TUESDAY, DECEMBER 24, 1974
WASHINGTON, D.C.

Volume 39  Number 248

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CIVIL AERONAUTICS BOARD

Travel group charters; deletion of termination date; comments by 1-3-75. 41995; 12-4-74

CONSUMER PRODUCT SAFETY COMMISSION

Administrative policy and procedures; comments by 12-30-74. 37780; 10-24-74

ENVIRONMENTAL PROTECTION AGENCY

Coal preparation plants; standards of performance for new stationary sources; comments by 12-30-74. 40512; 11-18-74
New portable air compressors; comments by 12-31-74. 42379; 12-5-74
Transportation equipment noise emission for medium and heavy duty trucks; comments by 12-31-74. 42379; 12-5-74

FEDERAL COMMUNICATIONS COMMISSION

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FEDERAL HOME LOAN BANK BOARD

Federal Home Loan Bank System; liquid assets; comments by 12-31-74. 41264; 11-26-74
Federal Savings and Loan System; interest on escrow funds; comments by 12-31-74. 41386; 11-27-74

FEDERAL POWER COMMISSION

Accounts and reports; construction work in progress; comments by 12-30-74. 40787; 11-20-74

HEALTH, EDUCATION, AND WELFARE DEPARTMENT

Education Office—Educational opportunity programs; funding criteria for fiscal year 1975; comments by 12-30-74. 41536; 11-29-74
Food and Drug Administration—Acrylonitrile copolymers intended for use in contact with food; comments by 1-3-75. 38607; 11-4-74
Federal-State cooperative program; food service sanitation; comments by 12-30-74. 35438; 12-1-74
Frozen strawberries; identity and quality standards; comments by 1-2-75. 35809; 10-4-74
Land and air conveyances, and vessels: food; comments by 12-30-74. 35438; 10-1-74
New animal drug applications; comments by 1-3-75. 38905; 11-4-74
Office of the Secretary—Handling of late proposals; policies and procedures; comments by 1-3-75. 41988; 12-4-74
Support for improvement of post-secondary education; comments by 1-2-75. 41748; 12-2-74

INTERIOR DEPARTMENT

Indian Affairs Bureau—Ahtanum Indian Irrigation Project; irrigation operation and maintenance charges; comments by 12-30-74. 41534; 11-29-74
Fort Hall Irrigation Project; irrigation operation and maintenance charges; comments by 12-30-74. 41534; 11-29-74
Wapato Indian Irrigation Project; irrigation operation and maintenance charges; comments by 12-30-74. 41534; 11-29-74

National Park Service—Cape Hatteras National Seashore, North Carolina; proposed fishing regulations; comments by 12-30-74. 43728; 12-18-74

INTERSTATE COMMERCE COMMISSION

Transportation of “waste” products for refuse and recycling; comments by 1-2-75. 41863; 12-3-74

NATIONAL CREDIT UNION ADMINISTRATION

Mergers of credit unions; comments by 1-2-75. 39476; 11-7-74

SECURITIES AND EXCHANGE COMMISSION

Alternative approach for certain brokers and dealers; net capital requirements; comments by 12-31-74. 41540; 11-29-74
Mutual fund sales literature; commission statement of policy; comments by 12-30-74. 40789; 11-20-74

TRANSPORTATION DEPARTMENT

Federal Aviation Administration—Airworthiness directive Boeing 727; comments by 12-30-74. 40036; 11-13-74
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Boeing model 747-100/200 series airplanes; proposed airworthiness directive; comments by 12-31-74. 41261; 11-26-74
Designation of the Kenansville, N.C. transition area; comments by 1-2-75. 41751; 12-2-74
Federal airways; proposed alteration; comments by 1-2-75. 41855; 12-3-74
Transition area; proposed alteration; comments by 1-2-75. 41855; 12-3-74

Next Week’s Meetings

AGRICULTURE DEPARTMENT

Forest Service—Tonto National Forest Grazing Advisory Board; to be held at Phoenix, Arizona (open with restrictions) 1-3-75. 40599; 11-19-74

ATOMIC ENERGY COMMISSION

Ad Hoc Isotopes subcommittee general advisory committee; to be held at Menlo Park, Calif., on 1-3-75. 43753; 12-18-74
CIVIL SERVICE COMMISSION
Federal Prevailing Rate Advisory Committee; to be held at Washington, D.C., on 1-9-75, 1-16-75, 1-23-75, 1-30-75. 43776; 12-18-74

HEALTH, EDUCATION, AND WELFARE DEPARTMENT
Alcohol, Drug Abuse, and Mental Health Administration—National advisory bodies; to be held at Washington, D.C., on 1-9-75, 1-16-75, 1-23-75, 1-30-75. 43776; 12-18-74

INTERIOR DEPARTMENT
Land Management Bureau—Albuquerque District Advisory Board; to be held at Albuquerque, New Mexico (open) 1-3-75. 39561; 12-16-74
Arizona Phoenix District Advisory Board; to be held at Kingman, Ariz. (open with restrictions) 1-3-75. 39561; 12-16-74
Arizona Strip District Advisory Board; to be held in St. George, Utah (open with restrictions) 1-3-75. 43095; 12-10-74
National Advisory Board Council; to be held in Denver, Colo. (open) 1-3-75. 43095; 12-16-74

REMINDEERS—Continued
New Mexico Grazing District 3 Advisory Board; to be held in Las Cruces, New Mexico (open) 1-3-75. 39483; 11-7-74
Safford District Advisory Board; to be held at Safford, Ariz. (open with restrictions) 1-3-75. 42015; 12-4-74
Susanville District Grazing Advisory Board, Calif.; to be held at Susanville, Calif. (open with restrictions) 1-3-75. 42015; 12-4-74
Office of the Assistant Secretary—Oil Shale environmental advisory panel; to be held at Lakewood, Colo., on 1-9-75. 43743; 12-16-74

STATE DEPARTMENT
Office of the Secretary—Department of Defense Wage Committee; to be held at Washington, D.C. (closed) 12-31-74. 39747; 11-11-74

VETERANS ADMINISTRATION
Veterans Administration Wage Committee; to be held in Washington, D.C. (closed) 1-2-75. 41787; 12-2-74

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 acts will appear every Wednesday in the FEDERAL REGISTER and copies of the laws may be obtained from the U.S. Government Printing Office.
S. 1353 .......................... Pub. Law 93-524 Vessels, net tonnage for waste materials (Dec. 18, 1974; 88 Stat. 1694)
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.
rules and regulations

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

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

Title 4—Accounts

CHAPTER III—COST ACCOUNTING STANDARDS BOARD

SUBCHAPTER C—PROCUREMENT PRACTICES

PART 351—CONTRACT CLAUSE

PART 351—BASIC REQUIREMENTS

Additional Exemption

The purpose of this publication by the Cost Accounting Standards Board is to make modifications to Parts 351, Contract Coverage, 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 contracts subject to its rules and regulations as “covered contracts”. Section 719 (h) (2) of Pub. L. 91-379 authorizes the Cost Accounting Standard Board to prescribe rules exempting from its requirements such classes or categories of national defense contractors and subcontractors as it determines, on the basis of the size of the contracts involved or otherwise, are appropriate and consistent with the purposes sought to be achieved by Pub. L. 91-379. The Board has granted several exemptions to classes or categories of contractors and subcontractors and also has established a procedure under which waiver of the Board’s requirements may be granted for individual contracts.

A proposed exemption increasing the minimum contract amount requiring compliance with Cost Accounting Standards Board rules, regulations and standards from $100,000 to $500,000 was published by the Board on September 27, 1974 (39 FR 34669). The Board received 82 responses to the September 27 proposal. Comments were received from individual companies, government agencies, professional associations, industry associations, public accounting firms, and individuals. All of these comments have been carefully considered by the Board, and the Board takes this opportunity to express its appreciation for the helpful suggestions which have been furnished.

The comments below summarize the major issues discussed by respondents in connection with the initial publication and explain the Board’s disposition of these issues.

Issuance of the exemption. Practically all the commentators expressed concern in the proposed exemption, giving either unqualified support or support with added comments that additional exemptions should also be considered. However, three commentators—a consulting firm, a major aerospace company and a Government agency—disagreed with the proposed exemption, stating that an increase in the threshold for compliance with CAS requirements was inconsistent with the Board’s objective of establishing uniformity and consistency among contractors doing business with the Government.

The Board agrees that adoption of the proposed regulation will exempt a substantial number of contractors and subcontractors who otherwise would be covered, and considered, and permit such companies to follow accounting practices other than those set out in Cost Accounting Standards. However, the Board is aware that compliance with its rules, regulations and standards may involve additional administrative effort, particularly on the part of small companies, which may not be commensurate with the benefits to the Government and the contractor resulting from such compliance.

The Board, after considering the efforts required by both the Government and its contractors to assure compliance on all covered contracts in excess of $100,000, is persuaded that maximum benefit to the Government with minimum cost can be achieved by limiting the mandatory application of its standards to contractors who receive awards which constitute a substantial majority of the national defense procurement dollars. As was stated above the maximum allowed threshold of $100,000 requires little added effort.

With respect to the commentators’ statements concerning the difficulties, when making an award exceeding $100,000, of determining whether a contractor or subcontractor had in existence a prior award exceeding $500,000, the Board feels that an administrative requirement can be established for obtaining this information. A similar requirement now exists concerning the disclosure statement, whereby contractors are required to submit a disclosure statement, state that they have previously filed a disclosure statement, or submit a certificate of monetary exemption. The Board feels that a similar requirement can be set concerning the $500,000 level. The Board is not persuaded that this matter would create problems of sufficient significance to eliminate coverage down to the $100,000 level.

Increase exemption on all contracts to $500,000. A number of commentators suggested that the $500,000 single contract threshold for compliance with Board rules, regulations, and standards be changed to exempt all contracts of $500,000 or less. Those giving 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.

The Board, in proposing the $500,000 threshold, did so with the intent of exempting those companies which do not receive contracts in excess of $500,000 from the Government. However, it was decided in the interest of consistency in cost accounting practices that once a contractor had received a covered contract of that size, compliance with existing rules, regulations and standards on contracts at the level established in Pub. L. 91-379 was appropriate. This is also consistent with the desire expressed by contractors to follow a single set of accounting practices. Further, the requirement for coverage of contracts in excess of $100,000 where the contractor already has received a covered contract in excess of $500,000 will permit the small contracts to be available for equitable adjustment if subsequently issued standards should become applicable. Moreover, once the administrative effort has been expended to comply with standards for contracts in excess of $500,000, compliance with standards on contracts above the statutory threshold of $100,000 requires little added effort.

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44339
In considering the advantages of the exemption as proposed compared to its assessment and the feasibility of such an adjustment, the Board is persuaded that its proposal relative to coverage of awards in excess of $500,000 should not be changed.

Exemption based on sales. A number of commentators urged that the Board establish an exemption based on sales, using either minimum annual dollar amount or percentage of sales in relation to the Government or total annual sales, or a combination of these two factors. The most frequently suggested amount was $10 million of sales to the Government or Government sales amounting to 10 percent of total annual sales. The objective sought by these commentators was an exemption of those companies or business units whose sales to the Government constituted a reasonably small portion of their total annual sales and whose business was essentially commercially oriented.

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, and has arrived at a decision at this time. The nature of the problems involved in administering an exemption based on sales, in either of the situations suggested by commentators, the representation concerning the amount of sales must be made by the contractor and subsequently verified by the Government. This verification would impose very substantial and time-consuming efforts on both the Government and the contractor. Particularly in the case of Government sales as a percentage of total sales, Government representatives 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 Government procurement activities and would present new and unique problems to both parties as well as engendering substantial additional effort on the part of Government representatives.

An exemption based on sales would require a measurement period during which a contractor's sales would be calculated, and subsequent determination of compliance with standards would be determined. Contracts 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 standards under contracts received in subsequent periods, the volume or amount of sales that brought the contractor under the Board's rules would not be subject to standards, 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 will 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 purpose of the regulation.

Retroactivity. Several commentators requested that the Board modify its proposal so as to provide retroactive exemption, inasmuch as 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 modify existing contractual agreements between the government procurement agencies and their contractors. However, the Board sees nothing inconsistent in its regulations or with Pub. L. 89-379 in modification by the procurement agencies of contracts in this category, assuming the contract would be placed in the position of the Government representatives.

Definition of contractor. One commentator noted that the preatory comments to the Board's September 27, 1974, publication specifically mentioned the fact that receipt of a contract in excess of $500,000 by one business unit of a multi-unit company would not in itself cause the company to follow Board requirements. This commentator requested that the definitions of "defense contractor" and "defense subcontractor" contained in §331.30 and (c) be modified to reflect this intention by the Board.

As the Board stated in its September 27 publication, its contract requirements and regulations have been applied to business units, such as a profit center, division, subsidiary, or common 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 a performing business unit is well established and unchallenged, and clarification of the definitions of "contractor" and "subcontractor" does not appear necessary.

Effect of final payment under contracts subject to CAS clause. Several commentators recommended that the exemption of contracts of $500,000 or less should not be dependent on the final payment on contracts which are subject to Board requirements, on the grounds that final payment can occur a substantial period of time after completion of work on a contract and that there are many technicalities in closing out a contract which does not involve cost accounting applications. The Board considers this point to be well taken and has changed the requirement in §331.30(b)(8) where it first applied.

The Board has interpreted the phrase "minimum contract amount requiring compliance" in a manner not at all intended by the Board. These commentators interpreted this phrase to permit the price of a contract subject to standards to be reduced by the value of those individual contract items or subassemblies of final contract items whose prices could be considered to be "excluded" from the minimum contract amount. They requested that the regulation be clarified to reflect their interpretation of the Board's introductory comments.

Those requesting this clarification misunderstood the Board's intentions. The Board does not intend that the price of a contract be adjusted to exclude the values of one or more items which, if purchased separately, might be exempt from the Board's promulgations. Consequently, the change in the regulation requested by commentators on this point would be completely inappropriate.
2. Amend the same § 331.30 by adding the following new paragraph (b)(3).

These amendments would have the following effect:

§ 331.50 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 contracts awarded after January 1, 1975, and on all other contracts or subcontracts which may be exempt under the cost accounting standards clause, shall cause or require 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.

(b) Any contract or subcontract of $500,000 or less, unless it is awarded to a contractor who, on the date of such award, (i) has already received a contract or subcontract in excess of $500,000 but has already submitted a disclosure statement as required by 4 CFR 331.30(b), 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)(6), an intra-corporate transfer shall be considered to be a subcontract. Notwithstanding this exception, any contractor entitled to an exemption shall 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 pursuant to paragraph (b) of this section, and shall require such offeror to submit a disclosure statement disclosing the practices used in connection with the pricing of this proposal, or unless post-award submission has been authorized by the contracting officer in accordance with regulations of the Cost Accounting Standards Board (see 4 CFR 331.60). If an applicable disclosure statement has already been submitted, the offeror may satisfy the requirement for submission by providing the following information:

1. Certification (Applicable Only to Proposals Resulting in Contracts Subject to Cost Accounting Standards Board Requirements).

   By submission of this offer, the offeror certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable disclosure statement.

4. Amend § 331.50, Contract clause, by adding after “law or regulation” in subsection (d)(2), the following: “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 in the substance of this clause except paragraph (b) of this section, and shall require each inclusion in all other subcontracts of any tier, except that this requirement shall apply 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 paragraph (d) of § 331.30(b) of Title 4, Code of Federal Regulations (4 CFR 331.30)(b).”

5. Amend section 331.40, 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),” and by inserting in the second sentence of paragraph (a) after the figures “$100,000,” the following, “except as provided in 4 CFR 331.30(b).” This amendment would have the following effect:

§ 331.40 Filing requirement.

(a) The requirements of this part are applicable to all defense 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 whose costs were included in the total price of any contract except contracts which were subject to the requirements of the Cost Accounting Standards Board set forth in § 331.50, captioned Cost Accounting Practices and Certification. The following instructions and information shall 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.

6. Amend § 331.130, Instructions and Information, by adding to paragraph (a) of the instructions set forth in this section at the end of the third sentence thereof, the following, “or contracts exempt under the provisions of 4 CFR 331.30(b),” and by adding to the fourth sentence of paragraph (a) of the instructions set forth in this section the words “or contracts exempt under the provisions of 4 CFR 331.30(b),” at the end thereof.

