. The Commissioner advises that the rules for disclosure will depend upon the nature of the approval requested or obtained. Accordingly, the food additive petitions and antibiotic forms submitted for animal drugs are subject to the disclosure rules established for these petitions and forms in §§ 121.51(h) and 431.71 or to the disclosure rules established for new animal drug applications in §§ 135.33a and 146.16. The Animal Drug Amendments changed the law by requiring approval of an individual new animal drug application for every new animal drug product.

The Commissioner advises that the rules for disclosure will depend upon the nature of the approval requested or obtained. Accordingly, the food additive petitions and antibiotic forms submitted for animal drugs are subject to the disclosure rules established for these petitions and forms. The new drug applications submitted for veterinary drugs prior to the Animal Drug Amendments are similarly subject to the disclosure rules established in § 314.14.

278. Pursuant to the Controlled Substances Act (Pub. L. 91-515, 84 Stat. 1272), as amended by the Secretary of Health, Education, and Welfare is required to submit to the Attorney General a scientific and medical evaluation and recommendations relating to the scheduling of drugs. The preparation of these recommendations has been delegated to the Commissioner. Requests have been made for copies of such recommendations.

The Commissioner advises that all recommendations relating to the Controlled Substances Act are available for public disclosure.
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A Protocol for a Test or Study

279. A comment contended that the amount of money expended in developing a protocol should be irrelevant to its trade secret status and that the presence of factors that should properly be considered in making this determination is whether it gives the owner an opportunity to obtain a competitive advantage and whether the protocol is in fact secret.

The Commissioner does not concur with this comment. Cost is one factor, but not the sole factor, in determining whether information constitutes a trade secret. However, the final regulations refer directly to the exemption for trade secrets and confidential commercial information in §4.61, rather than to attempt to specify all of the relevant factors involved.

280. Comments also contended that uniqueness is not necessary for a trade secret, and that this element should not be included in the criteria for determining whether a protocol constitutes a trade secret.

The Commissioner concludes that, if a protocol is distinguishable in a significant respect from those developed by others, it cannot be regarded as providing a competitive advantage. Nevertheless, the regulations have been revised to refer only to §4.61, rather than to attempt to set out the various criteria that will be used in determining when the standards set out in §4.61 are met.

281. A comment stated that the criteria for the trade secret status of protocols seem to have eliminated the necessity of showing that a protocol is "used in one's business." It was suggested that the Restatement definition should apply, and that there must be a showing of commercial value. If protocols are not trade secrets or privileged or confidential commercial or financial information which provides a competitive advantage, and that the exemption for a particular ingredient is not helpful because there is no assurance that the mix is a unique combination of all ingredients which makes the product unique and effective. It was suggested that a manufacturer be permitted to show that the entire list constitutes a trade secret.

The Commissioner rejects the suggestion that a list of ingredients is always confidential commercial information. To conform these regulations with the Drug Listing Act, however, they have been revised to state that inactive ingredients in drug products not required to be stated on the label and not previously disclosed to the public are not available for public disclosure. The Commissioner also agrees that a combination of ingredients as well as a single ingredient may qualify for exemption and the final regulations have been revised to reflect this.

282. The primary concern expressed in comments about release of this type of information was the possibility that it might reveal "cranks and dissidents." Alternatively, it was suggested that release not be permitted until the firm involved agrees. It was also suggested that the manufacturer be given an opportunity to analyze adverse reaction reports by the appropriate agency before the reports are made public, in order to provide a fair and balanced disclosure.

The Commissioner rejects the suggestion that a protocol be released to the public. The fact that the comments are based, i.e., that the public, scientists, and the Food and Drug Administration are incapable of making responsible judgments on this information. This type of information, when released, will be evaluated in the same manner as any other information that is publicly available.

283. Questions have arisen about the status of adverse reactions to drug products subject to the requirements of the new drug or prescription drug sections of the law. Adverse reactions for new drugs are required to be reported to the Food and Drug Administration pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act and adverse reactions for prescription drugs must be furnished to the Food and Drug Administration pursuant to the factory inspection provisions in section 704 of the act.

The Commissioner advises that such adverse reaction information is available for public disclosure with only the names and other identifying information of individuals deleted. The brand name of the product and the name of the manufacturer will not be deleted.

284. Questions have arisen about whether adverse reactions reported to an IND file are available for public disclosure.

The Commissioner concludes that the same rule applies to adverse reaction information in an IND file as it does to adverse reaction reports by third parties, and the criteria for determining the status of an ingredient.

285. A comment contended that an ingredient should be regarded as a trade secret if it provides a competitive advantage and that the criteria of uniqueness, importance to the product, and knowledge to competitors should be deleted.

The Commissioner intended the criteria set out in this provision of the proposed regulations to amplify the phrase "competitive advantage," and believes that they are an adequate reflection of the factors which comprise competitive advantage with respect to ingredients. Nevertheless, the final regulations have been revised to refer directly to §4.61 rather than to attempt to specify all of the criteria applicable in determining the status of an ingredient.

ASSAY METHOD OR OTHER ANALYTICAL METHOD

286. Comments contended that an assay method is a trade secret regardless whether it must be available to permit other manufacturers to comply with limits established under Food and Drug Administration regulations.
The Commissioner does not agree with these comments. For many years the Food and Drug Administration has routinely made available for public disclosure, and has included in its widely distributed manuals, analytical methods which are contained in petitions and applications, and which are needed for regulatory assays for food and drugs. The Association of Official Analytical Chemists (AOAC) publishes official analytical methods. Other methods are frequently published in the scientific literature. Accordingly, methods of this type are not customarily regarded as commercial information. Moreover, such methods are needed by State and local officials to assure compliance with legal requirements. They provide no competitive advantage for one manufacturer over another, but rather permit regulatory officials to assure compliance with the law. Even if such methods were not made publicly available to competing manufacturers, such methods would not hinder the marketing of competing products. Accordingly, the Commissioner concludes that all such methods will be made public except where they serve no regulatory function whatever. The final regulations have been revised to state this policy.

289. A comment indicated that it was not clear whether the Restatement definition of a trade secret must be met before trial. The Commissioner states that it will be retained as confidential. It was also stated that if the assay method is not required for the approval of a new drug, it does not provide a competitive advantage for the manufacturer over another, and hence cannot be regarded as exempt.

The Commissioner advises that, with any other information in the possession of the Food and Drug Administration which could be exempted as a trade secret, the information must be a trade secret within the meaning of the Restatement. The Food and Drug Administration has determined that assay methods are describable except where they perform no regulatory function and are shown to fall within the exemption established in § 4.61.

MANUFACTURING METHODS OR PROCESSES, INCLUDING QUALITY CONTROL PROCEDURES

290. Several comments noted that, although manufacturing involves building, processing, quality control procedures, and quantitative formulas are specifically exempt from disclosure unless there has been a prior public disclosure, they do not extend to situations where all data to be marked as confidential and adequate grounds given to justify each individual item so marked. Clarification of these seemingly conflicting provisions was requested.

The Commissioner advises that a company's manufacturing methods and processes, quality control procedures, and recipients of refunds from advanced deposits of fees paid to the Food and Drug Administration for certification services constitute proprietary information, except from public disclosure.

The Commissioner concludes that such information is exempt from public disclosure only to the extent that it may disclose sales data or the share of individual companies in the market.

FOOD STANDARD TEMPORARY PERMITS

293. Questions have been raised about the availability for public disclosure of petitions received pursuant to § 10.5 of the regulations (21 CFR 10.5) requesting a temporary permit to vary from a standard of identity, or an extension of such a permit.

The Commissioner advises that all such petitions and related correspondence are available for public disclosure upon publication of the notice granting the permit in the Federal Register, except to the extent that such records contain information otherwise exempt from disclosure, e.g., manufacturing procedures or quantitative formulas. Prior to a notice in the Federal Register granting the petition, the existence of the petition is proper. Records of the company to begin marketing under the same terms and conditions as the first manufacturer. A new paragraph (c) is added to § 10.5 to state this policy.

PROCESSING RECORDS FOR LOW-ACID CANNED PRODUCTS

296. The Commissioner published in the Federal Register of May 14, 1973 (38 FR 12716) and subsequently amended in the Federal Register of January 29, 1974 (39 FR 3780) and April 1, 1974 (39 FR 11876) new regulations governing emergency permit controls for thermally processed low-acid foods packaged in hermetically sealed containers (21 CFR 90.30). The final regulations require that manufacturers subject to these regulations furnish to the Food and Drug Administration various records relating to their processing. Questions have arisen with respect to the status of such records under the Freedom of Information Act.

The Commissioner advises that all such records constitute manufacturing or processing records that fall within the trade secret exemption from the Freedom of Information Act. In order to make this policy clear, a new paragraph (l) is added to § 90.20 in this final order.

COSMETIC PRODUCT INFORMATION

297. The Commissioner has promulgated regulations relating to voluntary...
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registration of cosmetic product establishments, voluntary filing of cosmetic product ingredient and cosmetic raw material composition statements, and voluntary filing of cosmetic product experience and voluntary filing of cosmetic product experience and composition statements and product experience reports pending promulgation of final regulations under the Freedom of Information Act in order to determine whether such information, submitted voluntarily, will be retained as confidential by the Food and Drug Administration or will be disclosed to the public upon request.