This amendment would have the following effect:

§ 331.130 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. For timing of requirement to file a disclosure statement, see § 331.40. A statement is 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 contracts exempt under the provisions of 4 CFR 331.30(b). A separate disclosure statement must be submitted covering the practices of each of the contractor’s 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 (i) established catalog or market prices of commercial items sold in substantial quantities to the general public, or (ii) 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.

NOTICE: Forms CASB-DS-1 and CASB-DS-2, referred to in 4 CFR §§ 351.140 and 351.150, respectively, when revised, will be modified in accordance with the modifications to 4 CFR 351.150.

ARTHUR SCHORNHAUT, Executive Secretary.

[FR Doc. 74-29825 Filed 12-23-74; 8:45 am]

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 25527) proposing the removal of naloxone and its salts from Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91-513). 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 treatment in the United States and do not have at this time a potential for abuse or abuse liability to justify continued 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 redelegated to the Administrator of the Drug Enforcement Administration by § 101.00 of Title 28 of the Code of Federal Regulations, the Administrator hereby orders that § 1038.12(b)(1) of Title 21 of the Code of Federal Regulations be amended to read as follows:

§ 1308.12 Schedule II.

(b) * * * * *

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

(i) Raw opium

(ii) Opiate extracts

(iii) Opium fluid extracts

(iv) Prepared opium

(v) Granulated opium

(vi) Tincture of opium

(vii) Apomorphine

(viii) Codeine

(ix) Ethylmorphine

(x) Stilbamidine hydrochloride

(xi) Hydromorphone

(xii) Metopon

(xiii) Morphine

(xiv) Oxycodone

(xv) oxygesterone

(xvi) Thebaine

This order is effective December 24, 1974.

Dated: December 18, 1974.

JOHN R. BARTLETT, Jr., Administrator, Drug Enforcement Administration.

[FR Doc. 74-29925 Filed 12-23-74; 8:45 am]

Title 49—Transportation

CHAPTER X—INTERSTATE COMMERCE COMMISSION

SUBCHAPTER A—GENERAL RULES AND REGULATIONS

[Amend 1 To Sixth Rev. S.O. 1124]

PART 1033—CAR SERVICE

Demurrage and Free Time at Ports

DECEMBER 19, 1974.

At a Session of the Interstate Commerce Commission, Railroad Service Division, 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. 370, 383, 384, as amended; (39 U.S.C. 1, 12, 15, and 17(2)). Interpreter or applicable Secs. 10(10-17), 16(4), and 17(2), 49 Stat. 101, as amended, 54 Stat. 911; (49 U.S.C. 10(10-17), 16(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 Division.

[Seal] ROBERT L. OSWALD, Secretary.

[FR Doc. 74-33999 Filed 12-23-74; 8:45 am]
The Federal Insurance Administrator finds that comment and public procedure and the use of delayed effective dates in identifying the areas of communities which have special flood or mudslide hazards, in accordance with 24 CFR Part 1915, would be contrary to the public interest. The purpose of such identification is to guide new development away from areas threatened by flooding. Since this publication is merely for the purpose of informing the public of the location of areas of special flood hazard and has no binding effect on the sale of flood insurance or the commencement of construction, notice and public procedure are impracticable, unnecessary, and contrary to the public interest. Inasmuch as this publication is not a substantive rule, the identification of special hazard areas shall be effective on the date shown. Accordingly, § 1915.3 is amended by adding in alphabetical sequence a new entry to the table, which entry reads as follows:

§ 1915.3 List of communities with special hazard areas.

<table>
<thead>
<tr>
<th>State</th>
<th>County</th>
<th>Location</th>
<th>Map No.</th>
<th>State map repository</th>
<th>Local map repository</th>
<th>Effective date of identification of areas which have special flood hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delaware</td>
<td>Ballston</td>
<td>Union Springs, city of.</td>
<td>H 00016 01</td>
<td>Delaware Insurance Department, Room 420, Administrative Building, Montco, Montco.</td>
<td>Mayor, City Hall, Town of Union Springs, Delaware.</td>
<td>Delaware.</td>
</tr>
<tr>
<td>Delaware</td>
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<td>Union Springs, city of.</td>
<td>H 00016 04</td>
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<td>Malvern, town of.</td>
<td>H 00016 01</td>
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<td>County Commissioner, Cresent, Delaware.</td>
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<td>H 00016 04</td>
<td>Delaware Insurance Department, Room 420, Administrative Building, Montco, Montco.</td>
<td>County Commissioner, Cresent, Delaware.</td>
<td>Delaware.</td>
</tr>
<tr>
<td>California</td>
<td>Orange</td>
<td>Anaheim, town of.</td>
<td>H 00017 01</td>
<td>Department of Water Resources, P.O. Box 369, Sacramento, Calif. 95812.</td>
<td>Mayor, P.O. Box 94, Anaheim, Ark.</td>
<td>California.</td>
</tr>
<tr>
<td>California</td>
<td>Orange</td>
<td>Anaheim, town of.</td>
<td>H 00017 04</td>
<td>Department of Water Resources, P.O. Box 369, Sacramento, Calif. 95812.</td>
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<td>Dec. 6, 1974</td>
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Do. | Lamoille | Beslicora, town of. | H 500227 01 | through | Mayor, Town of Beslicora, Beslicora, Vt. | Do. 1969
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Do. | do | Rockford, town of. | H 500298 01 | through | Mayor, City Hall, Rockford, Wsh. 99201. | Do. 1969
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Do. | Green | | H 500307 01 | through | Wisconsin Insurance Department, 212 North Boscott St., Madison, Wis. 53703. | County Disposal and Zoo Control Commission, Green County Courthouse, County of Green, Green, Wsh. | Do. 1969
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Issued: December 11, 1974.


[FED. Doc.74-23727 Filed 12-23-74; 8:45 am]
§ 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 Assistants to the Secretary of Defense. * * *
§ 213.3307 Department of the Army.
(b) Office of the Army. * * *
§ 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) Two Members of the Board. * * *
(c) 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) One Special Assistant 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. * * *
§ 213.3314 Department of Commerce.
(a) Office of the Secretary. * * *
(16) One Confidential Assistant to the Director, Office of Foreign Direct Investments. * * *
(18) [Revoked] * * *
(b) Agricultural Stabilization and Conservation Service. * * *
(4) Three Confidential Assistants to the Administrator. * * *
§ 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] * * *
(9) [Revoked] * * *
(13) [Revoked] * * *
(k) Office of the Assistant Secretary for Planning and Evaluation. * * *
(13) [Revoked] * * *
(1) Social Security Administration. * * *
(2) [Revoked] * * *
(4) [Revoked] * * *
(a) Office of the Assistant Secretary for Human Development. * * *
(13) [Revoked] * * *
(10) [Revoked] * * *
(d) Social and Rehabilitation Service. * * *
(a) Office of the Special Assistant to the Secretary for Civil Rights. * * *
(1) One Special Assistant to the Special Assistant. * * *
§ 213.3317 General Services Administration.
(a) Office of the Administrator. * * *
(4) Three Confidential Assistants to the Assistant Administrator. * * *
(6) Four Confidential Assistants to the Administrator.

(8) Two Special Assistants to the Assistant Administrator.

(16) One Confidential Assistant to the Associate Administrator for Federal Management Policy.

(17) One Secretary (Assistant to one Commissioner and on behalf of the Secretary for Public Affairs).

(2) Public Buildings Service.

(2) Four Confidential Assistants to the Commissioner.

(a) Federal Supply Service.

(2) Two Confidential Assistants to the Commissioner.

(d) National Archives and Records Service.

(h) Automated Data and Telecommunications Service.

§ 213.3339 U.S. Tariff Commission.

(e) [Revoked]

§ 213.3342 Export-Import Bank of the United States.

(f) [Revoked]

(h) [Revoked]

§ 213.3348 National Aeronautics and Space Administration.

(c) One Secretary to each of the following: The Associate Administrator for Manned Space Flight, the Associate Administrator for Advanced Research and Technology.

§ 213.3350 Action.

(1) [Revoked]

§ 213.3359 National Aeronautics and Space Administration.

(a) One Secretary to each of the following: The Associate Administrator for Manned Space Flight, the Associate Administrator for Advanced Research and Technology.


(a) Office of the Secretary.

(b) Office of the Secretary.

§ 213.3364 Department of Housing and Urban Development.

(a) Office of the Secretary.

(6) [Revoked]

§ 213.3384 Department of Housing and Urban Development.

(a) Office of the Secretary.

(6) [Revoked]

§ 213.3384 Department of Housing and Urban Development.

(a) Office of the Secretary.

(6) [Revoked]

§ 213.3388 Federal Energy Administration.

(c) Office of Public Affairs.

(2) [Revoked]

(f) [Revoked]

§ 213.3394 Department of Transportation.

(a) Office of the Secretary.

(14) [Revoked]

(16) [Revoked]

(17) Six Congressional Liaison Officers, Office of the Director of Congressional Affairs.

(g) St. Lawrence Seaway Development Corporation.

(1) One Special Assistant to the Administrator.

(b) Federal Aviation Administration.

(6) [Revoked]

§ 213.3394 Department of Transportation.

(1) Office of the Assistant Secretary for Housing Production and Mortgage Credit—Federal Housing Administration Commissioner.

(6) [Revoked]

§ 213.3394 Department of Transportation.

(1) Urban Mass Transportation Administration.

(1) One Assistant Administrator for Public Affairs.


United States Civil Service Commission,

[SEAL] James C. Spyr, Executive Assistant to the Commissioners.

[FR Doc.74-29965 Filed 12-23-74; 7:45 am]

PART 213—EXCEPTED SERVICE

Department of Transportation; Correction

In the Federal Register of August 10, 1973 (38 FR Doc. 53–16321), 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.

PART 775—FEED GRAINS

Subpart—Feed Grain Program for Crop Years 1974–1977

1975 NATIONAL FEED GRAIN ALLOTMENTS

On July 17, 1974, a notice of proposed rule making was published in the Federal Register (39 FR 25863) stating that the Secretary of Agriculture proposed to make determinations and issue regulations relative to the 1975 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 25863) 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 106(b)(2) of the Agricultural Act of 1949, as amended by the Agriculture and Consumer Protection Act of 1973, Pub. L. 93–56, 87 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 grain

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which shall be the number of acres he determines, on 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 usage 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 as follows:

§ 775.4a 1975 national feed grain allotment.

Based on estimated utilization (less imports) for the 1975–1976 marketing year of 5,924 million bushels of corn, 875 million bushels of sorghum, and 445 million bushels of barley and estimated national yields of 93.0 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 of 89.0 million acres is necessarily proclaimed.

(Sec. 105, 88 Stat. 1054, as amended; 87 Stat. 221; (7 U.S.C. 1441) note)

Effective date: December 24, 1974.


Earl L. Butz,
Secretary.

[FR Doc. 74-29009 Filed 12-23-74; 8:48 am]

CHAPTER XVII—FARMERS HOME ADMINISTRATION, DEPARTMENT OF AGRICULTURE

SUBCHAPTER B—LOANS AND GRANTS PRIMARILY FOR REAL ESTATE PURPOSES

PART 1822—RURAL HOUSING LOANS AND GRANTS

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

Revised: Eligibility Requirements

On page 37618 of the Federal Register of October 23, 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.


P. 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 farmowner or an organization, as those terms are defined...
Title 9—Animals and Animal Products

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

SUBCHAPTER C—INTERSTATE TRANSPORTATION (INCLUDING FOUL TRIF) 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(1) 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.

Accordingly, Part 76 is amended as follows:

1. §76.1(1) is amended to read:

§76.1 Definitions.

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

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

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 33 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; sec. 1, 75 Stat. 481; secs. 3 and 11, 76 Stat. 130, 133; 21 U.S.C. 111-115, 119g, 115, 117, 120, 121, 123-126, 134b, 134i; 37 FR 28464, 28477; 39 FR 5972)

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 proceedings 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 the date of publication in the Federal Register.

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

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

[FED REG 30 76703 Filed 12-23-74; 8:45 am]

PART 76—HOG CHOLERA AND OTHER COMMUNICABLE SWINE DISEASES

Hog Cholera Eradication and Feasibility

This amendment deletes the Commonwealth of Puerto Rico from the list of Hog Cholera Eradication States in 9 CFR 76.2(d), as amended, and adds said State to the list of Hog Cholera Free States in § 76.2(p) upon the basis of a determination that such State fulfills hog cholera free status under § 76.2(p).

The special provisions of 9 CFR Part 56, as 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:

In § 76.2, the reference to the Commonwealth of Puerto Rico in paragraph (i) is deleted, and paragraph (g) is amended by adding thereto the name of said State.

(Secs. 4-7, 23 Stat. 32, as amended; secs. 1 and 2, 33 Stat. 791-792, as amended; secs. 1-4, 33 Stat. 1264, 1265, as amended; sec. 1, 75 Stat. 481; secs. 3 and 11, 76 Stat. 130, 133; 21 U.S.C. 111-115, 119g, 115, 117, 120, 121, 123-126, 134b, 134i; 37 FR 28464, 28477; 39 FR 5972)

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

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 proceedings 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 the date of publication in the Federal Register.

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

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

[FED REG 30 76703 Filed 12-23-74; 8:45 am]
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 amendment are impracticable, unnecessary, and contrary to the public interest, and good cause is found for making the amendment in less than 30 days after publication in the Federal Register.

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

J. M. HEIT,
Deputy Administrator, Veterinary Services, Animal and Plant and
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 PRICING RULES

PART 211—MANDATORY PETROLEUM ALLOCATION REGULATIONS

Limitation of Refinery Fuel Use of Propane and Butane, Clarification of Subparts of Propylene 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 fall, and it is anticipated that a prohibition of the use of propane and butane will be 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 “natural gas liquids.” A definition of “natural gas liquids” has also been added. The definitions of “butane,” “propane” and “propane-butane mix” have been revised. An allocation level of one hundred percent of base period use subject to the allocation 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 whole- sample purchaser. For those suppliers, therefore, allocate these products to themselves in their capacities as wholesale purchasers-consumers or end-users. Other suppliers of these products to refiners for refinery fuel use will also allocate to refiners in accordance with the revised regulations.

FEA has also revised and combined §§ 211.10(6) (8) and 211.10(9) making it clear that circumstances of situations where butane-consumers of refinery gas and “propane-butane mix” have been included. There is a regulation in the public 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 may 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 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 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 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 directed to: Executive Communications, FEA, and must be received before 4:30 p.m., e.s.t., December 31, 1974.
through Friday. The person making the request should be prepared to describe the interest concerned; if appropriate, to state why he or she is a proper representative of a group or class of persons which has an such an interest; and to give a concise summary of the proposed oral presentation and a phone number where he or she may be contacted through January 8, 1975. Persons selected to be heard will be so notified by the FEA before 5:30 p.m., e.t., January 6, 1975 and must submit 100 copies of his or her statement to Executive Communications, FEA, Room 3515, Federal Building, Washington, D.C., 20461, before 9 a.m., e.t., January 8, 1975.

The FEA reserves the right to select the persons to be heard at the hearing, to schedule their respective presentations, and to establish the procedures governing the conduct of the hearing. Each presentation may be limited, based on the number of persons requesting to be heard.

An FEA official will be designated to preside at the hearing. It will not be a judicial or evidentiary-type hearing. Questions may be asked only by the persons conducting the hearing, and there will be no cross-examination of persons presenting statements. Any decision made by the FEA in response to the subject matter of the hearing 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 of he or she 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 hearing, to Executive Communications, FEA, before 4:30 p.m., e.t., January 6, 1975. Any person who makes an oral statement and who wishes to ask a question at the hearing may submit the question, in writing, to the presiding officer. The FEA or the presiding officer, if the question is submitted at the hearing, will determine whether the question is relevant, and whether time limitations permit it to be presented for oral argument.

Any further procedural rules needed for the proper conduct of the hearing will be announced by the presiding officer.

A transcript of the hearing will be made and the entire record of the hearing, including the transcript, will be retained by the FEA and made available for inspection at the Administrator's Reception Center, FEA, Room 3500, 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. Anyone may buy a copy of the transcript from the reporter.

Interested persons are invited to submit data, views, or arguments with respect to the emergency amendment to Executive Communications, Federal Energy Administration, Box E, Washington, D.C. 20461.

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 must be so identified and 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.


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.

1. Section 210.34 is amended to delete the definition of "refinery gas" from paragraph (b) and to revise paragraph (a) to read as follows:

§ 210.34 Petroleum refinery products.

(a) Petroleum refinery products such as petroleum wax, petroleum coke, asphalt and natural oils which are not crude oil, refined petroleum products, or residual fuel oils are exempt from the provisions of Parts 211 and 312 of this chapter.

2. Section 211.1 is amended to redefine paragraph (b) (2) to read as follows:

§ 211.1 Scope.

(2) 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 exempt from this definition.

3. Section 211.10 is amended in paragraph (g) by deleting paragraph (g) (9) and revising paragraph (g) (8) to read as follows:

§ 211.10 Supplier's method of allocation.

(g) Allocations fractions greater than one. * * *

(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-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 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 § 211.9(o) or § 211.90(o) and provided further, That (2) the 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.

4. Section 211.51 is amended by revising the definition of "energy production" and by adding definitions of "natural gas liquids," "natural gasoline," "propane," "propane-butane mix" and "refinery fuel use" in the appropriate alphabetical order to read as follows:

§ 211.51 Definitions.

"Butane" means the chemical C4H10, in its commercial forms, including both normal butane and iso-butane, their mixtures and mixtures of butane and propane containing ten (10) percent by weight or less of propane. Included within the definition of butane is the butane content of natural gas liquids and refinery gas when used for refinery fuel use.

"Energy production" means the exploration, drilling, mining, refining, processing, production and distribution of coal, natural gas, geothermal energy, petroleum or petroleum products, chile oil, nuclear fuels and reactor fuels. It also includes the construction of facilities and equipment used in energy production, such as pipelines, mining equipment and similar capital goods. Excluded from this definition are synthetic natural gas manufacturing, electrical generation whose power source is petroleum based, gasoline blending and manufacturing and refinery fuel use.

"Natural gas liquids" means a mixed hydrocarbon stream containing, in whole or in substantial part, mixtures of ethane, butane (iso-butane and normal butane), propane or natural gasoline.

"Natural gasoline" means the liquid hydrocarbon mixtures containing substantial quantities of pentanes and heavier hydrocarbons, which have been extracted from natural gas.

"Propane" means the chemical C3H8 in its commercial forms including propane-butane mixxes in which propane...
constitutes greater than ten (10) percent of the total 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 "propane" and "propane-butane mix."

7. Section 211.83 is amended in paragraph (c) by deleting the word "and" in subparagraph (2) (iv); by replacing the period (.) after subparagraph (2) (v) with a semicolon (;); and by adding the word "and" thereafter; 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.

(6) Refinery fuel use.

§ 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.
a level not justified on the basis of costs for most existing production. As the foregoing summary indicates, there is no simple ideal solution to the regulation of natural gas liquid prices, and the regulations adopted by the FEA 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 stated to 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 costs and selling 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 and 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 to reflect increased non-product costs incurred in processing natural gas liquids; (3) provision for the addition of an increment to May 15, 1973 selling prices to account for actual or anticipated shrinkage attributable to the production of natural gas liquids since that date; (4) provision for the increased costs attributable to propane to be applied selectively among classes of purchaser by refiners, gas processors, and resellers in determining propane prices for sales to different classes of purchaser; (5) a requirement that refiners who process natural gas liquids exclude revenues which represent recovery of increased costs of crude oil from the revenues received in the sale of natural gas liquid products, for the purpose of determining net-back payments to royalty owners or producers; and (6) a price rule for natural gas liquids extracted in gas processing facilities constructed after the effective date of these regulations which provides an incentive for the construction of such facilities by permitting somewhat higher prices to be charged for products produced in the FEA than otherwise. The FEA is also soliciting comments on 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 for natural gas liquids, with respect to which a refinery, to ensure that undue volumes of propane are not consumed for this purpose.

II. Definitions and applicability. As indicated in the September 10 Notice, the application of price rules to natural gas liquids is complicated by the fact that a price for natural gas liquids is typically not determined until the natural gas liquid product is produced at the refinery—whereby producers, ownership, holders, and gas processors sell their product to the price-ultimate price of the product. The price-ultimate price is determined by: (1) the relative cost of the natural gas and associated crude oil; (2) the cost of making the product in the refinery; (3) the price of the natural gas liquid product, upon which the amount of net-back revenues are based, are increased above their May 15, 1973 levels pursuant to the regulations adopted today, or unless the contractual terms are revised to afford a larger percentage net-back. The FEA has determined that it would be administratively impracticable to regulate historical margins directly since net-back revenues are allocated between parties, except to provide specifically that the net-back revenues are allocated shall not constitute a basis upon which a first sale price may be increased.

The new Subpart E of Part 212 adopted today applies to all sales other than sales of natural gas liquids and natural gas liquid products by all entities, including refiners, refiners, holders, gas plant operators, and refiners. The definition of 'refiner' set forth in § 212.31, 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 (Financial) and Subpart K (Natural Gas Liquids) provide that where a refiner that refines crude oil and processes natural gas is involved, the provisions of Subpart E will be applied to the refiner's gas processing activities in order to calculate the increased product and nonproduct costs attributable to natural gas liquid products, which will then be used, together with increased prices determined under Subpart E for products refined derived from crude oil, to determine the lawful selling price for refiner's total volumes of propane, butane, and natural gasoline, and for any covered products which are produced from propane, butane or natural gasoline.

III. Adjusted May 15, 1973 prices. May 15, 1973 is the date to which reference is made under FEA regulations in determining lawful prices for the sale of all covered products. This is done, in general, by use of those product costs incurred on May 15, 1973, or during the month of May, 1973, as the costs against which current product costs are measured, for purposes of determining the amount of increased product costs. The amount of increased product costs may then be applied to May 15, 1973 selling prices to determine current lawful selling prices. This method of price determination serves, in general, to preserve the 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.

Originally, this May 15, 1973 date was chosen by the Cost of Living Council ('Council') for use in that part of its Phase IV petroleum regulations which was applicable to refiners. The Phase IV regulations were implemented by the Council in August, 1973. Upon review of the period which preceded the initiation of the Phase IV controls, the Council determined that the month of May, 1973 represented the most recent relatively stable time period during which market forces appeared to have been operating relatively free of the effects of price controls, particularly with respect to crude oil prices. Accordingly, May was chosen as the most appropriate reference point to determine historical margins under a system of price controls designed to "freeze" prices at a time that approximated free market conditions, and to allow a dollar-for-dollar pass through of increased product costs, incurred since that time. Although another date, January 10, 1973, was initially selected as a basis for the historical margins under the price regulations applicable to refiners and retailers, May 15, 1973 was ultimately selected as the best single date on which to base the price controls applicable to all sectors of the petroleum industry.

In the case of natural gas liquids, however, the FEA has concluded that May 15, 1973 selling prices of individual firms do not in some cases reflect a stable price situation based on relatively free market conditions, nor do they necessarily reflect historical margins. Propane prices, for example, ranged between 4 and 22 cents per gallon on May 15, 1974. This 18 cent spread in prices represented
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 for propane in August, 1971, for example, was 6.5 cents per gallon, and reflected a more normal market situation. In many cases the low May 15, 1973 prices of certain sellers were in large part the result of economic controls that had been under 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 allowable prices, on the basis of atypically low prices that were in effect on May 15, 1973, for some sellers, but not for others.

The FEA has determined that the arithmetic average of the prices for which some fifty firms were selling propane on May 15, 1973 represents a price level that is more representative for purposes of determining allowable prices, than are the prices of each and every firm. Therefore, those firms that were selling at lower prices than the arithmetic average price, which is more representative of the market prices upon which the regulations are intended to be based, will be permitted to use an adjusted "free market" May 15, 1973, price, for purposes of FEA price regulations.

The FEA has concluded that a conservative but appropriate adjusted-May 15, 1973 price for propane, which may be used by any firm in lieu of its actual May 15, 1973 selling price for propane, is 8.5 cents per gallon. This figure is based on the arithmetic average of the prices of some fifty firms for propane on May 15, 1973, which was 9.03 cents per gallon. Also, the Cost of Living Council collected comprehensive data on the selling prices of propane in August, 1973. Since all prices were frozen on June 13, 1973, sales reductions since then were due to increased prices of crude oil and natural gas, which can increase the cost of natural gas producers, who were the only ones affected by the freeze.

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the prices of natural gas begin to move closer to the prices of crude oil, on a BTU basis. Prior to the availability of new sources in foreign countries, the prices of crude oil derived products and natural gas liquid products will be determined by the market, 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 to obtain a given volume of natural gas liquids may be attributed 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 an entirely different concept of a "first sale" price rule which leaves the parties to "net-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 these costs are attributable is relatively stable, such costs may be added to prices on a current basis. This will contribute to administrative simplicity. Gas processors will simply be required, for each month, to establish that the increased shrinkage costs for that month justify the prices charged for 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 have different increased shrinkage costs, the increased costs attributable to each particular volume of natural gas may be allocated directly to the prices charged for the 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 propane.

VI. Unequal application among classes of purchaser of increased costs to determine prices for propane. FEA price regulations provide that the amount of increased product costs is 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 a relaxation of 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 application requirement, except to the extent that 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 implications of covering all products generally, 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 smallest increment of increased product cost be applied to prices charged to any class of purchaser that includes an independent marketer and that same restriction will be extended to include prices charged in sales to any class of purchaser that includes residential users.

Although no limitation was proposed on the extent of the 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 initially. Accordingly, under the new regulation, the greatest amount of increased product cost added to the May 15, 1973 selling price of propane to a particular class of purchaser may not exceed the smallest 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 8 cents per gallon to a class of purchaser that included an independent marketer, and of 11 cents per gallon to another class of purchaser, and that seller added increased costs of 5 cents per gallon to its current selling price of 14 cents per gallon to the class of purchaser that included an independent marketer, and of 17 cents per gallon to the other class of purchaser, the increased cost requirement for propane 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 prices which are based solely on wholesale prices, and which would therefore typically be less than prices for BTU equivalent crude petroleum derived fuels. This provision should also tend to make additional 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 problems created by the application of its regulations 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 selling price of the liquid products, they seek to commit their natural gas to the processor that has the highest lawful selling price for these products, in order to maximize their return. And since those refiners that also refine crude oil are permitted to determine selling prices for products under a method that reflects the increased cost of crude oil, while independent natural gas processors do not have increased crude oil costs, the lawful selling prices of such refiners are generally higher than those of natural gas processors.

The FEA is therefore considering its regulations in order specifically to provide that the revenues received in sales of natural gas liquid products shall be reduced by the amount of increased crude oil costs that were recovered in such sales, for purposes of determining net-back revenues.

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 replaces "market prices" with maximum lawful prices, which depend upon the differing costs attributable to various sellers.

VIII. Prices for natural gas liquid products from gas plants that have been placed in operation after the effective date of this regulation. Prices for natural gas liquid products produced in gas plants that were placed in operation after the effective date of this regulation. Prices for natural gas liquid products produced in gas plants that were placed in operation after the effective date of this regulation.

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 replaces "market prices" with maximum lawful prices, which depend upon the differing costs attributable to various sellers.

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(44111) 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 thereby to maximize supply. Comments are requested with respect to this provision of the rule. The additional incentive is not regarded as sufficient, data to support the need for 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 either the criteria by which increased extraction can be appropriately measured, or what the needed incentives to achieve further liquid extraction would be. It may be possible, for example, to provide by regulation that where the percentage of propane extracted from the natural gas stream by a particular gas plant is below 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.

§ 212.83(q) 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 liquid products will be priced at levels which represent generally a lower price per BTU than fuels derived from crude petroleum.

The argument that natural gas liquid prices must be priced on a BTU equivalence basis with crude oil derived products, in order to avoid additional price-stimulated demand on a diminishing quantity of natural gas liquid products, is a foregone conclusion. The FEA has concluded, however, that in the present circumstances the allocation regulations offer the most appropriate method of dealing with this problem.

One aspect of this problem that was repeatedly raised in this proceeding was the assertion that refiners would turn to propane for use as a refinery fuel, unless propane were permitted to be priced at the same level per BTU as fuels derived from crude petroleum.

The authority of the FEA to allocate petroleum products is fully adequate to limit this, however. Refiners, like other industrial users of fuel, are subject to limitations in their use of propane as a source of fuel. An appropriate regulatory change is being issued, on an emergency basis, to prevent the possibly excessive use of propane as refinery fuel.

The regulations issued today are predicated in large part on the proposition that natural gas and natural gas liquid products are being processed and distributed in a manner that reflects historical supplier-purchaser relationships.

Should it appear that new relationships are being created with the intent to avoid the impact of the price regulations, revision to the allocation regulations, or other appropriate steps by FEA, will be taken.

Written comment procedures

Interested persons are invited to submit data, views or arguments with respect to the specific matters concerning the incentives for new and expanded gas processing facilities upon which comments have been solicited to Executive Communications, Federal Energy Administration, Box BO, Washington, D.C. 20461.

In consideration of the foregoing, Part 212 of Chapter II, Title 10 of the Code of Federal Regulations, is amended as set forth below, effective January 1, 1975.


Robert E. Montgomery, Jr.,
General Counsel,
Federal Energy Administration.

1. Section 212.31 is amended in the definition of "producer" to read as follows:

§ 212.31 Definitions.

"Producer" means a firm or that part of a firm which produces crude petroleum or natural gas, or any firm which owns crude petroleum or natural gas when it is produced.

2. Section 212.81 is revised to read as follows:

§ 212.81 Applicability.

This subpart applies to each sale of a covered product which is purchased or refined by a refiner, except as provided in Subparts F and X.

5. Section 212.83 is amended in paragraphs (c) (1) (iii) and (d) and § 212.83(c), a refiner in computing base prices for propane for the twelve month period of August 1, 1974 through July 31, 1975:

(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 products) sold by that refiner from crude petroleum, for the 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; and

(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 of propane purchased or landed in the twelve month period of July 1, 1974, through June 30, 1975.

(d) May not apportion to propane any increased product costs attributable to propane produced from natural gas as determined pursuant to the provisions of § 212.146 of Subpart K of this part; and

(e) May not apportion to propane any increased product costs incurred prior to July 1, 1974, and not recovered through July 31, 1974.

Notwithstanding the provisions of paragraphs (c) (1) and (2) 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 apportioned to the weighted average May 15, 1973 selling price to any class of purchaser shall not exceed by more than 10 percent the amount of increased cost applied to the weighted average May 15, 1973 selling price to any other class of purchaser, and, provided further, that no greater amount of increased 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.

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

§ 212.93 Price rule.

(f) Exception to equal application rules for propane. Notwithstanding the provisions of paragraph (e) above, a seller may comply with 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

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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. Further, that no greater amount of increased 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.

§212.151 Allocation of increased product costs.

§212.152 Inclusion of increased product costs.

§212.153 Calculation of increased non-product costs.

§212.154 Net-back sale.

For purposes of this subpart—

"Cost of natural gas shrinkage" means the reduction in selling price per thousand cubic feet (MCF) of natural gas processed, which is attributable to the reduction in volume or BTU value of the natural gas resulting from the extraction of natural gas liquids, as determined pursuant to the method set forth in §212.152. The calculation of cost of natural gas shrinkage shall not include any cost attributable to the removal of natural gas liquids or natural gas liquid products which were lawfully priced in first sale transactions with a class of purchaser prior to May 15, 1973, prices of which are not more than $1.05 per thousand cubic feet (MCF) of natural gas processed.

"Natural gas liquid products" means the separate products derived from natural gas liquids, including butane (isobutane and normal butane), propane, ethane, natural gasoline and natural gas liquids, not including ethane.

"Net-back sale" means any sale for which the net-back amount is limited pursuant to §212.147(c) and §212.153(c) (1) (ii).

"Sales of ethane." This subpart does not apply to sales of ethane.