Accordingly, the Commissioner concludes that clarification of these regulations at this time is appropriate in order to conform them with the provisions of Part 4.

288. Section 710.7 of the regulations (21 CFR 710.7) provides that a copy of Form FD-2511 (Registration of Cosmetic Product Establishment) is available for public inspection in its entirety. The Commissioner concludes that this section does not contain information relating to specific products. Accordingly, no modification in this provision is warranted.

292. Section 720.8 of the regulations (21 CFR 720.8) provides that: (a) a request for confidentiality of cosmetic ingredient information, pursuant to Part 720, may be submitted; (b) the Commissioner is authorized to determine if such information is of major importance to the agency for a final decision; (c) the Commissioner may take action to protect against unfair disclosure of materials regarded by the industry as confidential commerical information, and at the same time assure that information that is of major importance to the Food and Drug Administration regulatory programs will in fact be submitted.

301. Questions have arisen as to the procedure by which a person who has submitted a request for confidentiality of cosmetic ingredient information pursuant to Part 720 may appeal a decision by the Bureau of Foods that the information does not constitute a trade secret and is thus available for public disclosure. The Commissioner concludes that this policy is appropriate in order to conform them with the provisions of Part 4.

302. Subsequent to publication of the proposed regulations in May 1972, jurisdiction over the Federal Hazardous Substances Act (21 U.S.C. 381) has been transferred to the Consumer Product Safety Commission pursuant to the Consumer Product Safety Act (Pub. L. 92-573, 86

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Accordingly, the proposed amendment of §191.213 (21 CFR 191.213) is withdrawn.

RELIANCE UPON FOOD AND DRUG ADMINISTRATION FREEDOM OF INFORMATION FILES

305. In preparing the final regulations, the Commissioner has relied both upon the extensive comments filed in the proposed regulations published in May 1972, and upon the numerous requests for documents recorded by the agency since enactment of the Freedom of Information Act. Accordingly, the Commissioner hereby incorporates by reference the Freedom of Information files of the agency as part of the administrative record on which the decision on these final regulations is based.

ADDITIONAL TIME FOR COMMENT

306. The final regulations promulgated in this final order reflect both the proposal published in May 1972 and the actual practice of the Food and Drug Administration in handling requests for documents in the intervening 2 years. Comments submitted on the proposal and requests for documents during the past 2 years have raised most of the issues discussed in this preamble and resolved in the final regulations. Accordingly, these regulations embody very few new decisions.

The Freedom of Information Act is a self-executing statute for which no regulations are required for implementation. The Food and Drug Administration is therefore obligated to disclose documents not specifically exempt from disclosure. The proposed regulations published in this final order will become effective 30 days after publication in the Federal Register.

The Commissioner concludes that the entire final order will become effective (insert date 30 days after date of publication in the Federal Register), and that all of the provisions will be implemented pending reconsideration of any specific provisions as a result of the receipt of additional comments. This will work no hardship since, if any close or controversial issues arise, the Commissioner will utilize the provisions of §4.45 to consult with any person who may be adversely affected by disclosure of information, and that person will have the opportunity, as set forth in §4.46, to seek judicial determination on the issue of disclosure in the event that he disagrees with the Commissioner’s conclusion.

JUDICIAL REVIEW OF FINAL REGULATIONS

307. The Commissioner notes that one of the major purposes of the initial proposal published in May 1972 and these final regulations is to establish a uniform status under the Freedom of Information Act of every category of document contained in Food and Drug Administration files, in order to avoid ad hoc decisions and to facilitate the efficient handling of requests for records.

The comments disclose a wide divergence of opinion with respect to the rules contained in these final regulations. Some comments stated that far too much was being released, and others stated that not enough was being released. The Commissioner anticipates that the same disagreement will exist with respect to portions of the final regulations as was reflected in the comments received on the proposal.

Accordingly, the Commissioner invites any person who believes that the final regulations do not properly interpret and apply the Freedom of Information Act to institute legal action in the courts to contest their validity. The Commissioner reserves finality of such administrative remedies with respect to these matters will be exhausted, that the matters will be ripe for judicial review, and that any person will have standing to bring suit to contest these regulations since they affect the rights of the entire public, including those who have submitted or will submit information to the Food and Drug Administration and those who have requested or will request disclosure of such information to the Food and Drug Administration. The Commissioner believes that it would be in the public interest for all such issues to be litigated promptly so that these matters are settled and the applicable rules clearly understood by everyone who is affected.

Accordingly, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 201 et seq., 52 Stat. 1040 et seq. as amended; 21 U.S.C. 321 et seq.), the Public Health Service Act (sec. 1 et seq., 58 Stat. 622 et seq. as amended; 42 U.S.C. 201 et seq.), and the Freedom of Information Act (Public Law 90–23, 81 Stat. 54–56 as amended by 86 Stat. 1561–1565; 5 U.S.C. 552) and under authority delegated by the President (sec. 121, 38 U.S.C. 730), Parts 1, 2, 4, 8, 10, 90, 121, 135, 146, 312, 314, 431, 601, 720, and 730 are amended as follows:

SUBCHAPTER A—GENERAL

PART I—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. In Part I, by adding a new paragraph (c) to §1.6 to read as follows:

§1.6 Presentation of views under section 305 of the act.

(6) Records relating to this proceeding constitute investigatory records for law enforcement purposes and shall be treated as inter- and intra-agency memoranda.

(1) Notwithstanding the rule established in §4.21 of this chapter, no record relating to a section 305 hearing is available for public disclosure except on appeal or under the consideration of criminal prosecution based upon that record being closed, except as provided in §4.82 of this chapter. The Commissioner will exercise his discretion in discrediting or relating to a section 305 hearing pursuant to §4.82 of this chapter prior to the consideration of criminal prosecution being closed on any particular basis under §4.83 of this chapter.

(2) After the consideration of criminal prosecution is closed, such records are available for public disclosure except to the extent that the exemptions from disclosure in Subpart D of Part 4 of this chapter are applicable. No statements of witnesses obtained through promises of confidentiality are available for public disclosure.

(3) The consideration of criminal prosecution based upon a particular section 305 hearing shall be deemed to be closed under this procedure when a recommendation for criminal prosecution has been finally made to recommend criminal prosecution to the United States attorney, or such recommendation has been finally made to recommend criminal prosecution has been instituted and the matter and all related appeals have been concluded, or the statute of limitations has run.

(4) Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(5) Names and other information which would identify a Food and Drug Administration employee shall be deleted from section 305 hearing records prior to public disclosure only pursuant to §4.32 of this chapter.
PART 4—PUBLIC INFORMATION

Subpart A—Official Testimony and Information

4.1 Testimony by Food and Drug Administration employees.
4.2 Production of records by Food and Drug Administration employees.
4.3 Certification and authentication of Food and Drug Administration records.

Subpart B—General Policy

4.20 Policy on disclosure of Food and Drug Administration records.
4.21 Unemployment records.
4.22 Partial disclosure of records.
4.23 Request for existing records.
4.24 Preparation of new records.
4.25 Retroactive application of regulations.
4.26 Indexes of certain records.
4.27 Submission of records marked as confidential.
4.28 Food and Drug Administration determinations of confidentiality.
4.29 Prohibition on withdrawal of records from Food and Drug Administration files.
4.30 Food and Drug Administration Public Records and Documents Center.
4.31 Permanent file of requests for Food and Drug Administration records.
4.32 Disclosure of Food and Drug Administration employee names.

Subpart C—Procedures and Fees

4.40 Filing a request for records.
4.41 Time limitations.
4.42 Fees.
4.43 Waiver of fees.
4.44 Premissumission review of request for confidentiality of voluntarily submitted information.
4.45 Situations in which confidentiality is uncertain.
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Subpart A—Official Testimony and Information

§ 4.1 Testimony by Food and Drug Administration employees.

(a) No officer or employee of the Food and Drug Administration or of any other officers or employees in the Department of Health, Education, and Welfare, except as authorized by the Commissioner of Food and Drugs pursuant to this section or in the discharge of his official duties under the laws administered by the Food and Drug Administration, shall give any testimony before any tribunal pertaining to any function of the Food and Drug Administration or with respect to any information required in the discharge of his official duties.

(b) Whenever a subpoena, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the giving of any testimony, such officer or employee shall, unless otherwise authorized by the Commissioner, appear in response thereto and respectfully decline to testify on the ground that it is prohibited by this section.

(c) A person who desires testimony from any employee may make written request therefor, verified by oath, directed to the Commissioner setting forth his interest in the matter sought to be disclosed and designating the use to which such testimony will be put in the event of compliance with such request:

Prohibited. That a request therefor made by a health, food, or drug officer, prosecuting attorney, or member of the judiciary of any State, Territory, or political subdivision thereof, acting in his official capacity, verified by oath. If it is determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf, that the purpose of the request will be in the public interest and will promote the objectives of the act and the agency, the request may be granted.

Where a request for testimony is granted, any employee of the Food and Drug Administration may be designated to appear, in response to a subpoena, and testify with respect thereto.

§ 4.2 Production of records by Food and Drug Administration employees.

(a) Any request for records of the Food and Drug Administration, whether it be by letter or by a subpoena duces tecum or by any other writing, shall be handled pursuant to the procedures established in Subpart B of this part, and shall comply with the rules governing public disclosure established in Subparts C, D, E, and F of this part and in other regulations cross-referenced in § 4.100.