§212.155 Definitions.

"First sale price" means the highest price at which natural gas liquid products were lawfully priced in the first sale of natural gas liquid products in excess of the per gallon revenues received in such net-back sale on May 15, 1973, except to the extent permitted by this subpart.

§212.156 Net-back sale.

§212.157 Adjusted May 15, 1973 first sale price.

§212.158 Natural gas liquid products.

§212.159 Calculation of increased product costs.

§212.160 Calculation of increased non-product costs.

§212.161 Calculation of increased product costs for natural gas liquid products from gas plants that began operation after May 15, 1973.

§212.162 Allocation of increased product costs.

§212.163 Inclusion of increased product costs.

§212.164 Calculation of increased non-product costs.

§212.165 Net-back sale.

For purposes of this subpart—

"Cost of natural gas shrinkage" means the reduction in selling price per thousand cubic feet (MCF) of natural gas processed, which is attributable to the reduction in volume or BTU value of the natural gas resulting from the extraction of natural gas liquids, as determined pursuant to the method set forth in §212.152. The calculation of cost of natural gas shrinkage shall not include any cost attributable to the removal of natural gas liquids or natural gas liquid products which were lawfully priced in first sale transactions with a class of purchaser prior to May 15, 1973, prices of which are not more than $1.05 per thousand cubic feet (MCF) of natural gas processed.

"Natural gas liquid products" means the separate products derived from natural gas liquids, including butane (isobutane and normal butane), propane, ethane, natural gasoline and natural gas liquids, not including ethane.

"Net-back sale" means any sale for which the net-back amount is limited pursuant to §212.147(c) and §212.153(c) (1) (ii).

"Sales of ethane." This subpart does not apply to sales of ethane.
of the actual May 15, 1973 selling prices for natural gas liquid products which were used to determine first sale prices of natural gas liquids on May 15, 1973, first sale prices of not more than $0.05 per gallon for propane, not more than $0.09 per gallon for butane and not more than $1.10 per gallon for natural gasoline.

§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 each product sold in 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

\[
\left( \frac{V - V_n}{V_n} \right)
\]

where:

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

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

(b) Aggregation of increased product costs. Where increased product costs attributable to increased production costs measured with respect to particular volumes of natural gas or natural gas liquids processed in a gas plant in a month are required, (1) the increased product costs attributable to any particular volume of natural gas may be allocated to the particular sales volumes of natural gas liquid products which are produced therefrom; or, in the alternative, (2) the total amount of increased product costs measured with respect to the total volume of natural gas and natural gas liquids processed in a gas plant in a month may be allocated to the total sales volumes of natural gas liquid products produced 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 propane derived from a particular volume of natural gas or natural gas liquids derived from the sales of natural gas liquid products from gas plants that began operation after May 15, 1973.

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

For purposes of determining increased product costs for natural gas liquid products from gas plants that began operation after May 15, 1973.

§212.149 Net-back calculations.

For purposes of calculating net-back revenues, revenues from sales of natural gas liquid products shall be reduced by any amounts that represent recoupment of increased non-product costs, if any, 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 be charged unless records adequate to demonstrate such increased product costs are otherwise maintained.
and increased non-product costs are maintained. The FEA will treat gas plant operations as separate entities subject to these regulations of the responsibility for compliance with these regulations. Where one or more gas plants are under common ownership, the records required by this section may be kept in the aggregate for all of the gas plants concerned.

Title 10—Energy

INAPPLICABILITY OF THE “STRIPPER WELL LEASE” EXEMPTION TO GAS WELLS

Facts. Firm P produces crude petroleum and petroleum condensates, including natural gas liquids, from Property A, and less than ten barrels per well per day of crude petroleum and petroleum condensates, including natural gas liquids, from Property B, State X, where both properties are located, had classified the production of Property A as production of an oil well from an oil reservoir, and the production of Property B as production of a gas well from a gas reservoir. Firm P, during the preceding calendar year, produced less than ten barrels per well per day of crude petroleum and petroleum condensates, including natural gas liquids, were extracted from the natural gas liquids, per well, which produce crude petroleum and petroleum condensates, including natural gas liquids, since these wells do not produce gas wells which produce condensates, including natural gas liquids, since neither the purpose nor the language of the “stripper well lease” exemption can be regarded as extending to such production.

Robert E. Montgomery, Jr., General Counsel, Federal Energy Administration.

December 19, 1974.

PRODUCTION WELLS FOR PURPOSES OF THE “STRIPPER WELL LEASE” EXEMPTION

Facts. Firm P, a producer of petroleum, produced during the preceding calendar year, 10.37 barrels per day of petroleum and petroleum condensates, including natural gas liquids, from 40 production wells located on Property A, as defined in 10 CFR 210.32. In addition, there were five injection wells in operation on that property last year. An injection well is one which is used to inject water, air, gas, steam or other materials into the ground to aid in the recovery of crude petroleum through producing wells. Wells which formerly produced crude petroleum may be used for injection purposes, or new wells may be drilled solely for the purpose of injecting materials into oil-bearing formations and reservoirs.

The average daily production per well from Property A was 10.37 barrels, based on the 40 production wells, whereas the average daily production per well would be 9.13 barrels if 45 wells, including the five injection wells, were used to calculate the average daily production figure.

Issue. Is Firm P’s property, whose average daily production of petroleum and petroleum condensates, including natural gas liquids, per well did not exceed 10 barrels per day during the preceding calendar year, exempt from the mandatory price and allocation regulations? "Stripped" as a term used for exempt status pursuant to § 210.32 is further 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 specify that the definition of a "stripper well lease" under § 210.32, Firm P may apply the "stripper well lease" exemption to the production of natural gas liquids obtained from Property B, since that property does not qualify as a "stripper well lease" under § 210.32.

The purpose of the Congress, in extending exempt status for the first sale of "stripper well" production in the Emergency Petroleum Allocation Act of 1973 (Pub. L. 93-159), (EPAA) was to assure economic viability and continued production of crude oil from exempt oil wells. The legislative history of this exemption reveals that Congress understood the "stripper well" concept in the same way that the oil industry applies the phrase, "stripper well" as meaning 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 EPAA regulations intended to extend the "stripper well" language to encompass the production of "crude petroleum and petroleum condensates, including natural gas liquids, from Property B, as defined in 10 CFR 210.32. In addition, there were five injection wells in operation on that property last year. An injection well is one which is used to inject water, air, gas, steam or other materials into the ground to aid in the recovery of crude petroleum through producing wells. Wells which formerly produced crude petroleum may be used for injection purposes, or new wells may be drilled solely for the purpose of injecting materials into oil-bearing formations and reservoirs.

The average daily production per well from Property A was 10.37 barrels, based on the 40 production wells, whereas the average daily production per well would be 9.13 barrels if 45 wells, including the five injection wells, were used to calculate the average daily production figure.

Issue. Is Firm P’s property, whose average daily production of petroleum and petroleum condensates, including natural gas liquids, per well did not exceed 10 barrels per day during the preceding calendar year, exempt from the mandatory price and allocation regulations? "Stripped" as a term used for exempt status pursuant to § 210.32 is further 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 specify that the definition of a "stripper well lease" under § 210.32, Firm P may apply the "stripper well lease" exemption to the production of natural gas liquids obtained from Property B, since that property does not qualify as a "stripper well lease" under § 210.32.

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Neither the Congress nor the EPAA regulations intended to extend the "stripper well" language to encompass the production of "crude petroleum and petroleum condensates, including natural gas liquids, from Property B, as defined in 10 CFR 210.32. In addition, there were five injection wells in operation on that property last year. An injection well is one which is used to inject water, air, gas, steam or other materials into the ground to aid in the recovery of crude petroleum through producing wells. Wells which formerly produced crude petroleum may be used for injection purposes, or new wells may be drilled solely for the purpose of injecting materials into oil-bearing formations and reservoirs.

The average daily production per well from Property A was 10.37 barrels, based on the 40 production wells, whereas the average daily production per well would be 9.13 barrels if 45 wells, including the five injection wells, were used to calculate the average daily production figure.
Thus, the FEA regulations by their specific language provide that only wells "which produce crude petroleum" are to be counted in calculating arm's-length sales of 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 for 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.

[FPS Doc.74-39930 Filed 12-20-74;3:22 pm]

[Rules 1974-77]

ALLOCATION OF REFINERY'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 products to domestic purchasers in arm's-length sales. Some of the covered products refined by Firm A, however, are consumed by it as refinery fuel, as other plant operating fuels, or as delivery vehicle fuel, some are transferred to Firm A's 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.

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 the total volume of the covered products which it (a) sells in arm's-length sales; (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(e). These transactions must therefore be treated in calculating the equal application of increased product cost provisions of §212.83(c), and would be inconsistent with the purposes of the Emergency Petroleum Allocation Act of 1972, since the dollar-for-dollar pass through of increased product costs provided for by the Act would not be realized on an equitable basis if Firm A were permitted to avoid the impact of the pass-through provisions.

The reasons for this means of accounting for export sales is self-evident, since 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 export sale and again in domestic sales. This requirement that recovery of increased product costs be accounted for as recoupment of increased product costs only to the extent that the selling prices in such sales are higher than the weighted average prices at which the same products were sold to the same classes of purchasers on May 1, 1974.

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

The volumes of products sold in export sales by Firm A, which are exempt from the price limitations of the FEA pursuant to §212.83, are nevertheless regarded as sales of covered products under Part 212 for purposes of determining cost recovery. Thus, although the FEA does not recoup 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 prices in such sales are higher than the weighted average prices at which the same products were sold to the same classes of purchaser on May 1, 1974.

The reason for this means of accounting for export sales is self-evident, since 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 export sale and again in domestic sales. This requirement that recovery of increased product costs be accounted for as recoupment of increased product costs only to the extent that the selling prices in such sales are higher than the weighted average prices at which the same products were sold to the same classes of purchasers on May 1, 1974.

It should also be noted that the "V" factor in the cost formula of §212.83 encompasses as sales volumes not only the volumes of petroleum products refined from crude petroleum other than covered products which are disposed of by the refiner in arm's-length transactions, but also the volumes of these products which are accounted for in transactions of the types described above. In general, the "V" factor appearing in §212.83(e) serves to establish a proportion of increased product costs which may be allocated to covered products.

The total volume of products, 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.

This ruling defines the manner in which increased product cost provisions of the price regulations are to have been accounted for under the price regulations since their inception, except with respect to refinery fuel. The FEA is aware that there was a basis upon which refiners could have concluded that the increased cost of refinery fuel derived from crude oil was permitted to be treated as an increased product cost prior to

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to December 1, 1974. An amendment to the cost allocation formulae of § 210.32, effective December 1, 1974, now explicitly requires that the cost of crude oil and of purchased covered products which are used as refinery fuel, this ruling is interpretive of the regulations as amended December 1, 1974. In all other respects, it is interpretive of the price regulations since they were first promulgated.

Robert E. Montgomery, Jr.,
General Counsel,
Federal Energy Administration.

December 19, 1974.

[FR Doc.74-30086 Filed 12-20-74; 3:25 p.m.]

RULINGS

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

Facts. Firm P, a producer, produces crude petroleum and petroleum condensates, including natural gas liquids, and casinghead gas from oil wells operated on a property, 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 in their gaseous phase, is separately transmitted to a processor at a nearby natural gas processing plant, where the natural gas liquids (propane, butanes, and natural gas) are extracted from the gas.

The processor, pursuant to prior contractual agreements with Firm P, determines an amount of liquids, which it has extracted and sold, that is attributable to the gas transmitted to it by Firm P, and notifies Firm P of the volumes of which it is entitled under the processing agreement.

Issue. What volumes of liquid hydrocarbons are included in the measurement of production by Firm P, for purposes of the "stripper well lease" exemption of 10 CFR § 210.32?

Ruling. For purposes of measuring the volumes of liquids produced by Firm P under § 210.32 of FEA regulations, Firm P should include only those volumes of unseparated liquids which were transmitted and sold as part of the "crude petroleum" liquid stream. It may exclude all those volumes of separated natural gas liquids, which were ultimately extracted from its casinghead gas, but were not sold as crude petroleum and petroleum condensates.

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 keeps the account of these production volumes for Firm P.

The purpose of the stripper well lease exemption was to provide needed incentive to the refineries to use supplies of crude petroleum by avoiding the shutdown of the traditional "stripper well" because of high costs of production in relation to the relatively small volumes of crude oil produced from each well. The increase in crude oil supplies, which the exemption is intended to promote, does not, however, have any necessary relationship to whether or to what extent any "wet" gas obtained by an oil producer is processed to obtain separated natural gas liquids. Firm P therefore should determine its production for purposes of the stripper well lease exemption based upon 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.

Although the stripper well concept is applicable only to the production of an oil well (See FEA Ruling 1974-28), the FEA nevertheless included the phrase "natural gas liquids" when it defined the production to be taken into account for purposes of the exemption provisions of § 210.32 as "crude petroleum and petroleum condensates, including 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 petroleum to storage, gathering and pipeline facilities. "Natural gas liquids" are among the petroleum condensates: which often are separated at a well from the associated gas produced by an oil well (often by a simple series of baffles), and in order to include all of the liquid products which are moved as crude petroleum, "natural gas liquids" are included as "petroleum condensates" whenever they are commingled with crude petroleum. Natural gas liquids are not included therefore, when they are transmitted separately from the crude petroleum, in gaseous state or liquid state, to a processing plant for separation into the component products.

The stripper well lease exemption was not intended by FEA to be applied to, or withheld from, particular properties simply because one producer produced a substantial amount of "wet" gas, which yields large volumes of natural gas liquids, and another may not. Nor would the intent of the exemption be served were its applicability to depend upon whether a particular producer's processing contract calls for the attribution of the resulting liquid volumes back to the lease. The effects of applying "stripper well" concepts to processed volumes of liquids would be as varied as the many different arrangements between producers and processors, and would further depend on the existence or efficiency of particular gas plants.

Accordingly, Firm P's production for purposes of § 210.32 includes all liquid hydrocarbons which are treated as crude petroleum. Typically, Firm P may maintain records of the volumes of these liquids which are sent to a pipeline by means of "run tickets", and may maintain similar evidence of sales volume. These will reflect the volumes of all liquids treated as "crude petroleum," including petroleum condensates and unseparated, mixed natural gas liquids in their gaseous phase, which are ultimately separated from the "wet" gas, and separately accounted for.

Robert E. Montgomery, Jr.,
General Counsel,
Federal Energy Administration.

December 19, 1974.

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Title 12—Banks and Banking

CHAPTER I—CONTROLLER OF THE CURRENCY, DEPARTMENT OF THE TREASURY

PART 7—INTERPRETIVE RULINGS

Customer-Bank Communication Terminals

National bankers, associations of bankers, or bank holding companies from 14 different states have approached the Comptroller's Office concerning the use by national banks of mechanisms which allow bank customers electronically to order bank services from bank computers, and for bank computers to instruct bank service personnel to perform bank 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 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 hereafter to help assure the orderly development of the nation's banking system.

I. 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. Now the attempt is here to catalog every possible type of terminal. In general, these terminals permit an existing bank customer to initiate transactions resulting in a each
withdrawal from his account, a crediting of funds to his account, a transfer between his checking and saving accounts, and payment transfers from his account into accounts maintained by other bank customers.

Both manned and unmanned CBCTs are now in widespread use. The CBCT typically involves: (a) A card issued to and carried by the customer which is inserted into the machine; and (b) a keyboard by which the customer or operator of the CBCT can interact with the machine to accomplish the transaction the customer wishes to accomplish. The customer's card sometimes contains information as to what transactions 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 connected 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 with the CBCT by tape or other means and the tape periodically is removed and taken to the bank for processing. All transactions conducted at a CBCT are subject to verification either by on-line checking 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 control of the bank or of a third party. When a third party is involved, however, its functions usually are related to ownership, maintenance, and servicing of the CBCT. It is not directly involved financially in the transaction between the customer and the bank.

Manned CBCT's now in use always involve a third party in addition to the bank and its customer. In a typical operation, the CBCT would be located in a supermarket and manned by an employee of the store. Transactions which involve receipt of funds or cash withdrawals are verified by the employee and are debited 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, which is a financial, 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 interpretative ruling issued herewith, such as a device or teller's window which is a part of a bank's main office or of an authorized branch. See, e.g., Dunn v. First National Bank of Cartersville, 345 F. Supp. 853 (N.D. Ga. 1972); Driscoll v. Northwestern National Bank, 434 F. 2d 178 (8th Cir. 1970), reversing 349 F. 2d 945 (10th Cir. 1965), cert. denied, 384 U.S. 941 (1966). 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 a credit or charge transaction or guaranteeing payment of a check.

II. Historical and statutory background. Branch banks were an uncommon phenomena when the National Currency Act of 1863 and its replacement and revision, the National Bank Act of 1864, were passed. These Acts thus contained no provision dealing with branch banks. Section 8 of the National Bank Act of 1864 required the "usual business" of a national bank to be transacted "at an office or banking house located in the place specified in its organization certificate." 13 Stat. 102. As early as 1871 the Supreme Court interpreted this statute to permit a national bank's cashier to certify checks "in the same manner as by the bank itself," 7 Con. St. 4838 (1876). This Court opinion. Indeed, one opponent of the bill objected to the speed with which "the comptroller's office had the case on appeal ready for Congress." 67 Cong. Rec. 2842 (1926) (Rep. Nelson). It seems clear that Congress intended to define these tellers windows as branches, and to authorize them within the applicable state law limits.

Rep. McFadden's bill became the McFadden Act of 1927, 44 Stat. 1228. The Act permitted a national bank, with the approval of the Comptroller, to establish and operate new branches within the limits of the city, town, or village in which the bank is situated, if such establishment and operation were permitted by state law to state banks. The Act further defined "branch" as follows:

The term "branch" as used in this section shall be held to include any branch bank, branch office, branch agency, additional office, branch store or branch banking house of a national bank in any State or Territory of the United States or in the District of Columbia at which deposits are received, or cheques 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. McFadden, this Act established competitive equality "among all member banks of the Federal Reserve System." 58 Cong. Rec. 5813 (1927).

The branch definition of the McFadden Act never has been amended and is found at 12 U.S.C. 364(D). 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 bank was situated. If such 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 established minimum capital requirements for branches of national banks. The Banking Act of 1933 also permitted "outside" branches to be established by state member banks.

III. The exclusivity of the Federal definition of "branch". The Supreme Court in First National Bank in Plant City v. Dicke, 356 U.S. 122, 132 (1958), rejected the contention that "state law definitions of what constitute branch banks..."
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 standards prescribed by 12 U.S.C. § 36(f).” North Davis Bank v. First National Bank, 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. 59, substantially amended and replaced the National Currency Act of 1863. In that banking system the paramount extention of both of these statutes was to “ * * give every possible support to the public credit” by a uniform currency * * * furnished by national associations, organized under a charter of Congress * * * Abraham Lincoln, Special Message on Financing the War, Senate Journal, pp. 121–122 (37th Cong., 3rd Sess. 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 as operated in the seaborne 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. 23, 1863). Secretary of the Treasury Chase emphasized at page 19 of his 1863 Annual Report that the recommended changes 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 * * * with this intention the 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 therefore 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 in section 36(e) Congress entrusted to the state authorities outside the reach of Congress the decision. But to allow the States to define the content of the term "branch" would make one judge see the extent of their own powers. 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, but instead constitutes itself the test to be applied in the first instance to determine the extent to which a state law is to be permitted to operate upon national banks in controversy of the National Bank Act’s general supremacy over state law. See, e.g., Tiffany v. National City Bank of New York, 409 U.S. 428 (1973); Easton v. Iowa, 188 U.S. 229 (1903).

This construction of 12 U.S.C. § 36(f) accords with the settled principle that every federal statute is to be given a federal and nation-wide meaning. New York v. Feland, 313 U.S. 283, 285 (1941). This principle is particularly applicable where a federal statute defines the extent to which a federal instrumentality is subject to state law. See, e.g., First Agricultural National Bank v. State Tax Commission, 392 U.S. 343, 347 (1968). The need to give a federal context to words used in a federal statute is not diminished because the statute might have been enacted to allow national banks to compete with the state banks on equal terms. Federal Deposit Insurance Corp. v. Tremaine, 133 F. 2d 827 (2d Cir. 1943).

Thus the Comptroller is called upon to construe the branch definition of the McFadden Act as a federal law and to apply that construction in a consistent manner to CBCT’s throughout the United States.

IV. Constructing and applying the "branch" definition. The principal statutory question is whether a CBCT is a "branch bank, branch office, branch agency, additional office, * * * branch place of business" within the meaning of the McFadden Act. A branch bank commonly is thought of as a building or place of business where a banking institution maintains a safe deposit department which is instituted under the supervision and control of the main office. A CBCT is obviously not a national bank office, principally a small but very respectable element who are so adverse to branch banking that they would protest against the national bank teller carrying on business anywhere and everywhere with a "small but very respectable building, agency, or travelling bank, or branch anything that they would protest against the national bank.” 67 Cong. Rec. 2850 (1929). Rep. Langendarf in comparing tellers windows to branches said, “you after you order teller windows are increased in the cities. They are not teller windows in any sense of the word. They are complete banking establishments, large buildings costing fortunes to build” which were physically separate establishments end in effect branches. 67 Cong. Rec. 2850 (1929). Rep. Noeller described the tellers windows as “large monumental establishments, huge buildings costing fortunes to build” which were physically separate establishments end in effect branches. 67 Cong. Rec. 2850 (1929). CBCT’s do not have any limitation placed on the power of the states to grant branches anywhere and everywhere with a "small but very respectable element who are so adverse to branch banking that they would protest against the national bank teller carrying on business anywhere and everywhere. They constitute a branch of a national bank as in Texas, whose constitution prohibits branching.

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* See the discussion of this customer limitation in Independent Bankers of Oregon v. Camp, 397 F. Supp. 1323, 1325 (D. Or. 1975), remanded 9th Cir. 525 F.2d 1203 and 72-2399 (Dec. 4, 1973).
The Comptroller believes, moreover, that a contrary interpretation of the McFadden Act would establish an undesirable competitive inequality in some states between national and state chartered banks. In the state of Washington, a bank may establish only within the same county as the bank's main office, or elsewhere within the state by merger. CBCT's may operate 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." 390 U.S. at 136-137. This statement was made in the context of a statute which had reviewed the legislative history of the McFadden Act, and determined that the Act dealt with competition between state chartered and national banks. 390 U.S. at 136-137.

I am persuaded to vote for this measure for the reason that crowded conditions, traffic regulations, lack of parking facilities in our cities necessitate a change in banking facilities to suit the convenience of the complex and crowded business world. Banks, bankers, and customers in large cities are in a situation to telephone, electric light and gas companies, or the post office, all of which have branches for the customers' convenience, economy in time, and energy, and many other factors demand that the old order give way to a modern and sensible plan. Party traditions and prejudices should not fetter or bind us to the detriment of our country or the service of our constituents.

The current CBCT's are merely the forerunner of an expected family of customer operated electronic terminals which will change the face of the banking industry. A few banks already offer a service which permits a customer to activate their computer directly from the customer's telephone and thus initiate various banking transactions. Technology already exists through which a customer, with the aid of a telephone, electronic communIcation devices as within the meaning of 12 U.S.C. 36(f), may control the operation of an automobile or 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, a careful review of the contractual rights and liabilities under which a CBCT is operated shows that even if a CBCT is considered to be a branch office, agency, or branch place of business — it is not receiving deposits, paying checks, or making loans within the meaning of 12 U.S.C. 360(f).

Such an analysis is made in an appendix, supra, 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 bank purposes other than structuring the technical and legal aspects of the transaction to avoid the branch banking statutes. Compare Hampton City, supra, 398 U.S. at 126, 126-127.

State reaction to CBCT's has been varied and conflicting. At least three states, Oregon, Washington, and Massachusetts, authorize some sort of CBCT by specific legislation which does not treat these facilities as branches. Indeed, the legislation in the State of Washington, which was signed on April 30, 1974, authorizes the establishment of "satellite facilities" anywhere within the state, and specifically provides "that the same facilities may not be the establishment of a branch." Branch banking in the State of Washington, as already noted, is limited for the time being, to the same county.

The Attorney General of Texas, Kansas, and Florida have authorized the use of CBCT's in some circumstances, although branch banking is prohibited in each of these states. The Attorney General of Illinois, another state which prohibits branch banking, however, has determined that the same off-premises activities permitted in Texas and Florida would constitute illegal branch banking if performed in Illinois. The Attorney General of Nebraska — another non-branching state — has ruled that a CBCT is a branch, but his opinion has been reversed by a state court.

The competitive picture is greatly influenced by recent regulations of the Federal Home Loan Bank Board permitting the use of CBCT's by federal thrifts, or those chartered savings and loan associations of remote service units. See 39 FR 33991 (June 28, 1974). Similar regulations have been issued by the Federal Reserve System and the National Credit Union Administration. 39 FR 30107 (Aug. 21, 1974). In some states, such as Nebraska, savings and loan associations have been quick to take advantage of the regulations, andCBCT's have become a reality in Nebraska.

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U.S. 1194 (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, as 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 evolving CBCT and technology. Persuasive legal arguments can be made in support of either interpretation of the statute. 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 considering the current technology and the underlying business needs of the country. Merchants Bank v. State Bank, 77 U.S. 604, 648 (1871). A more recent construction of these statutes by the Supreme Court upheld a national bank’s power to advertise as being “one of the most usual and useful weapons” in “modern competition for business.” Franklin National Bank v. New York, 347 U.S. 574, 577 (1954). A number of other Supreme Court cases during the last century have construed these statutes in a similar flexible and reasonable fashion.

A CBCT basically is a means of a bank customer transmitting his requests or instructions to a bank, and receiving responses thereto. Communications between a bank and a bank customer concerning disposition of the customer’s account are a part of the banking business. So long as the conduct of this business does not constitute branching, it may be done away from the banking house (Merchants Bank v. State Bank, supra), and is not subject to regulation by state law (Franklin National Bank v. New York, supra).

VI. Limitations. Even though a CBCT is not a branch, the Comptroller possesses regulatory authority which can be exercised to limit CBCT’s to insure the sound development of the banking system. This regulatory authority should be used sparingly, however, because

* * * regulation has too often resulted in protection of the status quo. 2. Indesirable bumps and hiccups when the agencies have endeavored to confine regulation to a necessary minimum and have otherwise fostered competition.

Annual Report of the Council of Economic Advisors, 106-107 (1970). Particularly in this new area where technology and consumer response are changing rapidly, the Comptroller believes that any limitations used by him 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 § 7.7491, Customer-Bank communication terminals. 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 notice 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 on an equal competitive footing with national banks and with savings and loan associations. This facility 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 on an equal competitive footing with national banks and with savings and loan associations. This urge not to establish a CBCT is in part to avoid any access to the Federal Reserve System: the Federal Reserve System: the Federal Reserve System.

VII. 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, however, permits the Comptroller to adopt interpretive rules to become effective immediately. 5 U.S.C. § 553(d). Since the interpretive ruling issued herewith will not restrict the rights of any bank and will not result in the restriction of their activities, the Comptroller believes that there is no public benefit which will result from this ruling, no reason exists to delay its effective date.

Part 7 of 12 CFR Chapter I 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 money either from his account or from a previously authorized line of credit, or an

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provisions to consummate the following kinds of transactions: Cash withdrawals from demand accounts, savings accounts and credit card accounts; deposit to demand accounts, savings accounts, and credit card accounts; deposit to demand, to savings or from savings to demand, or from credit card to demand; payment of demand, savings, and credit card accounts; and transfers of funds. Consumption of these transactions by the bank for the customer is contingent upon certain contractual obligations, two contractual rights and obligations attached and ‘deposits are received, or checks paid, or credit balances increased in an electronic banking situation because the CBCT’s involved are not sophisticated enough to carry out the procedures, such as authentication and verification, necessary to assure safe and sound banking and prevent losses to customers and banks.

UNMANNED AUTOMATED TERMINALS

When an unmanned automated terminal is opened off-line, i.e., not connected by wire to the bank’s computer, a deposit transaction is not consummated until the bank actually notifies the customer’s instructions, and the amount of funds necessary to implement the instruction are received and verified. This notification, receipt, and verification process takes place after collection from the CBCT of the funds left there and of a tape or other medium upon which all transactions are recorded. The bank cannot 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 not yet received. These funds do not become deposits for any purpose—excluding the application of 12 U.S.C. 3501—until they are accepted at the chartered banking premises. See, e.g., Bernstein v. Northwestern National Bank, 197 F. 2d 521, 524 (8th Cir. 1952). The bank cannot give credit for transactions which provide for the transfer of funds to the bank. The customer’s instructions to transfer the funds must be verified against the bank’s computer, just as with a check. The bank must make sure the customer is credited for the funds and the establishment’s computer is debited for the funds before any such device is put into operation. Any amendments to the CBCT’s may be made at the discretion of the appropriate regional administrator, and are subject to verification that the withdrawal is within the approved line. With these unmanned CBCT’s this verification takes place as these transactions are not individually with an on-line CBCT, or later with an off-line CBCT. In these circumstances the CBCT is the original contract which establishes the loan relationship between the customer and bank. Each request by the customer for a cash advance must be verified and accepted by the bank. The transaction then is consummated, and then, when the bank verifies at its office that the credit agreement conditions are satisfied. This conclusion of ordinary credit transactions under the regulations of the Federal Reserve Board, which provide with regard to consumer loans: A transaction shall be considered consummated at the time a contractual relationship is created between the creditor and a customer irrespective of the time of performance of either party.

12 CFR 220.3(c). The time of consumption of a cash withdrawal under the credit agreement here involved is when that transaction is verified at the bank. Thus no loan is made at the CBCT.

It should be noted again that the legal effect is 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.


JAMES E. SMITH, Comptroller of the Currency.

APPENDIX

Communications between customers and their banks through CBCT’s involve instructions at the bank. See, e.g., Zanetti, Atti, Gen. Op. No. 74-156 (June 12, 1974). If the CBCT is off-line, the transaction is verified at the bank when the tape or other record is retrieved from the CBCT. If the withdrawal was not in accordance with the agreement between the bank and its customer for any reason, the bank may not charge the customer’s account, even if the customer’s account, then an authorized withdrawal has taken place and the customer is liable to the bank for the funds he improperly obtained.

Similarly, a cash withdrawal from an open and credit account, approved overdraft account, does not constitute making a loan at the CBCT. Such withdrawals are from an already approved line of credit, and are subject to verification that the withdrawal is within the approved line. With most unmanned CBCT’s this verification takes place as these transactions are not individually with an on-line CBCT, or later with an off-line CBCT. In these circumstances the CBCT is the original contract which establishes the loan relationship between the customer and bank. Each request by the customer for a cash advance must be verified and accepted by the bank. The transaction then is consummated, and then, when the bank verifies at its office that the credit agreement conditions are satisfied. This conclusion of ordinary credit transactions under the regulations of the Federal Reserve Board, which provide with regard to consumer loans: A transaction shall be considered consummated at the time a contractual relationship is created between the creditor and a customer irrespective of the time of performance of either party.

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bank customer is dealing directly not with the bank, but with a third party, as the following discussion illustrates.

A customer, for example, might give to an establishment which operates a CBOT a check of which the customer is a payee, such as a payroll check from the customer's employer, and request the establishment to return cash in less than the face amount of a check and transfer the remaining amount from the establishment's bank account to the customer's account, thereby effecting a deposit in the customer's account of a portion of the check. The establishment might be agreeable to doing this, not only because it accommodates the customer, but also because it reduces the amount of cash the establishment must keep on hand to cash customer's checks.

The bank's computer is used to assure the customer that the establishment has adequate funds to transfer to the customer's account and to assure the establishment that the customer is presenting a valid bank card for identification purposes. The computer, acting on the basis of bank records and instructions programmed by bank personnel, identifies the customer's card as a valid card, accepts information as to the amount of the transfer between accounts, affects the transaction immediately or prepares it for later posting in accordance with the bank's procedures, and confirms the transaction to the customer and the establishment. The cash received by the customer is from the establishment, not from the bank, and all transactions involving the bank occurred at the bank's own computer.