(b) Whenever a subpoena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the production of any record, such officer or employee shall, unless otherwise authorized in response thereto, respectfully decline to produce the record on the ground that it is prohibited by this section, and state that the production of the record(s) involved will be handled by the procedures established in this part.

§ 4.3 Certification and authentication of Food and Drug Administration records.

(a) Upon request, the Food and Drug Administration will certify the authenticity of copies of records that are requested to be disclosed pursuant to this
part or will authenticate copies of records previously disclosed.

(b) A request for certified copies of records or for authentication of records shall be sent in writing to the Public Records and Documents Center (HFC-18), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20852.

Subpart B—General Policy

§ 4.20 Policy on disclosure of Food and Drug Administration records.

(a) The Food and Drug Administration will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade secrets and confidential commercial or financial information, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) Except where specifically exempt pursuant to the provisions of this part, all Food and Drug Administration records shall be made available for public disclosure.

(c) All nonexempt records shall be made available for public disclosure upon request regardless whether any justification or need for such records has been shown.

§ 4.21 Uniform access to records.

Any record of the Food and Drug Administration that is disclosed in an authorized manner to any member of the public for disclosure or disclosure to all members of the public, except that:

(a) Data and information subject to the exemptions established in § 4.61 for trade secrets and confidential commercial or financial information, and in § 4.63 for personal privacy, shall be disclosed only to the persons for the protection of whom these exemptions exist.

(b) The limited disclosure of records permitted in § 1.6(c) (1) of this chapter for section 305 hearing records, in § 4.88 (b) regarding certain limitations on exemptions, in § 4.103(b) for certain correspondence, and in § 4.104(b) for certain summaries of oral discussions, shall be subject to the special rules stated therein.

§ 4.22 Partial disclosure of records.

If a record contains both disclosable and nondisclosable information, the nondisclosable information will be deleted and the remaining record will be disclosed. The nondisclosable information is so intricately intertwined that it is not feasible to separate them or release the disclosable information would compromise or impinge upon the nondisclosable portion of the record.

§ 4.23 Request for existing records.

(a) Any written request to the Food and Drug Administration for existing records not prepared for routine distribution to the public shall be deemed to be a request for records pursuant to the Freedom of Information Act, whether or not the Freedom of Information Act is mentioned in the request, and shall be governed by the provisions of this part.

(b) Records or documents prepared by the Food and Drug Administration for routine public distribution, e.g., pamphlets, speeches, and educational materials, shall be furnished free of charge upon request as long as the supply lasts. The provisions of this part shall not be applicable to such requests except when the supply of such material is exhausted, and it is necessary to reproduce individual copies upon specific request.

(c) All existing Food and Drug Administration records are subject to routine destruction according to standard record retention schedules.

§ 4.24 Preparation of new records.

(a) The Freedom of Information Act and the provisions of this part apply only to existing records that are reasonably described in a request filed with the Food and Drug Administration pursuant to the procedures established in Subpart C of this part.

(b) The Commissioner may, in his discretion, prepare new records in order to respond adequately to a request for information when he concludes that it is in the public interest and promotes the objectives of the act and the agency.

§ 4.25 Retroactive application of regulations.

The provisions of this part apply to all records in Food and Drug Administration files.

§ 4.26 Indexes of certain records.

(a) Indexes shall be maintained, and revised at least quarterly, for the following Food and Drug Administration records:

(1) Final orders published in the Federal Register with respect to every denial or withdrawal of approval of a new drug application or a new animal drug application for which a public hearing has been requested.

(2) Statements of policy and interpretations adopted by the agency and still in force and not published in the Federal Register.

(3) Administrative staff manuals and instructions to staff that affect a member of the public.

(b) A copy of each such index is available at cost from the Public Records and Documents Center (HFC-18), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20852.

§ 4.27 Submission of records marked as confidential.

Marking records submitted to the Food and Drug Administration as confidential, or with any other similar term, raises no obligation by the Food and Drug Administration to regard such records as confidential, to return them to the person who has submitted them, to review them pursuant to the procedures established in § 4.44, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed.

§ 4.28 Food and Drug Administration determinations of confidentiality.

A determination that data or information submitted to the Food and Drug Administration will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 4.44.

§ 4.29 Prohibition on withdrawal of records from Food and Drug Administration files.

Except pursuant to the procedure established in § 4.44 for presubmission review of records, no person may withdraw records submitted to the Food and Drug Administration. All Food and Drug Administration records shall be retained by the agency until disposed of pursuant to routine record disposal procedures.

§ 4.30 Food and Drug Administration records and documents center.

(a) The office responsible for agency compliance with the Freedom of Information Act and this part is:

Public Records and Documents Center (HFC-18), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20852.

(b) All requests for agency records shall be sent in writing to this office.

§ 4.31 Permanent file of records for Food and Drug Administration.

The Food and Drug Administration shall maintain a permanent file of all requests for Food and Drug Administration records and all responses thereto, including a copy of all of the records furnished in response to a request. This file is available for public review during working hours.

§ 4.32 Disclosure of Food and Drug Administration employee names.

The names of Food and Drug Administration employees will not be deleted from disclosable records except where such deletion is necessary to prevent disclosure of an informant or danger to the life or physical safety of the employee or under other extraordinary circumstances.

Subpart C—Procedures and Fees

§ 4.40 Filing a request for records.

(a) All requests for Food and Drug Administration records shall be filed in writing, by mailing the request or delivering it to the Public Records and Documents Center (HFC-18), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20852.

(b) A request for Food and Drug Administration records shall reasonably describe the records being sought, in a way that they can be identified and located, request should include all pertinent details that will help identify the records sought.
(1) If the description is insufficient to locate the records requested, the Food and Drug Administration will so notify the person making the request and indicate the additional information needed to identify the records requested.

(2) Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought.

(3) Upon receipt of a request for records, the Public Records and Documents Center shall enter it in a public log. The log shall state the date and time received, the name and address of the person making the request, the nature of the records requested, the action taken on the request, the date of the determination letter sent pursuant to § 4.41(b), the date(s) any records are subsequently furnished, the number of staff-hours and grade levels of persons who spent time responding to the request and the payment requested and received.

§ 4.41 Time limitations.

(a) All time limitations established pursuant to this section shall begin as of the time at which a request for records is logged in by the Public Records and Documents Center pursuant to § 4.40(c). A written request for records shall not begin any time requirement until it is redirected to the Public Records and Documents Center and is logged in there in accordance with § 4.40(c).

(b) Within 10 working days (excepting Saturdays, Sundays, and legal public holidays) after a request for records is logged in at the Public Records and Documents Center, a letter shall be sent to the person making the request determining whether, or the extent to which, the agency will comply with the request, and, if any records are denied, the reasons therefor.

(1) If all of the records requested have been located and a final determination has been made with respect to disclosure of all of the records requested, the letter shall so state.

(2) If all of the records have not been located or a final determination has not yet been made with respect to disclosure of all of the records requested, e.g., because it is necessary to consult the person affected pursuant to § 4.45, the letter shall state the extent to which the records involved shall be disclosed pursuant to the rules established in this part.

(3) In the following unusual circumstances, the time for sending this letter may be extended for up to an additional 10 working days to permit the person making the request settling forth the reasons for such extension and the time within which a determination is expected to be accomplished:

(i) The need to search for and collect the requested records from field facilities or other establishments that are field facilities or other establishments that are separate from the Public Records and Documents Center.

(ii) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request.

(iii) The need for consultation, which shall be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request or among two or more components of the Food and Drug Administration having a substantial subject-matter interest therein.

(iv) If any record is denied, the letter shall state the right of the person requesting such records to appeal any adverse determination to the Assistant Commissioner for Health, Department of Health, Education, and Welfare, in accordance with the provisions of 45 CFR 5.82.

(5) If the request for records will result in a fee of more than $25.00, the letter shall specify or estimate the fee involved and shall require prepayment, as well as payment of any amount not yet received as a result of any previous request, before the records are made available. If the fee is less than $25.00, prepayment shall not be required unless the payment has not yet been received for records disclosed as a result of a previous request.

(c) Whenever possible, the determination letter required by paragraph (b) of this section, relating to a request for records that involves a fee of less than $25.00, shall be accompanied by the requested records. Where this is not possible, the records shall be forwarded as soon as possible, consistent with other obligations of the agency.

(d) If records are requested involving a fee of more than $25.00, the records shall be forwarded as soon as possible after receipt of prepayment from the person requesting the records, consistent with other obligations of the agency.

§ 4.42 Fees.

(a) Unless waived in accordance with the provisions of § 4.43, the following fees shall be imposed for disclosure of any record pursuant to this part.

(1) Copying of records. Ten cents per copy of each page.

(2) Copying of microfilm or microfiche. Fifty cents per microfilm frame or microfiche.

(3) Computerized records. The sum of the actual costs of:

(i) The computer time involved, based upon the prevailing level of cost to government or private computer time and upon the particular types of computer and associated equipment and the amounts of time on such equipment that are utilized.

(ii) The supplies or materials necessary to produce the requested records.

(iii) The services of the personnel in accordance with paragraphs (a) and (5) of this section.

(4) Clerical searches. $1.25 for each one-quarter hour spent by clerical personnel searching for and producing a requested record, including time spent copying any record.

(5) Nonclerical searches. $3.75 for each one-quarter hour spent by professional or managerial personnel searching for and producing a requested record, including time spent copying any record.