By arrangement between the parties, the bank also may assume certain risks, for example that the establishment may accept the check from the customer without fear of dishonor. This is a credit risk of the sort ordinarily taken by a bank, including the possibility of charging the face amount of a check so processed back to the customer's account. The establishment is not an agent of the bank because it is acting as it does for its own business purposes, and, accordingly, is a bona fide third party. Transactions involving cash withdrawals from a customer's account would follow essentially the same process, including a transfer between the customer's and the establishment's accounts.

With regard to such manned CBOT's it seems clear that the banking aspects of the transactions initiated by a customer are consummated at the bank, and not at the location of the CBOT. As with unmanned CBOT's these transactions are structured to fit the operational capabilities of the CBOT and the bank's computer and to comply with prudent banking practices. It could not be said that there contractual and operational arrangements have no significant purpose other than to remove the possibility that the monies received will become "deposits" within the meaning of the branch banking law. See Walker Bank, supra, 396 U.S., at 109. Additionally, the customer's direct transactions are not with the bank at all, but with a bona fide third party.

Rule 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:

Federal Reserve bank of-- | Rate | Effective
---|---|---
Boston | 71 | Dec. 19, 1974
New York | 71 | Dec. 19, 1974
Philadelphia | 71 | Dec. 19, 1974
Cleveland | 71 | Dec. 19, 1974
Richmond | 71 | Dec. 19, 1974
Atlanta | 71 | Dec. 19, 1974
Chicago | 71 | Dec. 19, 1974
St. Louis | 71 | Dec. 19, 1974
Minneapolis | 71 | Dec. 19, 1974
Kansas City | 71 | Dec. 19, 1974
Dallas | 71 | Dec. 19, 1974
San Francisco | 71 | Dec. 19, 1974

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 §§ 701.28 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 Nicholson, Jr.,
Administrator.

December 17, 1974.
1. Section 701.26 is redesignated as § 701.27–1, and the heading revised to read:
§ 701.27–1 Purchase of accounting services.

2. Section § 701.27 is redesignated as § 701.27–2, and the heading revised to read:
§ 701.27–2 Participation in accounting service center.

3. A new § 701.26 is added to read as follows:
§ 701.26 Credit union service center.
(a) For the purposes of this section, "Service Center" means a credit union service center which provides services to include, but not necessarily limited to, physical facilities, centralized management, and accounting services.
(b) "Accounting Service" means the maintenance of bookkeeping, accounting, or other records related to the purposes and functions of a credit union by manual, mechanical or electronic methods, and the furnishing of reports and information derived from such records.
(c) "Centralized management" means the single authority responsible for supervising, controlling and directing the day-to-day operations of the service center.
(d) One or more Federal credit unions may contract with a vendor other than a Federal credit union to provide a credit union service center. The contract shall be in writing, shall have the approval of the Administrator, and shall expressly provide for:
(i) Segregating the credit union's assets and records;
(ii) Maintaining the credit union's individual identity;
(iii) Establishing minimum security devices and procedures in accordance with Part 748 (12 CFR 748);
(iv) Complying with the mandatory requirements with regard to the advertisement of insured status in accordance with Part 746 (12 CFR 746);
(v) Describing the services to be provided by the vendor and establishing the costs of these services subject to periodic review and negotiation;
(vi) Complying with the provisions of section 701.14 of this Part concerning all services performed;
(vii) Immediate availability and possession of the Federal credit union's books and records for examination by the Administrator and audit by the supervisory committee;
(viii) Establishing centralized management in consonance with the board of directors of each credit union directing and controlling the affairs of the credit union;
(bx) Notifying the credit union's surety company and obtaining written assurance from surety that coverage extends to the service center and its employees;
(x) Appointing the service center and its employees as agents of the credit union for purposes of transacting contracted services; and
(xi) Terminating, assigning, and mediating the contract.
(b) The files of the Federal credit union shall contain specific information concerning the procedures to be used by the vendor in complying with the terms of the contract. Such information may be in the form of a standard operating or users manual.
(c) A Federal credit union, in addition to regular payments for services as provided under the contract, shall not advance for or disburse charges for more than 3 months' services. Where such advance payment is made it shall be amortized over a period not in excess of the period of the written agreement.
(d) Requests for approval shall be submitted to the Regional Director in writing with a copy of the contract and all pertinent facts in support of the proposal not later than 60 days prior to the proposed implementation of the contract. A Federal credit union shall notify the Regional Director in writing within 30 days of the termination of the contract.
(e) The Regional Director will investigate each request to participate in a credit union service center activity and make a recommendation as to whether it should be approved or disapproved. The request, contract and the recommendation of the Regional Director shall be forwarded to the Administrator who shall approve or disapprove the application. The Regional Director will be informed of the Administrator's action on the application and will promptly notify the Federal credit union concerned.
(f) Notwithstanding the provisions of paragraph (c) (2) of this section, the Regional Director may approve a Federal credit union's request supported by a standard contract of the same service center which has received prior approval by the Administrator in accordance with the provisions of paragraph (c) (2) of this section.
(g) No official or employee of a participating Federal credit union may have a pecuniary interest in the credit union service center pursuant to this section. No official of a participating Federal credit union may receive from the vendor of such services any salary or compensation other than the reimbursement of necessary expenses incurred in connection with the vendor's activities.

Title 13—Business Credit and Assistance
CHAPTER 1—SMALL BUSINESS ADMINISTRATION
[Revision 13]
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 rescinds revision 12, including amendments 4 and 5. The initial revision of Part 121 was revised to incorporate 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(b) 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(d) has been revised to clarify that a concern organized for profit can qualify as a small business concern if it is owned by or subject to the control of a nonprofit entity.
4. Section 121.3-2(r) has been revised by adding thereto material appearing in § 121.3-16 of revision 12.
5. Section 121.3-2(b) has been revised by adding thereto material appearing in § 121.3-16 of revision 12.
6. Section 121.3-16(b) (3) (II) has been revised to make it clear that an appeal may be taken not only from the classification which the contracting officer has designated in the solicitation, but also from his designation of the appropriate Small Business Administration size 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 121.3-9 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 regulation.
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 2334). Part 121 of Chapter 1 of Title 13 of the Code of Federal Regulations is hereby conform with arrangement of Schedule B.

§ 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 Census (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.

121.3-10 Appeals. See § 121.3-9.

121.3-9 Definitions of small business for Government procurement.

121.3-10 Definition of small business for SBA loans.

121.3-11 Definition of small business for Government procurement.

121.3-12 Definition of small business for Government procurement.

121.3-13 Definition of small business for Government procurement.

121.3-14 Definition of small business for the purpose of lease guarantees.

121.3-15 Definition of small business for the purpose of surety bond guarantees.


§ 121.3 Statutory provisions.

(a) Small Business Act, as amended. Sec. 3. For the purpose of this Act, a small business concern shall be one which is independently owned and operated and which is not dominant in its field of operation. In the foregoing definition, the Administrator, in making a detailed definition, may use these 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) It shall also be the duty of the Administration and it is hereby empowered, whenever it determines such action is necessary—

(6) To determine within any industry the concerns, firms, persons, corporations, partnerships, or other business enterprises which are to be designated "small business concerns" for the purpose of effectuating the provisions of this Act. To carry out this purpose, the Administrator, when requested, to do so, shall issue in response to each such request an appropriate certificate certifying concern as a "small business concern" in accordance with the criteria expressed in this Act. Any such certificate shall be subject to revocation when the Administrator deems it advisable, and the Certificate shall be a "small business concern." Offices of the Government having procurement or lending powers, or engaged in Federal property or allocating materials or supplies, or promulgating regulations affecting the distribution of materials or supplies, shall accept as conclusive the Administrator's determination as to which enterprises are "small business concerns," as authorized and directed under this paragraph.

(b) Small Business Investment Act of 1958, as amended. Sec. 105. As used in this Act—

RULES AND REGULATIONS

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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. When a procurement is 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 which it bids. If a multi-item procurement requires the successful bidder to deliver all items and/or perform all services being procured under a single contract, size determinations will be made for each industry whose products or services account for the greatest proportion of the contract price. (5) Product classification decision. The SBA Regional Director or his delegates of the SBA Region in which the principal office of the applicant, not including its affiliates, is located, shall determine the appropriate SIC classification, except that for procurement purposes the determination shall be made by the official specified in Section 121.3-3, and for lease guarantee reinsurance purposes the determination shall be made by the Associate Administrator for Insurance Investment. Such determination shall be subject to appeal in the manner provided in Section 121.3-6.

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

(a) Affiliates: Concerns, other than investment firms, or subcontractors, or development companies qualifying under the Small Business Investment Act of 1958 and the regulations issued pursuant thereto, or investment 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 and whether or not affiliation exists, consideration shall be given to all appropriate factors, including common management, and contractual relationships: Provided, however, That restraints imposed on a franchise by its franchise agreement shall not be considered in determining whether the franchisor controls or has the power to control and, therefore, is affiliated with the franchisee, if the franchisee has the right to profit from its effort, commensurate with ownership, and bears the risk of loss or failure. Where a concern is a subcontractor pursuant to section 8(a) (2) of the Small Business Act and, in connection therewith, is the subject of a divestiture agreement approved by SBA for the benefit of socially or economically disadvantaged individuals, the receipts, employment, and other factors of the concern attributable to the section 8(a) (2) subcontract shall not be included in determining the size of either concern during the term of such divestiture agreement. Other contracts and business of such subcontractor may also be excluded in determining the size if, in the judgment of SBA, substantial beneficial interests of such other contracts and business will be the socially or economically disadvantaged individuals in question.

(b) Nature of Control. Every business concern shall be considered as having one or more parties who directly or indirectly control or have the power to control it. Control may be affirmative or negative and it is material whether it is exercised so long as the power to control exists.

Example: A party owning 50 percent of the voting stock of a concern would have negative control since he cannot block any action of the other stockholders. Also, the bylaws of a corporation may be drawn up in such a manner which would permit a stockholder to own more than 50 percent of the voting stock to block any actions taken by the other stockholders. Affiliation exists when one or more parties have the power to control a concern while at the same time another party, or other parties, may be the party or parties with the power to control.

(2) Affiliation: Concerns are in the same or related industries if the same or related industry is widely distributed with no individual stock totalling 40 percent of the concern attributable to the section 8(a) employment, and other factors of the concern and such minority 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 parties each 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 parties each 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 parties each 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 parties each 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.

(3) Voting power and a controlling interest: A party is considered to control or have the power to control a concern if he or a third party has the power to direct or cause the concern's voting actions. The term "party" includes, but is not limited to, two or more persons or all persons who directly or indirectly own 50 percent or more of the concern's voting stock.

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

(5) 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.

(6) Voting trusts. If the purpose of the voting trust or similar agreement is to separate voting power from beneficial ownership of voting stock for the purpose of shifting control of or the power to control a concern to another person or entity when the concern or another concern may qualify as a small business within the size regulations, such voting trust shall not be considered valid for this purpose, regardless whether the voting trust is or is not valid within the appropriate jurisdiction. However, if a voting trust is entered into for a legitimate purpose, such consideration is determined to be in the best interest of the small business program.

(iv) Stock options, convertible debentures, and agreements to merge. 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 effect on the power to control the concern. In making size determinations, such options, debentures, and agreements are treated as though the rights held thereunder had been exercised prior to the date of the determination.

Example: If, on the date of the determination, company "A" holds an option to purchase a controlling interest in company "B" and, except for a valid voting trust, the situation treated as though company "A" had exercised its rights and had become owner of a controlling interest in company "B" prior to the determination. Further, if, as of the date of a determination, company "A" has entered into an agreement to merge with company "B" in the future, the situation is treated as though the merger and taken place prior to the date of the determination.

(c) Affiliation through common management. A concern is considered as controlling or having the power to control another concern when one or more of the following circumstances are found to exist, and it is reasonable to conclude that under the circumstances, the concern is the controlling concern or has the power to direct or influence the operation of such other concern.

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

(2) 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, principal stockholders, and/or key employees of one concern organize a new concern in the same or 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 subcontracts, financial or technical assistance, and/or other facilities, whether for a fee or otherwise.
(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, consorting to engage in and carry on a business, including all persons who have the power to control such enterprise or whose affairs are controlled by it, whether or not they are incorporated as a Government contract, for joint profit for which purpose they combine their efforts, property, money, skill, or knowledge, but without creating 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 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 in incidentally a party to a joint venture, such concern is not considered as being affiliated with such venture insofar as its receipt is an investment.

(c) Joint venture—procurement assistance. Concerns bidding on a particular procurement as joint ventures 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, has it is bidding 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 size standards to include such concern's share of the joint venture receipts (as distinguished from its share of the individual concern's receipts) as if the concern had been an affiliate since it is necessary in computing the applicant's annual receipts to include the affiliate's receipts during the applicable accounting period, rather than only its receipts during the period in which it has been an affiliate.

(e) Franchise and license agreements. If a concern operates or is to operate under a franchise or license agreement, the following policy is applicable: In determining whether the franchise controls or has the power to control and, therefore, is affiliated with the franchisee, the restraint imposed on a franchisee by its franchise agreement shall be considered provided that the franchisee has the right to profit from its effort and the risk of loss or failure, commensurate with ownership. Even though the franchisee may be controlled by the franchisor or by virtue of the contractual relationship between them, the franchisee may be controlled by the franchisor or others through common ownership or management, in which case they would be considered as affiliated.

(f) "Annual receipts" means the gross income less returns and allowances, sales of fixed assets, and interest on 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 the period in which the respective 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 Federal income taxation, reported to the U.S. Treasury Department, Internal Revenue Service for Federal income tax purposes: "Annual receipts" for the purpose of receiving financial assistance under a Small Business Administration program, it is determined that (1) the applicant has completed at least 3 months of its current fiscal year, (2) its gross for receipts for the completed months of its current fiscal year are at least 25 percent lower than its receipts during the corresponding months of its most recently completed fiscal year, and (3) the reduction in receipts was primarily due to the shortage of energy or materials, its "annual receipts" for size determination purposes shall be computed by reducing its annual receipts for its most recently completed fiscal year by the determined percentage.

If a concern has been in business less than 3 years, its average annual receipts for the purpose of a size standard based on 3 years' receipts, shall be computed by determining its average weekly receipts for the period in which it has been in business and multiplying such figure by 52. If a concern has been in business less than 3 years, its average annual receipts for the purpose of a size standard based on 3 years' receipts, shall be computed by determining its average weekly receipts for the period in which it has been in business and multiplying such figure by 52. If a concern had an affiliate during a prior year, its "annual receipts" for the purpose of a size standard based on 3 years' receipts, shall be computed by reducing its annual receipts for the period in which it has been in business and multiplying such figure by 52. If a concern had an affiliate during a prior year, its "annual receipts" for the purpose of a size standard based on 3 years' receipts, shall be computed by reducing its annual receipts for the period in which it has been in business and multiplying such figure by 52. If a concern had an affiliate during a prior year, its "annual receipts" for the purpose of a size standard based on 3 years' receipts, shall be computed by reducing its annual receipts for the period in which it has been in business and multiplying such figure by 52.

(g) "Control through contractual relationships" means furnishing at an installation within the several States, the District of Columbia, Puerto Rico, Virgin Islands, the Trust Territory of the Pacific Islands, or the District of Columbia, or three or more services which may include but are not limited to such maintenance activities as janitorial and custodial services, protective guard services, commodity delivery, house moving and delivery, safety engineering services, messenger services, grounds maintenance and landscaping services, and air-conditioning and refrigeration maintenance; Provided, however, that if the contractor determines prior to the issuance of bids that the estimated value of one of the foregoing services constitutes a major portion of the estimated value of the entire contract, the contract shall not be classified as base maintenance but in the industry in which such service is classified.

(h) "Bona fide feed stocks" means crude and any other hydrocarbon material actually charged to refinery processing units, as distinguished from materials used as components in products to be delivered after merely filtering, settling, or blending.

(i) "Crude oil capacity" means the maximum daily average crude runs to stills that can be maintained for an extended period with allowance for necessary shutdown time for routine maintenance, repairs, etc. It approximates the maximum daily average crude runs to stills that can be maintained for an extended period.