§ 4.43 Waiver of fees.

(a) No fee shall be charged for disclosure of records pursuant to this part where:

(1) The cost of providing the records is less than $5.00. In making this determination, the cost of other requests by the same individual or organization, or related individuals or organizations, shall be aggregated.

(2) The records are requested by a congressional committee or subcommittee or the General Accounting Office.

(3) The records are requested by a Federal department or agency.

(4) The records are requested by a Federal court.

(5) The records are requested by a foreign government or by a State or local government or any agency thereof for purposes that are in the public interest and will promote the objectives of the act and the agency.

(b) The Assistant Commissioner for Public Affairs may waive payment of fees when he determines, based on a petition that the person making the request for records is indigent and that the disclosure has a strong public interest justification. All statements made in any such petition are subject to the False Certification or authentication of records, § 4.40(c).

§ 4.45 Certification or authentication of records.

(a) Certification or authentication of records shall be conducted with all practicable speed.

(b) The Assistant Commissioner for Public Affairs may waive payment of fees when he determines, based upon a verified petition, that such reduction or waiver is in the public interest by furnishing the information can be considered primarily as benefiting the general public.

(1) Any such petition shall contain a statement of the intended purpose to which the records requested will be put showing how it will primarily benefit the general public, and, if the total fee would otherwise exceed $25.00, a statement of...
The reason why the volume of records requested is not given is a statement of the income and financial resources available to the person making the request.

(2) The Assistant Commissioner for Public Affairs may make available part or all of the records from those requested, in response to any such request for waiver of fees where he concludes that such records adequately meet that part of the request which differs from the request.

(3) In making a determination of the broad public interest involved, the Assistant Commissioner for Public Affairs will weigh the agency resources involved against the likely benefit to the public.

(4) Determinations pursuant to this provision will be made within the discretion of the agency.

(5) No fee shall be charged if a record requested is not found or for any record that is totally exempt from disclosure.

§ 4.44 Presubmission review of request for confidentiality of voluntarily submitted data or information.

(a) Any person who is considering submission of data or information voluntarily made available to the Food and Drug Administration may forward to the Director of the Bureau involved, or to the Associate Commissioner for Compliance, a request for presubmission review of the records involved.

(b) Pending a determination of a request submitted under paragraph (a) of this section, the Food and Drug Administration will consult with a person who will be affected by a proposed disclosure of such data or information.

(c) A letter denying a request for records, in whole or in part, shall state the reasons for the denial and shall state that an appeal may be made to the Assistant Secretary for Health, Department of Health, Education, and Welfare, pursuant to the provisions of 45 CFR 5.83.

(d) Deletion of nondisclosable data and information from disclosable records shall not be deemed to be a denial of a request for records.

§ 4.48 Nonspecific and overly burdensome requests.

The Food and Drug Administration will make every reasonable effort to comply with all requests for disclosure of a substantial amount of agency resources to search for and compile will be processed taking into account the staff hours required, the tasks from which these resources must be diverted, the impact this diversion will have on the agency's consumer protection activities, and the public policy reasons justifying the requests. A decision on the processing of such a request for information that is uncertain.

§ 4.49 Referral to primary source of records.

Upon receipt of a request for a record or document which is contained in Food and Drug Administration files but which is available elsewhere at a lower cost, the person requesting the records shall be referred to the primary source of the record or document.

§ 4.50 Availability of records at National Technical Information Service.

The Food and Drug Administration is furnishing a number of records to the National Technical Information Service (NTIS). 5385 Port Royal Rd., Springfield, VA 22152, which reproduces and distributes such information to the public at cost. A single copy of each such record shall be available for public review at the Food and Drug Administration. All persons requesting copies of such records shall be answered by referring the person requesting the records to NTIS.

§ 4.51 Use of private contractor for copying.

The Food and Drug Administration may furnish requested records to a private contractor for copying after deletion of all nondisclosable data and information. Under these circumstances, the Food and Drug Administration will
charge the person requesting the records for all of the fees involved pursuant to § 4.62.

§ 4.52 Request for review without copying.

(a) A person requesting disclosure of records shall be permitted an opportunity to review them without the necessity for copying them where the records involved contain only disclosable data and information. Under those circumstances, the Food and Drug Administration will charge only for the costs of searching for the records.

(b) Where a request is made for review of records without copying and the records involved contain both disclosable and nondisclosable information, the records containing nondisclosable information shall first be copied with the nondisclosable information blocked out and the Food and Drug Administration will charge for the costs of searching and copying.

§ 4.53 Indexing trade secrets and confidential commercial or financial information.

If a court requires the Food and Drug Administration to itemize and index records that the Food and Drug Administration has determined to be exempt from public disclosure as trade secrets or confidential commercial or financial information pursuant to § 4.61, the Food and Drug Administration will so inform the person affected, i.e., the person who submitted the records, and will require that such person undertake the itemization and indexing of the records and to intervene to defend the exempt status of the records. The failure of the affected person to itemize and index such disputed records and to intervene to defend the exempt status of the records will constitute a waiver by such person of such exemption, and the Food and Drug Administration will promptly make them available for public disclosure.

Subpart D—Exemptions

§ 4.60 Applicability of exemptions.

(a) The exemptions established in this subpart shall apply to all Food and Drug Administration records, except as provided in Subpart E of this part. Accordingly, a record that is ordinarily available for public disclosure in accordance with the provisions in Subpart F of this part, e.g., the exemption for trade secrets or confidential commercial or financial information referenced in § 4.100(c) is not available for such disclosure to the extent that it falls within an exemption contained in this subpart, except as provided by the limitations on exemptions specified in Subpart E of this part. For example, correspondence that is ordinarily disclosable under § 4.108 is not disclosable to the extent that it contains trade secrets except from disclosure under § 4.61 and is not subject to discretionary release under § 4.82.

(b) Where application of one or more exemptions results in a record being disclosed in part and nondisclosable in part, the rule established in § 4.22 shall apply.

§ 4.61 Trade secrets and commercial or financial information which is privileged or confidential.

(a) A trade secret may consist of any formula, pattern, device, or compilation of information which is used in one's business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it.

(b) Commercial or financial information that is privileged or confidential means valuable data or information which is used in one's business and is of a type customarily held in strict confidence or regarded as privileged and not disclosed to any member of the public by the person to whom it belongs.

(c) Data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.

§ 4.62 Inter- or intra-agency memorandum files.

All communications within the Executive Branch of the Federal government which are in written form or which are subsequently reduced to writing may be withheld from public disclosure except that factual information which is reasonably segregable in accordance with rule established in § 4.22 is available for public disclosure.

§ 4.63 Personnel, medical, and similar files; disclosure of which constitutes a clearly unwarranted invasion of personal privacy.

(a) The names or other information which would identify patients or research subjects in any medical or similar report, test, study, or other research project shall be deleted before the record is made available for public disclosure.

(b) The names and other information which would identify patients or research subjects should be deleted from any record before it is submitted to the Food and Drug Administration. If the Food and Drug Administration subsequently needs the names of such individuals, a separate request will be made.

(c) Requests for deletion of business or product names prior to disclosure of any record to the public shall not be granted on the ground of privacy, but such deletion may be justified under another exemption established in this subpart, e.g., the exemption for trade secrets and confidential commercial or financial information under § 4.61.

(d) Exemptions from disclosure of information relating to such investigation, is available for public disclosure at that time in accordance with the rule established in § 4.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in Subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure prior to the consideration of regulatory enforcement action based upon that record's being closed, except as provided in § 4.62. The Commissioner will exercise his discretion to disclose records relating to possible criminal prosecution pursuant to § 4.62 prior to consideration of criminal prosecution being closed only very rarely and only where it appears that disclosure is necessary to demonstrate a compelling public interest.

(2) After the consideration of regulatory enforcement action is closed, such records shall be made available for public disclosure except to the extent that other exemptions from disclosure in this subpart are applicable. No statements of witnesses obtained through promises of
runs.

The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed within the meaning of this section if:

(i) If it relates to administrative action, when a final decision has been made not to take such action or such action has been taken and the matter has been concluded.

(ii) If it relates to court action, when a final decision has been made not to recommend such action to a United States attorney based upon that record, or a recommendation has been finally refused by a United States attorney, or court action has been instituted and the matter and all related appeals have been concluded, or the statute of limitations runs.

(iii) If it relates to both administrative and court action, when the events described in both paragraphs (d) (3) (i) and (d) (3) (ii) of this section have occurred.

(iv) Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(e) Names and other information that would identify a Food and Drug Administration employee shall be deleted from investigatory records prior to public disclosure only pursuant to § 4.32.

Subpart E—Limitations on Exemptions

§ 4.80 Applicability of limitations on exemptions

(a) The limitations on exemptions established in this subpart shall apply to all Food and Drug Administration records, except as specifically provided herein. Accordingly, a record that is ordinarily exempt from public disclosure in the provisions in Subpart D of this part is available for such disclosure to the extent that it contains data or information that have previously been furnished by a statement or memorandum to any member of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.

(b) Any data or information furnished to the Food and Drug Administration for a presubmission review pursuant to the procedure established in § 4.44 shall not be further disclosed by the other party to the presubmission review unless the information has not previously been published or disclosed to anyone other than as provided in paragraph (a) of this section.