(j) "Certificate of Competency" means a certificate issued by SBA pursuant to the authority contained in section 8(b) of the Act. The certificate is not, and any foreign business entity, is not limited to an individual, partnership, corporation, limited partnership, or corporation by SBA.

(k) "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 U.S. economy through payment of taxes and/or labor, etc. "Concern" includes but is not limited to an individual, partnership, corporation, limited partnership, or corporation by SBA.

(l) "Department store" means a concern employing 25 or more persons engaged in the retail sale of some items in the United States; and which makes a significant contribution to the U.S. economy through payment of taxes and/or labor, etc. "Concern" includes but is not limited to an individual, partnership, corporation, limited partnership, or corporation by SBA.
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 the preceding merchandise lines do not exceed 80 percent of the concern's total sales and the aggregate of such merchandise lines account for at least 50 percent of the concern's total sales.

(m) “Forest products industry” as used in Section 121.3-9(b) means logging, wood preserving, and the manufacture of lumber and wood related products such as veneer, plywood, hardboard, particle board, or wood pulp, and of products of which lumber or wood related products are the principal raw material.

(n) “Medical and dental laboratory” means those facilities which provide services to doctors, dentists, hospitals, and similar health facilities, which facilities are privately owned and operated for the purpose of obtaining profits which shall inure to the benefits of its owner, stockholders or members.

(p) “Industry” means a grouping of establishments primarily engaged in similar lines of activity as listed and described in the Standard Industrial Classification Manual, prepared and published by the Bureau of the Budget (now Office of Management and Budget), Executive Office of the President.

(q) “Medical and dental laboratory” means those facilities which provide services to doctors, dentists, hospitals, and similar health facilities, which facilities are privately owned and operated for the purpose of obtaining profits which shall inure to the benefits of its owner, stockholders or members.

(r) “Nonmanufacturer” means any concern which, in connection with a specific Government procurement or other than a Government procurement or service contract, does not manufacture or produce the products required to be furnished by such procurement. Nonmanufacturer includes a concern which can manufacture or produce the products referred to in the specific procurement but does not so in connection with that procurement. For size determination purposes there can be no part of an item being procured. The manufacturer of the end item being procured is the concern which, with its own forces, transforms inorganic or organic substances into products or manufactures or processes the raw materials or components into such end item. Whether a bidder on a particular procurement is the manufacturer or a nonmanufacturer for purposes 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.

(s) A concern is not “dominant in its field” for size determination purposes if it does not exercise 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 is or is not “dominant in its field,” 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.

(t) “Number of employees” means the average employment of any concern, including the employees of its domestic and foreign affiliates, based on the number of persons employed on a full-time, part-time, temporary or casual basis during the pay period ending nearest the last day of the third month in each calendar quarter for the preceding four quarters: Provided, however, if, for the purpose of determining a concern's eligibility for financial assistance under a Small Business Administration program, it is determined that a concern's employment in its most recently completed calendar year and that such reduction in employment was primarily caused by a shortage of energy or materials, its “number of employees” for size determination purposes shall be determined by reducing its average employment for the preceding four calendar quarters by the determined percentile. If a concern has not been in existence for four full calendar quarters, “number of employees” means the average employment of such concern and its affiliates during the period such concern has been in existence based on the number of persons employed during the pay period ending nearest the last day of each pay period. The number of employees must be determined as of the last day of the third month in each calendar quarter.

(u) “Protest” means a statement in writing from any bidder or offeror on a procurement or applicable (or from any other party interested therein) alleging that another bidder or offeror on such procurement is not a small business concern. Such statement shall contain evidence of the protestant's claim. A protest received after the time limit set forth in § 121.3-6 shall be noted as a protest pursuant to § 121.3-6. For the purpose of Government procurements or sales, a size determination shall not be noted as a protest pursuant to § 121.3-6. If a concern has been an affiliate during a portion of the period in question, the protest shall remain in full force and effect until reversed by the Small Business Size Appeals Board pursuant to § 121.3-15, unless for lease or purchase purposes such 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.

(v) “Redevelopment area” for the purpose of small business size determinations means a geographical area within the United States which has been designated as a “redevelopment area” in accordance with the Public Works and Economic Development Act of 1965 (Pub. L. 89-105, 79 Stat. 806).
§ 121.3-5 Protest of small business status.

(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. Any protest shall be made by delivering a protest, or a copy thereof, to the contracting officer responsible for the particular procurement or sale involved. In order to apply to the procurement or sale in question, such protest must be filed prior to the close of business on the expiration of the 5-day period allotted, 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, telegram, 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 (1) within such 5-day period or (2) postmarked no later than 1 day after the date of such telephone protest. Any contracting officer who receives a protest shall promptly forward such protest to the SBA district office serving the geographical area in which the principal office of the protest concern, not including its affiliates, is located. A contracting officer may at any time after bid opening question the small business status of any bidder or offeror for the purpose of a particular procurement or sale by filing a protest with the SBA district office serving the 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 for the purpose of the procurement or sale in question whether filed before or after the close of business on the 5th working day, the appellant will be deemed to have waived its rights of appeal insofar as the pending procurement is concerned.

(b) Method of appeal—(1) Who may appeal. An appeal may be filed by—(i) Any concern or other interested party which has been adversely affected by a decision of a regional director or his delegatee; (ii) Any concern or other interested party which has been adversely affected by a decision of a contracting officer regarding product classification pursuant to § 121.3-8; (iii) Any concern or other interested party which has been adversely affected by a decision of a contracting officer regarding product classification pursuant to § 121.3-8; and (iv) The Small Business Administration Associate Administrator for the Small Business Administration program in accordance with regulations issued by the Administrator.

(2) Where to appeal. Written notices of appeal shall be addressed to the Chairman, Size Appeals Board, Small Business Administration, Washington, D.C. 20416.

(c) Time for appeal. (i) An appeal from a size determination or product classification by a regional director, or his delegatee, may be taken at any time, except that because of the urgency of pending procurements, appeals concerning the small business status of a bidder or offeror in a pending procurement must be taken within 10 working days after receipt of a decision of a regional director or his delegatee. Unless written notice of such appeal is received by the Size Appeals Board before the close of business on the 5th working day, the appellant will be deemed to have waived its rights of appeal insofar as the pending procurement is concerned.

(ii) An appeal from a contracting officer’s designation of the Standard Industrial Classification Industry into which the product or service to which a contract is awarded, and/or the Small Business Administration size standard applicable thereto may be taken: (a) Not less than 10 days, exclusive of Saturdays, Sundays, and legal holidays, before bid opening day or deadline for submitting proposals or quotations, in cases wherein the bid opening date or last date to submit proposals or quotations is more than 30 days after the issuance of the invitation to bid or request for proposals or quotations, or (b) not less than 5 days, exclusive of Saturdays, Sundays, and legal holidays, before the bid opening day or deadline for submitting proposals or quotations, in cases wherein the bid opening date or last date to submit proposals or quotations is 30 or less days after the issuance of the invitation to bid or request for proposals or quotations, and

(iii) The timeliness of an appeal under paragraph (c)(i) of this section shall be determined by the tim
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 to be timely and shall be considered 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.

(3) 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, the date of the determination from which the appeal is taken and its date;

(ii) If applicable, the SBA or contract number and date, and the name and address of the contracting officer;

(iii) A concise and direct statement of the reasons why the decision of a regional director, or his delegate, the contracting officer or the Associate Administrator for Finance and Investment is alleged to be erroneous;

(iv) Documentary evidence in support of such allegations;

(v) Action sought by the appellant.

(4) Notice to interested parties. The Size Appeals Board shall promptly acknowledge receipt of the Notice of Appeal and send a copy of such Notice of Appeal to the appropriate regional director or his delegate and to the contracting officer (if a pending procurement is involved). If the appellant is not the contracting officer or the Associate Administrator for Finance and Investment is alleged to be erroneous.

(5) Formal request for reconsideration. The Board shall promptly act upon presentation of appropriate evidence submitted in connection with the appeal or a reconsideration thereof to such appellant.

(c) Consideration by the Size Appeals Board. When a request for reconsideration is granted, the Board shall consider the appeal on the written submission of the parties. The Board may also, in its discretion, conduct an oral inquiry to obtain any additional information. After considering relevant information, the Board shall promptly render a decision which shall state the reason for such decision.

(d) Procedures in reconsideration. In reconsidering size appeals, and in reconsidering size appeals decisions, the Size Appeals Board shall hold oral hearings and assist the Board in performing its factfinding functions.

(e) Grounds for reconsideration. 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 within 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.

(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.

(a) Area. Alaska is a financially distressed area, as defined in §121.3-2 (d) and (9) and is designated as a "Certified Eligible" area.

Grounds for reconsideration shall be:

(1) A material error of fact in the original decision;
(2) Relevant information not previously considered by the Board or relevant information not previously available to any of the parties involved;
(3) When a request for reconsideration is granted, the Board shall 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.

(b) Financial assistance programs of the Small Business Administration and financial assistance under the Small Business Investment Act of 1958, as amended.

(c) Area. Alaska is a financially distressed area, as defined in §121.3-2 (d) and (9) and is designated as a "Certified Eligible" area.
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operation of a plant, facility, or other business establishment within such area.

(2) Government procurement assistance, sales of Government property, and
Government subcontracting. § 121.3-7(b) states that to determine 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 its affiliates, which 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. When computing the size status of a bidder or offeror, the number of employees, annual receipts, or other applicable standards of the bidder or offeror and all of its affiliates shall be included. In the submission of a bid or proposal on a Government contract, a concern shall accept the self-certification at face value for the particular procurement involved. If a concern has been determined by SBA to be ineligible, or has been determined by SBA to be ineligible subsequently has on the basis of a significant change in ownership, management or contractual relations, applied for recertification based on a contract for work which is classified in Division C, Contract Construction, of the Standard Industrial Classification Manual, as amended, prepared and published by the Bureau of the Budget, Executive Office of the President, is:

(1) Small if its average annual receipts for its preceding 3 fiscal years do not exceed $7.5 million: Provided, however, That, if the requirements of the contracts classified in an industry set forth in Schedule B of this part, it is small if its number of employees is the standard established therein for such industry.

(2) Small if it is bidding on a contract for dredging and (i) its average annual receipts for its preceding 5 fiscal years do not exceed $5 million and (ii) it performs the dredging of at least 40 percent of the yardage advertised in the plans and specifications with dredging equipment owned or obtained from another small business dredging concern.

(b) Manufacturing. Any concern bidding on a contract for a product it manufactured is:

(1) As small if it is bidding on a contract for food canning and preserving and its number of employees does not exceed 500 persons, exclusive of agricultural labor as defined in section (k) of the Federal Unemployment Tax Act, 5 U.S.C. 30111, 26 U.S.C. (I.R.C. 1954) 3306. Provided, however, That, if the number of employees does not exceed the size standard established for the industry.

(2) As small if it is bidding on a contract for a product classified within an industry set forth in Schedule B of this part and its number of employees does not exceed the size standard established for that industry.

(3) As small if it is bidding on a contract for a product classified within an industry not set forth in Schedule B of this part and its number of employees does not exceed the size standard established for that industry.

(4) As small if it is bidding on a contract for pneumatic tires within Census Classification Codes 30111 and 30112 which it manufactured or otherwise produced in the United States during the preceding calendar year is more than 50 percent of the value of its total worldwide manufacture, and its number of employees does not exceed the size standard established for that industry.

(5) As small if it is bidding on a contract for passenger cars within Census Classification Code 31711: Provided, That (i) the value of the passenger car within Census Classification Code 31711 which it manufactured or otherwise produced in the United States during the preceding calendar year is more than 50 percent of the value of the principal products which it manufactured or otherwise produced or sold during the preceding calendar year was less than 5 percent of the total value of such products manufactured or otherwise produced or sold in the United States during said period.

(6) Rebuilding on a factory basis or equivalent: As small if it is bidding on a contract for rebuilding machinery or equipment on a factory basis, the purpose of which is to restore such machinery or equipment to an as new or equivalent condition as possible and its number of employees does not exceed the number of employees specified for the classification code applicable to the manufacturer of the original item.

Form: The size standard contained herein is not limited to concerns who are manufacturers of the original item but it is applicable to all bidders or offerors. The term "rebuilding on a factory basis" as used in this subsection does not include ordinary repair services such as those involving minor repair or parts replacement.

(c) Nonmanufacturing. Any concern which submits a bid or offer in its own name, other than on a construction or service contract, but which proposes to furnish a product manufactured by said bidder or offeror, is deemed to be a small business concern when:

(1) Its number of employees does not exceed 500 persons, and

(2) In the case of Government procurement reserved for or involving the preferential treatment of small businesses, such nonmanufacturer furnished in the performance of the contract the
For the purpose of a size determination shall be made concern which converts liquid oxygen to the purpose, of qualify as a small business concern. For therefore, a small business sawmill can tracts out the treatment of the lumber.

Therefore, a small business concern which purchases some or all manufactured or produced in the United States; however, if the products to be furnished are woolen, worsted, knitwear, duck, and webbing, dealers and converters shall furnish such products 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 thread, dealers and converters shall furnish such products which have been finished by a small finisher. Finishing of thread is defined as all "dyeing, bleaching, glazing, Mildew proofing, coating, waxing, and all other operations required by the pertinent specifications but excluding mercerizing, spinning, throwing, or twisting operations."

If the procurement is for a refined petroleum product, other than a product classified in Standard Industrial Classification Industries No. 2951, Filling Mixture of Blocks, No. 2992, Asphalt Filling Mixture, No. 2993, Lubricating Oils and Greases, or No. 2999, Products of Petroleum and Coal, Not Elsewhere Classified, paragraph (g) of this section is for application. For size determination there must 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 inorganic or organic substances including raw materials and miscellaneous parts or components into such end item. Whether a bidder on a particular procurement procures such item by reconditioning a grade of products purchased in finished form, or manufactures the item, the concern which procures such items and packages them into a kit form is considered to be a nonmanufacturer for size determination purposes. Thus, 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 value of the 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 treated lumber, even if it contracts out the treatment of the lumber. Therefore, a small business sawmill can deliver to a large contractor sawmill treated lumber, contracting with a small wood truss manufacturer for the trusses. The wood truss manufacturer may then be considered a manufacturer for size determination purpose. 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 value of the 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 treated lumber, even if it contracts out the treatment of the lumber. Therefore, a small business sawmill can deliver to a large contractor sawmill treated lumber, contracting with a small wood truss manufacturer for the trusses. The wood truss manufacturer may then be considered a manufacturer for size determination purpose. Thus, 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 value of the kit and its contents is accounted for by items manufactured by small business.
phalt Felts and Coatings; No. 2992, Lubricating Oils and Grease; or No. 2999, Products of Petroleum and Coal, Not Elsewhere Classified; 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 (iii) the product to be delivered in the performance of such contract is small if its annual sales or annual receipts for its preceding 3 fiscal years do not exceed $1 million.

(3) Stockpile purchasers. Any concern primarily engaged in the purchase of materials which are not domestic products and which are not on the domestic market is small if its sales for the preceding fiscal year do not exceed $25 million.

§ 121.3-9 Definition of small business for sales of the Government. In the submission of a bid or proposal for the purchase of Government-owned property, a concern meets the criteria provided in this section and which either the bidder or the exchange agreement which meets the requirements in subparagraph (1) (1) and (ii) of this paragraph may furnish the product of a refinery not qualified as small business if such product is obtained pursuant to an exchange agreement, in effect on the date of the bid or offer, between the bidder or offeror and the refinery, in effect on the date of the bid or offer, between the bidder or offeror and the refinery, of the product to be delivered to the Government which requires exchanges in a stated ratio on a refined-product-for-a-refined-product basis, and precludes a monetary settlement, and that the products exchanged for the products offered and to be delivered to the Government meet the requirements in subparagraph (1) (i) and (iii) of this paragraph; and, provided further, That the exchange of products for products to be delivered to the Government will be completed within 90 days after the expiration of the delivery period under the Government contract; and that any product furnished pursuant to a bona fide exchange agreement must be delivered in the same Petroleum Administration for Defense (PAD) District pursuant to Schedule C of Part 121, as that in which the refinery is located; or

(2) its number of employees does not exceed 500 persons and the product to be delivered to the Government has been refined by a concern which qualifies under subparagraph (1) (i) of this paragraph. The proviso that the product to be delivered in the performance of the contract will contain at least 90 percent components refined by the bidder from either crude oil or bona fide feed stocks; provided, however, That a petroleum refining concern which meets the requirements in subparagraph (1) (i) and (ii) of this paragraph may furnish the product of a refinery not qualified as small business if such product is obtained pursuant to an exchange agreement which meets the criteria which the contractor is primarily engaged in the logging or forest products industry; or

(1) Is independently owned and operated;
(2) Is not a multi-plant concern.