(c) Any statement relating to prior public disclosure is subject to the False Reports to the Government Act, 18 U.S.C. 1001.

§ 4.82 Discretionary disclosure by the Commissioner.

(a) Except as provided in paragraph (b) of this section, the Commissioner may, in his discretion, disclose part or all of any Food and Drug Administration record that is otherwise exempt from disclosure pursuant to Subpart D of this part. The Commissioner shall exercise his discretion to disclose such records whenever he determines that such disclosure is in the public interest, will promote the objectives of the act and the agency, and is consistent with the rights of individuals, the property rights of persons in trade secrets, and the need for the agency to promote frank internal policy deliberations and to pursue its regulatory activities without disruption.

(b) The Commissioner shall not make available for public disclosure any record that:

(1) Exempt from public disclosure pursuant to § 4.61.

(2) Exempt from public disclosure pursuant to § 4.63.


(c) Discretionary disclosure of a record pursuant to this section shall involve the requirement that the record shall be disclosed to any person who requests it pursuant to § 4.21, but shall not set a precedent for discretionary disclosure of any similar or related record and shall not obligate the Commissioner to exercise his discretion to disclose any other record that is exempt from disclosure.

§ 4.83 Disclosure required by court order.

Records of the Food and Drug Administration which the Commissioner has determined are not available for public disclosure, either in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 4.44, shall nevertheless be made available for public disclosure in compliance with a final court order requiring such disclosure.

§ 4.84 Disclosure to consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(c), and other special government employees.

Data and information otherwise exempt from public disclosure may be disclosed to Food and Drug Administration consultants, advisory committees, State and local government officials commissioned pursuant to 21 U.S.C. 372(a), and other special government employees.

§ 4.85 Disclosure to other Federal government departments and agencies.

Any Food and Drug Administration record otherwise exempt from public disclosure may be disclosed to other Federal government departments and agencies, except that trade secrets prohibited by 21 U.S.C. 331(j) from disclosure outside the Department of Health, Education, and Welfare may be disclosed only to a department or agency that has concurrent jurisdiction over the matter and separate legal authority to obtain the specific information involved. Any disclosure under this section shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration.
§ 4.86 Disclosure in administrative or court proceedings.

Data and information otherwise exempt from public disclosure may be revealed in Food and Drug Administration administrative or court proceedings with the consent of the information owner. The Food and Drug Administration will request that the data or information be held in camera and that any other procedures be taken to reduce disclosure to the minimum necessary under the circumstances.

§ 4.87 Disclosure to Congress.

(a) All records of the Food and Drug Administration shall be disclosed to Congress upon an authorized request, except for trade secrets protected by 21 U.S.C. 331(f) from disclosure outside the Department of Health, Education, and Welfare.

(b) An authorized request for Food and Drug Administration records by Congress shall be made by the chief officer of a committee or subcommittee of Congress, acting pursuant to committee business.

(c) An individual member of Congress with respect to disclosure of records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration, shall have the same status and privileges as a member of Congress, except that:

(1) Investigatory records compiled for law enforcement purposes by foreign government officials who perform counterpart functions to the Food and Drug Administration shall be disclosed to the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration, shall be made available for disclosure to all members of the public.

§ 4.88 Communications with State and local government officials.

(a) A State or local government official commissioned by the Food and Drug Administration pursuant to 21 U.S.C. 372(a) shall have the same status with respect to disclosure of Food and Drug Administration records as any special government employee.

(b) Communications with State and local government officials with respect to law enforcement activities undertaken pursuant to a contract between the Food and Drug Administration and such officials shall be subject to the rules for public disclosure established in § 4.94.

(c) Communications with State and local government officials who are not commissioned pursuant to 21 U.S.C. 372(a) or under a contract to perform law enforcement activities shall have the same status as communications with any member of the public, except that:

(1) Investigatory records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level, and trade secrets and confidential commercial or financial information obtained by such officials, which are voluntarily disclosed to the Food and Drug Administration in a foreign country, shall be exempt from disclosure for a longer period of time if the foreign government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

(2) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to State and local government officials who perform counterpart functions to the Food and Drug Administration at the State and local level as part of cooperative law enforcement efforts does not invoke the rule established in § 4.21 that such records shall be made available for disclosure to all members of the public.

§ 4.89 Communications with foreign government officials.

Communications with foreign government officials shall have the same status as communications with any member of the public, except that:

(a) Investigatory records compiled for law enforcement purposes by foreign government officials who perform counterpart functions to the Food and Drug Administration shall be exempt from public disclosure to the same extent to which the records would be exempt pursuant to §§ 4.61 and 4.64, as if they had been prepared by the Food and Drug Administration employees, except that investigatory records shall be exempt from public disclosure to the same extent to which the records would be so exempt pursuant to §§ 4.61 and 4.64, as if they had been prepared by the Food and Drug Administration employees, except that investigatory records shall be exempt from disclosure for a longer period of time if the State or local government officials so require as a condition of their furnishing the information to the Food and Drug Administration.

§ 4.90 Use of data or information for administrative or court enforcement action.

Nothing in this part or this chapter shall prevent the Food and Drug Administration from using any data or information, whether obtained voluntarily or involuntarily and whether or not it is available for public disclosure, as the basis for taking any administrative or court enforcement action within its jurisdiction. Data and information otherwise exempt from public disclosure are nevertheless available for public disclosure to the extent necessary to effectuate such action, e.g., the brand name, code designation, and distribution information are released when a product is recalled.
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\( \text{(16) Master files for new drug applications, in } \text{§ 314.11 of this chapter.} \)

\( \text{(17) New drug application file, in } \text{§ 314.14 of this chapter.} \)

\( \text{(18) Data and information submitted for OTC drug review, in } \text{§ 330.10(a)(2) of this chapter.} \)

\( \text{(19) Data and information submitted for a biological product, in } \text{§ 601.50 of this chapter.} \)

\( \text{(20) Investigational new drug notice for an antibiotic drug, in } \text{§ 431.70 of this chapter.} \)

\( \text{(21) Investigational new drug notice for OTC drug review, in } \text{§ 601.51 of this chapter.} \)

\( \text{(22) Investigational new drug notice for a biological product, in } \text{§ 601.50 of this chapter.} \)

\( \text{(23) Applications for establishment and product licenses for biological products, in } \text{§ 801.51 of this chapter.} \)

\( \text{(24) Applications for establishment and product licenses for biological products, in } \text{§ 801.51 of this chapter.} \)

\( \text{(25) Cosmetic establishment registrations, in } \text{§ 710.7 of this chapter.} \)

\( \text{(26) Cosmetic product ingredient and cosmetic raw material composition statement, in } \text{§ 710.7 of this chapter.} \)

\( \text{(27) Cosmetic product experience reports, in } \text{§ 730.7 of this chapter.} \)

\( \text{(28) Electronic product information, in } \text{§ 1002.4 and 1002.42 of this chapter.} \)

\( \text{§ 4.101 Administrative enforcement records.} \)

\( \text{(a) All Food and Drug Administration records relating to administrative enforcement actions that are} \)

\( \text{subject to the rules for disclosure established in } \text{§ 4.64, the Commissioner determines that} \)

\( \text{they are subject to discretionary release pursuant to } \text{§ 4.82.} \)

\( \text{(b) To the extent that any of such records fall within the exemption for investigatory records established in} \)

\( \text{§ 4.64, the Commissioner determines that they are subject to discretionary release pursuant to} \text{§ 4.82.} \)

\( \text{(c) Records relating to administrative enforcement actions that are not disclosed to any member of the public constitute investigatory records that are subject to the rules for} \)

\( \text{disclosure established in } \text{§ 4.64. For example, an establishment inspection report is an investigatory record} \)

\( \text{and thus subject to } \text{§ 4.64 except as the Commissioner exercises his discretion to release it pursuant to} \text{§ 4.82.} \)

\( \text{§ 4.102 Court enforcement records.} \)

\( \text{(a) All records and documents filed in the courts are available for public disclosure unless the court orders otherwise. The} \)

\( \text{Food and Drug Administration will make available for public disclosure such records or documents if the agency can} \)

\( \text{determine that it has an accurate copy of the actual record or document filed in the court. If the Food} \)

\( \text{and Drug Administration cannot determine whether it has an accurate copy} \text{of such a record or document, the} \)

\( \text{person requesting a copy shall be referred to the court involved.} \)

\( \text{(b) After a recommendation for court action has been finally refused by a United States attorney, the Commissioner determines that} \)

\( \text{the pleadings recommended for filing with the court, is available for public disclosure. Prior to disclosure of any} \)

\( \text{record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information} \)

\( \text{that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.} \)

\( \text{§ 4.103 Correspondence.} \)

\( \text{(a) All correspondence to and from members of the public, members of Congress, organization or} \)

\( \text{company officials, or other persons, except members of the} \text{Executive Branch of the Federal Government or special government employees, is available for public disclosure.} \)

\( \text{(b) Any such correspondence is available for public disclosure at the time that it is sent or received by the} \text{Food and Drug Administration unless a different time for such disclosure is specified in other rules established or cross-referenced in this part, e.g., correspondence relating to a request for such summary.} \)

\( \text{§ 4.104 Summaries of oral discussions.} \)

\( \text{(a) All written summaries of oral discussions, whether in person or by telephone, with members of the public,} \)

\( \text{members of Congress, organization or company officials, or other persons, except a summary of oral discussions} \)

\( \text{prepared by the Food and Drug Administration unless such summary contains information that would reveal} \)

\( \text{confidential investigative techniques and procedures, e.g., the use of} \text{"markers" to document adulteration of a product. If such} \)

\( \text{discussions are disclosed in an authorized manner to any member of the public before the final report is} \)

\( \text{made, they are immediately, available for public disclosure to any member of the public who requests them.} \)

\( \text{(d) Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same} \)

\( \text{time that the final report is disclosed.} \)

\( \text{§ 4.106 Studies and reports prepared by or with funds provided by the Food and Drug Administration.} \)

\( \text{(a) The following types of reports and studies prepared by or with funds} \text{provided by the Food and Drug Administration are available for public disclosure upon their acceptance by the} \)

\( \text{Medical Category is complete and accepted by the responsible Food and Drug Administration official:} \)

\( \text{(1) Quarterly and annual reports of the agency.} \)

\( \text{(2) External investigations or review of agency needs and performance.} \)

\( \text{(3) Surveys, compilations, and summaries of data and information.} \)

\( \text{(4) Consumer surveys.} \)

\( \text{(5) Compliance surveys.} \)

\( \text{(6) Compliance programs, except that names of specific firms, the location of specific activities, and details about} \)

\( \text{sampling numbers or sizes shall be deleted until implementation of the program is completed.} \)

\( \text{(7) Work plans prepared by Food and Drug Administration bureaus, field offices, and other components, except that} \)

\( \text{names of specific firms, the location of specific activities, and details about sampling numbers or sizes shall be} \)

\( \text{deleted until implementation of the plan is completed.} \)

\( \text{(b) The following types of reports and studies prepared by or with funds provided by the Food and Drug Administration are not available for public disclosure:} \)

\( \text{(1) Internal audits of agency needs and performance.} \)

\( \text{(2) Records relating to the internal personnel management and budget process.} \)

\( \text{(3) Legislative budget resolutions or comments prior to submission to Congress.} \)

\( \text{§ 4.107 Food and Drug Administration manuals.} \)

\( \text{(a) All Food and Drug Administration staff manuals and instructions to staff that affect a member of the public are} \)

\( \text{available for public disclosure. An} \)
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§ 4.105 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.

(a) All written agreements and understandings signed by the Food and Drug Administration and other departments, agencies, and organizations are available for public disclosure.

(b) Manuals relating solely to internal personnel rules and practices are not available for public disclosure except to the extent that the Commissioner determines that they should be disclosed pursuant to § 4.108.

(c) All Food and Drug Administration action levels which are used to determine when the agency will take regulatory action against a violative product, limits of sensitivity and variability of analytical methods which are used in determining whether a product violates the law, and direct reference levels above which Food and Drug Administration employees are available for public disclosure.

§ 4.106 Data and information obtained by contract.

All data and information obtained by the Food and Drug Administration by contract, including all progress reports or final reports submitted pursuant to a contract, are available for public disclosure when accepted by the responsible agency official except to the extent that the Commissioner determines that such data or information shall be withheld from public disclosure.

§ 4.107 Data and information submitted voluntarily to the Food and Drug Administration.

(a) The name, title, grade, position description, salary, work address, and work telephone number for every Food and Drug Administration employee are available for public disclosure.

(b) Statistics on the prior employment experience of present agency employees, and subsequent employment experiences of past agency employees, are available for public disclosure.

§ 4.108 Data and information submitted voluntarily to the Food and Drug Administration.

(a) The provisions of this section shall apply only to data and information submitted voluntarily to the Food and Drug Administration, whether in the course of a factory inspection or at any other time, and not as a part of any petition, application, master file, or other required submission or request for action. Data and information that may be required to be submitted to the Food and Drug Administration but that are submitted voluntarily instead will be subject to the provisions of this section and will be handled as if they had been required to be submitted.

(b) A determination that data or information submitted voluntarily will be held in confidence and will not be available for public disclosure shall be made only in the form of a regulation published or cross-referenced in this part or by a written determination pursuant to the procedure established in § 4.44.

(c) The following data and information submitted voluntarily to the Food and Drug Administration are available for public disclosure in extraordinary circumstances:

(i) All safety, effectiveness, and functional data and information for a marketed product, except as provided in § 330.10(a)(2) of this chapter for OTC drugs.

(ii) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial or financial information.

(iii) Adverse reaction reports, product experience reports, consumer complaints, and other similar information shall be disclosed as follows:

(1) If submitted by a consumer or user of the product, the record is available for public disclosure after deletion of names and other information that would identify the person submitting the information.

(2) If submitted by the manufacturer of the product, the record is available for public disclosure after deletion of:

(a) Names and any information that would identify the person using the product.

(b) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(c) Names and any other information that would identify the manufacturer or the brand designation of the product, but not the type of product or its ingredients.

(4) Quantitative or semiquantitative data and information for a developmental ingredient or product that has not previously been disclosed to the public as defined in § 4.81 or that relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61:

(1) All safety, effectiveness, and functional data and information for a developmental ingredient or product that has not previously been disclosed to the public as defined in § 4.81 or that relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61:

(2) Manufacturing methods or processes including quality control procedures.

(3) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(4) Quantitative or semiquantitative formulas.

(e) For purposes of this regulation, safety, effectiveness, and functional data include all studies and tests of an ingredient or a product on animals and humans and all studies and tests on the ingredient or product for identity, stability, purity, potency, bioavailability, performance, and usefulness.
§ 4.112 Voluntary drug experience reports submitted by physicians and hospitals.

(a) A voluntary drug experience report to the Food and Drug Administration on Form 314-1690 shall be handled or dealt with in accordance with the rules established in § 4.111(c) (3) (i) (II).

(b) If a person requests a copy of any such record relating to a specific information regarding a specific ingredient or ingredient, such request will be denied unless accompanied by the written consent to such disclosure of the person who submitted the report to the Food and Drug Administration and the individual who is the subject of the report.

§ 4.113 Voluntary product defect reports.

Voluntary reports of defects in products subject to the jurisdiction of the Food and Drug Administration are available for public disclosure:

(a) If the report is submitted by the manufacturer, after deletion of data and information falling within the exemptions established in § 4.61 for trade secrets, confidential commercial or financial information and in § 4.63 for personal privacy.

(b) If the report is submitted by anyone other than the manufacturer, after deletion of names and other information that would identify the person submitting the report and any data or information falling within the exemption established in § 4.63 for personal privacy.

§ 4.114 Data and information submitted pursuant to cooperative quality assurance agreements.

Data and information submitted to the Food and Drug Administration pursuant to a cooperative quality assurance agreement shall be handled in accordance with the rules established in § 4.111.

§ 4.115 Product codes for manufacturing or sales dates.

Data or information in Food and Drug Administration files which provide a means for deciphering or decoding a manufacturing date or sales date or use date contained on the label or in labeling or otherwise used in connection with a product subject to the jurisdiction of the Food and Drug Administration are available for public disclosure.

§ 4.116 Drug listing information.

Information submitted to the Food and Drug Administration pursuant to section 510 of the act (21 U.S.C. 360) shall be subject only to the special disclosure provisions established in § 123.9 of this chapter.

§ 4.117 New drug information.

(a) The following computer printouts are available for public inspection in the Food and Drug Administration Public Records and Documents Center:

(1) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938, showing the NDA number, the trade name, the applicant, the approval date, and, where applicable, the date the approval was withdrawn and the date the Food and Drug Administration was notified that the marketing of the product was discontinued.

(2) A numerical listing of all new drug applications and abbreviated new drug applications approved since 1938 which are still approved, showing the same information as is specified in paragraph (a) (1) of this section except that it does not show a withdrawal date.

(b) Other computer printouts containing IND and NDA information are available to the extent that they do not reveal data or information prohibited from disclosure under §§ 4.61, 321.5, and 314.14 of this chapter.

§ 4.118 Advisory committee records.

All advisory committee records shall be handled in accordance with the rules established in Part 2 of this chapter.

PART B—COLOR ADDITIVES

4. In Part B, by revising § 8.9 to read as follows:

§ 8.9 Confidentiality of data and information in color additive petitions.

(a) The following data and information in a color additive petition are available for public disclosure, unless extra-ordinary circumstances are shown, after the new formula or new ingredient is published in the Federal Register or, if the petition is not promptly filed because of the deficiencies involved:

(1) All safety and functionality data and information submitted with or incorporated by reference in the petition.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial information in § 4.61 of this chapter.

(3) Adverse experience reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the person using the product.

(ii) Names and any information that would identify any third party involved with the report, such as a physician or hospital.

(4) A list of all ingredients contained in a color additive, whether or not it is in descending order of predominance. A particular ingredient or group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 4.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

(6) All records showing the Food and Drug Administration's testing of or submission of such data, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a manner that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(c) All correspondence and written summaries of oral discussions relating to a color additive petition are available for public disclosure in accordance with the provisions of Part 4 of this chapter when the color additive regulations are published in the Federal Register.

(d) For purposes of this regulation, safety and functionality data include all studies and tests of a color additive on animals and humans and all studies and tests on a color additive for identity, stability, purity, potency, performance, and usefulness.

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 10—DEFINITIONS AND STANDARDS OF IDENTITY

5. In Part 10, by adding a new paragraph (k) to § 10.5 as follows:

§ 10.5 Temporary permits for interstate shipment of experimental packs of foods or animals, and the requirements of definitions and standards of identity.

(k) All applications for a temporary permit, applications for an extension of a temporary permit, and related records are available for public disclosure when the notice of a permit or extension thereof is published in the Federal Register.

PART 90—EMERGENCY PERMIT CONTROL

6. In Part 90, by adding a new paragraph (1) to § 90.20 to read as follows:

§ 90.20 Thermal processing of low-acid foods packaged in hermetically sealed containers.

(1) The following data and information submitted to the Food and Drug Administration pursuant to this section are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter.
they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter:

1. Manufacturing methods or processes, including quality control information.

2. Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure, such as a summary of:
   a) Names and any information that would identify the person using the product.
   b) Names and any information that would identify any third party involved with the product, such as a physician or hospital or other institution.
   c) A list of all ingredients contained in a food additive, whether or not it is in descending order of predominance. A particular ingredient in a group of ingredients shall be deleted from any such list prior to public disclosure if it is shown to fall within the exemption established in § 4.61 of this chapter, and a notation shall be made that any such ingredient list is incomplete.
   d) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

The following data and information in a food additive petition are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter:

1. Manufacturing methods or processes, including quality control procedures.

2. Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

3. Quantitative or semiquantitative formulas.

PART 121—FOOD ADDITIVES

7. In Part 121, by revising § 121.51(h) to read as follows:

§ 121.51 Petitions proposing regulations for food additives.

(h) (1) The following data and information in a food additive petition are available for public disclosure, unless extraordinary circumstances are shown, after the notice of filing of the petition is published in the Federal Register or, if the petition is not promptly filed because of deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved:
   a) All safety and functionality data and information submitted with or incorporated by reference in the petition.
   b) A protocol for a test or study, unless it has previously been publicly disclosed or acknowledged.
   c) For purposes of this regulation, safety and functionality data include all studies and tests of a food additive on animals and humans and clinical studies and tests on a food additive for identity, stability, purity, potency, performance, and usefulness.

SUBCHAPTER C—DRUGS

PART 135—NEW ANIMAL DRUGS

8. In Part 135:

a. By revising § 135.33 to read as follows:

§ 135.33 Confidentiality of data and information in an investigational new animal drug notice.

(a) The existence of an NADA notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(b) The availability for public disclosure of all data and information in an NADA file shall be handled in accordance with provisions established in § 135.33a.

b. By adding new § 135.33a to read as follows:

§ 135.33a Confidentiality of data and information in a new animal drug application.

(a) For purposes of this section the "NADA file" includes all data and information submitted with or incorporated by reference in the NADA, InAD's incorporated into the NADA, supplemental NADA reports under §§ 135.14a and 135.14b, master files, and other related submissions. The availability for public disclosure of any record in the NADA file shall be handled in accordance with the provisions of this section.

(b) The existence of an NADA file will not be disclosed by the Food and Drug Administration before an approval has been published in the Federal Register, unless it has previously been publicly disclosed or acknowledged.

(c) If the existence of an NADA file has not been publicly disclosed or acknowledged, no data or information in the NADA file is available for public disclosure.

(d) If the existence of an NADA file has been publicly disclosed or acknowledged before an approval has been published in the Federal Register, no data or information contained therein is available for public disclosure before such approval is published, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After an approval has been published in the Federal Register, the following data and information in the NADA file are immediately available for public disclosure unless extraordinary circumstances are shown:

1. All safety and effectiveness data and information previously disclosed to the public, as defined in § 4.81 of this chapter.

2. A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the NADA file. Such summaries do not constitute the full reports of investigations under section 512(b)(1) of the act. (21 U.S.C. 360b(b)(1)) on which the safety or effectiveness of the drug may be approved. Such summaries shall consist of the following:
   a) For an NADA approved after July 1, 1975, summary drug information that would identify the investigator.
   b) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.
   c) For an NADA approved prior to July 1, 1975, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the approval is published in the Federal Register:
      (1) The Bureau of Veterinary Medicine may at an appropriate time prior to approval of the NADA require the applicant to prepare a summary of such data and information, which will be reviewed and, where appropriate, revised by the Bureau.
      (2) The Bureau of Veterinary Medicine may prepare its own summary of such data and information.
   (2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secret or confidential commercial information in § 4.61 of this chapter.

(f) Adverse reaction reports, product experience reports, consumer complaints, and information in an investigational new animal drug petition.
and other similar data and information, after deletion of:
(i) Names and any information that would identify the person using the product.
(ii) Names and any information that would identify any third party involved with the report, such as a physician, hospital, or other institution.

5. A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 4.81 of this chapter.

6. An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

7. All correspondence and written summaries of oral discussions relating to the NADA, in accordance with the provisions of Part 4 of this chapter.

8. All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time that any one of the following events occurs:
   (1) The NADA has been abandoned and no further work is being undertaken with respect to it.
   (2) A final determination is made that the NADA is not approvable, and all legal appeals have been exhausted.
   (3) Approval of the NADA is withdrawn, and all legal appeals have been exhausted.
   (4) A final determination has been made that the animal drug is not a new animal drug.
   (5) A final determination has been made that the animal drug may be marketed without submission of such safety and/or effectiveness data and information.
   (6) The following data and information in a new animal drug notice and a new animal drug application file shall apply to such notices and files for antibiotic drugs for new animal drug use.
   (a) The rules established in §§ 135.33 and 135.33a of this chapter with regard to the confidentiality of an investigational new animal drug notice and a new animal drug application file shall apply to such notices and files for antibiotic drugs for new animal drug use.
   (b) All records showing the Food and Drug Administration's testing of and action on a particular lot of a certifiable antibiotic drug for veterinary use are immediately available for public disclosure.

SUBCHAPTER D—DRUGS FOR HUMAN USE
PART 312—NEW DRUGS FOR INVESTIGATIONAL USE
10. In Part 312, by adding new § 312.5 to read as follows:
§ 312.5 Confidentiality of data and information in an investigational new drug notice (IND).
(a) The existence of an IND notice will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.
(b) The availability for public disclosure of all data and information in an IND file shall be handled in accordance with the provisions established in § 314.14 of this chapter for the confidentiality of data and information in new drug applications.
(c) Notwithstanding the provisions of § 314.14 of this chapter, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational new drug has been used a copy of any adverse reaction report relating to such use.

PART 314—NEW DRUG APPLICATIONS
11. In Part 314:
(a) By revising the heading and paragraph (b) of § 314.11 to read as follows:
§ 314.11 Master files.

(b) Section 301(j) of the act makes it an offense to divulge to unauthorized persons any information acquired from a new-drug application concerning any method or process that is a trade secret. Basic manufacturers sometimes submit data to the Food and Drug Administration in the form of so-called master files for the purpose of establishing the safety of ingredients that may be used in new drugs and authorize specified applicants to incorporate by reference such data in support of their applications. The confidentiality of such data shall be determined in accordance with Part 4 of this chapter and § 314.14. Because the applicant is legally responsible for the composition of the new drug and all its ingredients and includes in the master file for judicial or administrative proceedings concerning the drug, the Food and Drug Administration shall not withhold such information from the applicant when he needs it and he submits a written request for it. The Food and Drug Administration will inform the person who submitted the data of any such requests.

b. By adding new § 314.14 to read as follows:
§ 314.14 Confidentiality of data and information in a new drug application (NDA) file.
(a) For purposes of this section the "NDA file" includes all data and information submitted with or incorporated by reference in the NDA, IND's, reports under §§ 310.300 and 310.310 of this chapter, master files, and other related submissions. The availability for public disclosure of any record in the NDA file shall be in accordance with the provisions of this section.
(b) The existence of an NDA file will not be disclosed by the Food and Drug Administration before an approval letter has been sent to the applicant, unless it has previously been publicly disclosed or acknowledged. The Director of the Bureau of Drugs will maintain a list available for public disclosure of pending NDA's for which an approvable letter has been sent to the applicant.
(c) If the existence of an NDA file has not been publicly disclosed or acknowledged, no data or information in the NDA file are available for public disclosure.
(d) If the existence of an NDA file has been publicly disclosed or acknowledged before an approval letter has been sent to the applicant, no data or information contained in the file is available for public disclosure before such letter is sent but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of a Food and Drug Advisory Committee or pursuant to an exchange of important regulatory information with a foreign government.
(e) After an approval letter has been sent to the applicant for a pending NDA, the following data and information in the NDA file are immediately available for public disclosure unless extraordinary circumstances are shown:
   (1) All safety and effectiveness data and information previously disclosed to the public, as defined in § 4.81 of this chapter.
(2) A summary or summaries of the safety and effectiveness data and information submitted with or incorporated by reference in the NDA file. Such summaries do not constitute the full reports of investigations under section 505(b)(1) of the act (21 U.S.C. 355(b)(1)) on which the safety or effectiveness of the drug may be approved. Such summaries shall consist of the following:

(a) Names and any information that would identify patients or test subjects or the investigators.
(b) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.
(c) The Bureau of Drugs may at an appropriate time prior to approval of the NDA require the applicant to prepare a summary of such data and information, which will be reviewed and, where appropriate, redacted by the Bureau.
(d) The Bureau of Drugs may prepare its own summary of such data and information.

(3) Approval of the NDA is withdrawn, and all legal appeals are exhausted.

(4) A final determination has been made that the drug is not a new drug.

A final determination has been made that the drug may be marketed without submission of such safety and/or effectiveness data and information.

(g) The following data and information in an NDA file are not available for public disclosure unless they have been previously disclosed to the public as defined in §4.61 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in §4.61 of this chapter:

(1) Manufacturing methods or processes, including quality control procedures.
(2) Production, sales, distribution, and similar data and information, except that any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(h) The compilations of information specified in §4.117 of this chapter are available for public disclosure.

(i) For purposes of this regulation, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability.

PART 431—CERTIFICATION OF ANTIBIOTIC DRUGS

12. In Part 431, by adding a new Subpart D to read as follows:

Subpart D—Confidentiality of Information

Sec. 431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

431.71 Confidentiality of data and information in an antibiotic drug file.

(a) The following data and information in an NDA file are not available for public disclosure unless it has previously been publicly disclosed or acknowledged before an approval letter has been sent to the applicant, no data or information contained in the file is available for public disclosure before such letter is sent, but if the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific packing issue, etc., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(b) After an approval letter has been sent to the applicant for a pending antibiotic drug file, the following data and information in the NDA file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial or financial information in §4.61 of this chapter.

(3) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in §4.61 of this chapter.

(4) A final determination has been made that the drug is not a new drug.

(5) After an approval letter has been sent to the applicant for a pending antibiotic drug file, the following data and information in the NDA file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information.

(2) A final determination is made that the NDA is not approvable, and all legal appeals have been exhausted.

(3) Antibiotic has been used a copy of any adverse reaction report relating to such use.

§431.71 Confidentiality of data and information in an antibiotic drug file.

(a) For purposes of this section, an "antibiotic drug file" includes all data and information submitted with or incorporated by reference in any form submitted pursuant to §§431.50 or 431.60, INDs incorporated into any such form, master files, and other related submissions. The availability for public disclosure of any record included in an investigational drug file shall be handled in accordance with the provisions of this section.

(b) The existence of an antibiotic drug file will not be disclosed by the Food and Drug Administration before an approvable letter has been sent to the applicant, unless it has previously been publicly disclosed or acknowledged. The Director of the Bureau of Drugs will maintain a list of approved antibiotic drug files, and an applicant shown not approvable, and all legal appeals have been exhausted.

(4) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in §4.81 of this chapter.

(5) The following data and information in an NDA file are not available for public disclosure unless: (i) Names and any information that would identify patients or test subjects or the investigators. (ii) Names and any information that would identify patients or test subjects or the investigators.

(6) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established for trade secrets and confidential commercial or financial information in §4.61 of this chapter.

(7) All correspondence and written summaries of oral discussions relating to the NDA file, in accordance with the provisions of Part 4 of this chapter.

(8) All safety and effectiveness data and information not previously disclosed to the public are available for public disclosure at the time that any one of the following events occurs:

(1) The NDA has been abandoned and no further work is being undertaken with respect to it.

(2) A final determination is made that the NDA is not approvable, and all legal appeals have been exhausted.
(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

(6) All correspondence and written summaries of oral discussions relating to the antibiotic file, in accordance with the provisions of Part 4 of this chapter.

All records showing the testing of and access to a particular lot of a certifiable antibiotic drug by the Food and Drug Administration.

The following data and information shall not be disclosed to the public as defined in § 4.61 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter.

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(4) For purposes of this regulation, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability.

SUBCHAPTER F—BIOLOGICS

PART 601—LICENSING

13. In Part 601, by adding a new Subpart P to read as follows:

Subpart F—Confidentiality of Information

§ 601.50 Confidentiality of data and information in an investigational new drug notice for a biological product.

(1) The existence of an IND notice for a biological product will not be disclosed by the Food and Drug Administration unless it has previously been publicly disclosed or acknowledged.

(2) The availability for public disclosure of all data and information in an IND file for a biological product shall be handled in accordance with the provisions established in § 401.51.

(3) Notwithstanding the provisions of § 601.51, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational biological product has been used a copy of any adverse reaction report relating to such use.

§ 601.51 Confidentiality of data and information in applications for establishment and product licenses.

(1) For purposes of this section the "biological product file" includes all data and information submitted with or incorporated by reference in any application for an establishment or product license, IND's incorporated into any such application, master files, and other related submissions. The availability for public disclosure of any record in the biological product file is available for public disclosure, in accordance with the provisions of this section.

(b) The existence of a biological product file will not be disclosed by the Food and Drug Administration unless a product license has been sent to the applicant, unless it has previously been publicly disclosed or acknowledged. The Director of the Bureau of Biologics will maintain a list available for public disclosure of biological products for which a license has been issued.

(c) If the existence of a biological product file has not been publicly disclosed or acknowledged, no data or information in the biological product file is available for public disclosure.

(d) If the existence of a biological product file has been publicly disclosed or acknowledged before a license has been issued, no data or information contained in the file is available for public disclosure before such license is issued, but the Commissioner may, in his discretion, disclose a summary of such selected portions of the safety and effectiveness data as are appropriate for public consideration of a specific pending issue, e.g., at an open session of a Food and Drug Administration advisory committee or pursuant to an exchange of important regulatory information with a foreign government.

(e) After a license has been issued, the following data and information in the biological product file are immediately available for public disclosure unless extraordinary circumstances are shown:

(1) All safety and effectiveness data and information.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established for trade secrets and confidential commercial or financial information in § 4.61 of this chapter.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the persons using the product.

(ii) Names and any information that would identify any third party involved with the person using the product, such as a physician or hospital or other institution.

(4) A list of all active ingredients and any inactive ingredients previously disclosed to the public, as defined in § 4.61 of this chapter.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

(6) All correspondence and written summaries of oral discussions relating to the biological product file, in accordance with the provisions of Part 4 of this chapter.

All records showing the manufacturer's testing of a particular lot, after deletion of data or information that would show the volume of the drug produced, manufacturing procedures and controls, yield from raw materials, costs, or other material falling within § 4.61 of this chapter.

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(4) For purposes of this regulation, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability.

SUBCHAPTER G—COSMETICS

PART 720—VOLUNTARY FILING OF COSMETIC PRODUCT INGREDIENT AND COSMETIC RAW MATERIAL COMPOSITION STATEMENTS

14. In Part 720, by revising § 720.8 to read as follows:

§ 720.8 Confidentiality of statements.

(2) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(i) Names and any information that would identify the persons using the product.

(ii) Names and any information that would identify any third party involved with the person using the product, such as a physician or hospital or other institution.

(4) A list of all active ingredients and any inactive ingredients previously disclosed to the public, as defined in § 4.61 of this chapter.

(5) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and is shown to fall within the exemption established in § 4.61 of this chapter.

(6) All correspondence and written summaries of oral discussions relating to the biological product file, in accordance with the provisions of Part 4 of this chapter.

(7) All records showing the manufacturer's testing of a particular lot, after deletion of data or information that would show the volume of the drug produced, manufacturing procedures and controls, yield from raw materials, costs, or other material falling within § 4.61 of this chapter.

(8) All records showing the testing of and action on a particular lot by the Food and Drug Administration.

The following data and information in a biological product file are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.61 of this chapter or they relate to a product or ingredient that has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 4.61 of this chapter.

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which is not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

(4) For purposes of this regulation, safety and effectiveness data include all studies and tests of a drug on animals and humans and all studies and tests on the drug for identity, stability, purity, potency, and bioavailability.

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chapter, and to the provisions concerning data and information submitted voluntarily to the Food and Drug Administration under § 4.111 of this chapter, as well as to the exemptions in Subpart D of Part 4 of this chapter and the limitations on exemptions in Subpart E of Part 4 of this chapter.

(b) A determination pursuant to § 4.44 of this chapter that an ingredient or ingredients is not a trade secret or confidential commercial information under § 4.61 of this chapter constitutes final agency action that is subject to judicial review pursuant to 5 U.S.C. chapter 7. If suit is brought within 10 days after such a determination, the Food and Drug Administration will not disclose the records involved or require that the disputed ingredient or ingredients be disclosed in labeling until the matter is finally determined in the courts.

PART 730—VOLUNTARY FILING OF COSMETIC PRODUCT EXPERIENCES

15. In Part 730, by revising § 730.7 to read as follows:

§ 730.7 Confidentiality of reports.

The availability for public disclosure of all data and information contained in, attached to, or included with Forms FD-2704, 2705, 2706, and amendments thereto, shall be handled in accordance with the provisions established in Part 4 of this chapter. All such data and information are submitted voluntarily to the Food and Drug Administration and are thus subject to the specific provisions concerning data and information submitted voluntarily to the Food and Drug Administration in § 4.111 of this chapter, as well as to the exemptions in Subpart D of Part 4 of this chapter and the limitations on exemptions in Subpart E of Part 4 of this chapter.

Effective date. This order shall be effective on (insert date 30 days after date of publication in the Federal Register). Interested persons may, on or before (insert date 60 days after date of publication in the Federal Register), file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding matters not raised in the proposal published in the Federal Register of May 5, 1972 (37 FR 9128) and considered in the preamble to this order. Comments received will be available for public inspection at the above office during working hours, Monday through Friday. Any changes in this order justified by such comments will be the subject of a further order amending the specific regulations involved.


A. M. Schmidt,
Commissioner of Food and Drugs.
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