In the case of Government sales of timber reserved for or involving preferential treatment of small businesses, the term "sell" includes but is not limited to the exchange of sawlogs for raw logs on a product-for-product basis with or without monetary adjustments, 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 set-aside sales of timber. Under the latter circumstance, the contractor, which is primarily engaged in the logging or forest products industry, is considered to have a controlling interest in a concern after it has been awarded one or more set-aside sales of timber and it has already self-certified as a small business when:

(1) It is a small business within the meaning of subparagraph (1) (i) of this paragraph, and
(2) It agrees that it will not sell as 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 geographical areas set forth in Schedule D of this part, more than the percentage established therein for such area. The term "sell" includes but is not limited to the exchange of sawlogs for raw logs on a product-for-product basis with or without monetary adjustments, 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 set-aside sales of timber. Under the latter circumstance, the contractor, which is primarily engaged in the logging or forest products industry, is considered to have a controlling interest in a concern after it has been awarded one or more set-aside sales of timber and it has already self-certified as a small business when:

(1) It is a small business within the meaning of subparagraph (1) (i) of this paragraph, and
(2) It agrees that it will not sell as 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 geographical areas set forth in Schedule D of this part, more than the percentage established therein for such area.

(3) The term "sell" includes but is not limited to the exchange of sawlogs for raw logs on a product-for-product basis with or without monetary adjustments, 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 set-aside sales of timber. Under the latter circumstance, the contractor, which is primarily engaged in the logging or forest products industry, is considered to have a controlling interest in a concern after it has been awarded one or more set-aside sales of timber and it has already self-certified as a small business when:

(1) It is a small business within the meaning of subparagraph (1) (i) of this paragraph, and
(2) It agrees that it will not sell as 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 geographical areas set forth in Schedule D of this part, more than the percentage established therein for such area.

(4) The term "sell" includes but is not limited to the exchange of sawlogs for raw logs on a product-for-product basis with or without monetary adjustments, 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 set-aside sales of timber. Under the latter circumstance, the contractor, which is primarily engaged in the logging or forest products industry, is considered to have a controlling interest in a concern after it has been awarded one or more set-aside sales of timber and it has already self-certified as a small business when:

(1) It is a small business within the meaning of subparagraph (1) (i) of this paragraph, and
(2) It agrees that it will not sell as 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 geographical areas set forth in Schedule D of this part, more than the percentage established therein for such area.

(5) The term "sell" includes but is not limited to the exchange of sawlogs for raw logs on a product-for-product basis with or without monetary adjustments, 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 set-aside sales of timber. Under the latter circumstance, the contractor, which is primarily engaged in the logging or forest products industry, is considered to have a controlling interest in a concern after it has been awarded one or more set-aside sales of timber and it has already self-certified as a small business when:

(1) It is a small business within the meaning of subparagraph (1) (i) of this paragraph, and
(2) It agrees that it will not sell as 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 geographical areas set forth in Schedule D of this part, more than the percentage established therein for such area.

(6) The term "sell" includes but is not limited to the exchange of sawlogs for raw logs on a product-for-product basis with or without monetary adjustments, 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 set-aside sales of timber. Under the latter circumstance, the contractor, which is primarily engaged in the logging or forest products industry, is considered to have a controlling interest in a concern after it has been awarded one or more set-aside sales of timber and it has already self-certified as a small business when:

(1) It is a small business within the meaning of subparagraph (1) (i) of this paragraph, and
(2) It agrees that it will not sell as 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 geographical areas set forth in Schedule D of this part, more than the percentage established therein for such area.
business until the products have been manufactured. Accordingly, if, after acquiring the set-aside sale the bidder is purchased by, becomes controlled by, or merged with a large business, so much of such timber (if any) as is necessary shall be sold to one or more small businesses 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 under a small business set-aside sale of Government timber 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 the names, address, and size status of each concern whom the timber or sawlogs were sold or disposed, and the log species, grades, and volumes involved. Such concern, and any subsequent small business concern that acquires the sawlogs, also shall require its small business purchasers to maintain similar records for a period of 3 years. Further, if the timber purchased is not to be resold in the form of sawlogs, but is to be manufactured into lumber or timbers by a small business concern, the bidder must maintain records to show the name, address, and size status of the concern manufacturing the sawlogs into lumber or timbers.

§ 121.3-10 Definition of small business

A small business concern for the purpose of refinance of an SBA loan is a concern, including its affiliates, which, on the date of receipt of the loan application accepted by the SBA, is independently owned and operated, is not dominant in its field of operation, and can further qualify under the criteria set forth below, provided however, that a concern which applies for an SBA loan to refinance an existing SBA loan but which, since the date of the original financing, has by natural growth, as distinguished from merger, etc., grown to a size which exceeds the applicable size standard, is small for the purpose of refinancing if SBA administratively determines that refinancing is necessary to protect the Government's financial interest. A concern which is a small business concern under § 121.3-8 and which has applied for or received a Certificate of Competency is a small business eligible for an SBA loan to finance the contract covered by the Certificate of Competency. If no standard for an industry, field of operation, or activity has been set forth in this section, a concern seeking a size determination shall submit SBA Form 355 to the Assistant Administrator for Advocacy, and Engineering, and Technology, Washington, D.C. 20416, who shall determine what size standard shall be used or: an ad hoc basis until a size standard is established for sawlogs (therefore) as of activity. If an applicant for an SBA loan has external operating affiliates (i.e., affiliates which are primarily engaged in selling to the general public or to concerns other than the applicant concern or an affiliate thereof) and such external operating affiliates are engaged in industries subject to size standards different than that of the applicant concern the applicant concern's size status shall be determined by computing the percentage that the size of the applicant concern and its number of employees, including any internal operating affiliates (i.e., affiliates primarily engaged in selling to the applicant or an affiliate thereof) is of the size standard for the industry in which each external operating affiliate is primarily engaged; and adding to it the percentage that the size of each of its external operating affiliate is primarily engaged. In order for the applicant to be eligible under this provision, the total of such percentages must not exceed 150 percent of the applicable size standard for the industry in which such concern is primarily engaged, and its number of employees does not exceed 500 persons exclusive of agricultural labor as defined in subsection (c) of the Federal Employment Tax Act, 68 Stat. 454, 25 U.S.C. (I.R.C. 1955) 3306.

(c) Retail. Any retailing concern is classified:

(1) As small if it is primarily engaged in the food canning and preserving industry and its annual receipts do not exceed $2.5 million; (2) As small if it is primarily engaged in the shoe industry and its annual receipts do not exceed $2.5 million; (3) As small if it is primarily engaged in the restaurant industry and its annual receipts do not exceed $2.5 million; (4) As small if it is primarily engaged in the motion picture production industry and its annual receipts do not exceed $5 million; (5) As small if it is primarily engaged in owning and operating a hospital and its capacity does not exceed 150 beds (excluding cribs and bassinets); (6) As small if it is primarily engaged in owning and operating a convalescent or nursing home and its annual receipts do not exceed $1 million; (7) As small if it is primarily engaged in owning and operating a medical or dental laboratory and if it is operated in connection with an eligible proprietary hospital or clinic; (8) As small if it is operated in connection with an eligible proprietary hospital and its annual receipts do not exceed $1 million; (9) As small if it is primarily engaged in the motion picture exhibition industry and its annual receipts do not exceed $5 million; (10) As small if it is primarily engaged in rendering engineering services and its annual receipts do not exceed $2.5 million; (11) As small if, including its affiliates, it is primarily engaged in the generation, transmission, and/or distribution of electric energy for sale, and its total electric output for the preceding fiscal year did not exceed 4 million megawatt hours; (12) As small if it is primarily engaged in providing cable television service rental to homes, and its annual receipts do not exceed $2.5 million. (See 13 CFR 120.2(d) for SBA policy which bars concerns that originate programs from receiving financial assistance. This policy limitation is not applicable to small business investment company assistance.); (e) Shopping centers. (1) Any concern primarily engaged in operating shopping centers is small if (i) it does not have assets exceeding $5 million, (ii) it does not have net income in excess of $2.5 million, (iii) it does not have an average net income, after Federal income taxes, for the preceding 2 fiscal years in excess of $250,000 (average net income to be computed without benefit of any carryover loss), and (iv) it does not lease more than 25 percent of the gross leasable area to concerns which do not meet the concern size definitions contained in this section. (2) For the purpose of size determinations, shopping center operators will not be considered affiliated with their tenants merely because of lease agreements.
RULES AND REGULATIONS

(1) Transportation and warehousing. Any concern primarily engaged in passenger and freight transportation or warehousing is classified as:

(1) As small if its annual receipts do not exceed $1 million;
(2) As small if it is primarily engaged in the air transportation industry and its number of employees does not exceed 1,000 persons;
(3) As small if its annual receipts do not exceed the size standard established therein for that industry.

(2) As small if it is primarily engaged in trucking (local and/or long distance) and/or warehousing and/or packing and crating and/or freight forwarding and its annual receipts do not exceed $5 million.

(g) Wholesale. (1) Any wholesaling concern is classified as small if:

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

(h) Mining and mining services. Any mining or mining services concern primarily engaged in an industry set forth in Schedule F of this part is classified as small if its number of employees does not exceed the size standard established therein for that industry.

(i) Custom livestock feeding. Any concern primarily engaged in custom livestock feeding is classified as small if its annual receipts do not exceed $2 million.

(j) Agriculture production (crops), fish farming, and hatcheries, etc. Any concern primarily engaged in:

(1) In an industry set forth in Major Group 01—Agriculture Production—Crops (part of Standard Industrial Classification Industry No. 0278, Animal Specialties, Not Elsewhere Classified), (2) in the operation of a fish hatchery (part of Standard Industrial Classification Industry No. 0291, Fish Hatcheries and Preserves), (4) in the propagation of fur-bearing animals (part of Standard Industrial Classification Industry No. 1083, Fur, Furskins, and Related Products), (5) in the planting of oysters (part of Standard Industrial Classification Industry No. 1083, Shellfish), or (6) in the operation of hatcheries for chicks andpoults (Standard Industrial Classification Industry No. 0254, Poultry Hatcheries), where such hatchery operarion produces more than 50 percent of the poults hatched or retained by the operators for the production of broilers or turkeys for market, is classified as small if its annual receipts do not exceed $250,000.

§ 121.3-11 Definition of small business for assistance by small business investment companies or by development companies.

A small business concern for the purpose of receiving financial or other assistance from small business investment companies or development companies is one which:

(a) Together with its affiliates, is independently owned and operated, is not dominant in its field of operation, does not have assets exceeding $5 million, and does not have an average net income, after Federal Income taxes, for the preceding 2 years in excess of $200,000 (average net income to be computed without benefit of any carryover losses); or
(b) Qualifies as a small business concern under § 121.3-10.

§ 121.3-12 Definition of small business Government subcontractors.

(a) Any concern in connection with subcontractors of $1,000 or less which relate to Government procurements will be considered a small business concern if, including its affiliates, its number of employees does not exceed 500 persons.

(b) Any concern in connection with subcontractors exceeding $1,000 which relate to Government procurements will be considered a small business concern if it qualifies as such under § 121.3-8: Provided, however, That a nonmanufacturer is considered as small business for the purpose of Government subcontracting if, including its affiliates, its number of employees does not exceed 500 persons.

§ 121.3-13 Definition of small business for the purpose of lease guarantee.

A small business concern for the purpose of lease guarantee is defined as a small business under § 121.3-11.

§ 121.3-14 Definition of small business for the purpose of Government leases of uranium prospecting or mining rights.

In the submission of a bid or proposal for a Government lease of uranium prospecting or mining rights, a concern whose number of employees does not exceed 100 persons 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 validity of the self-certification at face value for the particular lease involved.

§ 121.3-15 Definition of small business for the purpose of surety bond guarantee assistance.

A small business concern for the purpose of surety bond guarantee assistance is defined as a small business under § 121.3-10, with the following exception:

(a) Construction. Any construction concern is small if its annual receipts for its preceding fiscal year or its average annual receipts for the preceding 3 fiscal years do not exceed $2 million: Provided, however, That, if the concern is primarily engaged in an industry set forth in Schedule F of this part, it is small if its annual receipts for its preceding fiscal year or its average annual receipts for its preceding 3 fiscal years do not exceed the maximum established therein for that industry.

Effective date: This revision shall become effective on December 24, 1974.

(All SBA programs listed in the Catalog of Federal Domestic Assistance Programs under Nos. 05.001—59.018.)


THOMAS S. KELLEFF, Administrator.

SCHEDULE A—Employment Size Standards for Concerns Primarily Engaged in Manufacturing

(These size standards are to be used when determining the status of applicant for SBA business loans, displaced business loans, economic opportunity loans, surety bond guarantee assistance, and other assistance for the Sections 7(a) and 8(a)(1) programs.)
<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Standard number (code)</th>
<th>Employment (number of employees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2271</td>
<td>Woven carpets and rug</td>
<td>700</td>
<td></td>
</tr>
<tr>
<td>2272</td>
<td>Twilled carpets and rug</td>
<td>600</td>
<td></td>
</tr>
<tr>
<td>2273</td>
<td>Carpets and rug, n.e.c.</td>
<td>600</td>
<td></td>
</tr>
<tr>
<td>2281</td>
<td>Yarn spinning, silk, cotton, worsted and silk</td>
<td>600</td>
<td></td>
</tr>
<tr>
<td>2294</td>
<td>Thread mills</td>
<td>600</td>
<td></td>
</tr>
<tr>
<td>2289</td>
<td>Tire cord and fabric</td>
<td>600</td>
<td></td>
</tr>
<tr>
<td>MAJOR GROUP 23—APPAREL AND CLOTHING PRODUCTS MADE FROM FABRICS AND SIMILAR MATERIALS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2221</td>
<td>Men's, youth's, and boys' clothing, except work shirts</td>
<td>300</td>
<td></td>
</tr>
<tr>
<td>MAJOR GROUP 24—FURNITURE AND FIXTURES</td>
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<td></td>
<td></td>
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<tr>
<td>2228</td>
<td>Metal office furniture</td>
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<tr>
<td>MAJOR GROUP 25—PAPER AND PAPERBOARD PRODUCTS</td>
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<td></td>
</tr>
<tr>
<td>2501</td>
<td>Pulp mills</td>
<td>750</td>
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<tr>
<td>2502</td>
<td>Paper mills, except building paper</td>
<td>750</td>
<td></td>
</tr>
<tr>
<td>2503</td>
<td>Paperboard mills</td>
<td>750</td>
<td></td>
</tr>
<tr>
<td>2504</td>
<td>Pallet coating and gluing</td>
<td>500</td>
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</tr>
<tr>
<td>2506</td>
<td>Bags, except molded paper</td>
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<tr>
<td>2507</td>
<td>Pressed and molded paper</td>
<td>600</td>
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<tr>
<td>2508</td>
<td>Sanitary paper products</td>
<td>500</td>
<td></td>
</tr>
<tr>
<td>2509</td>
<td>Stationery, tablets and related products</td>
<td>500</td>
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</tr>
<tr>
<td>2509</td>
<td>Conveyer paper and paperboard products, n.e.c.</td>
<td>500</td>
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</tr>
<tr>
<td>2510</td>
<td>Sanitary food containers</td>
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<td>2511</td>
<td>Building paper and building board</td>
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<td>MAJOR GROUP 26—CHEMICALS AND ALLIED PRODUCTS</td>
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<tr>
<td>2601</td>
<td>Alkalies and chlorine</td>
<td>1,000</td>
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<td>2603</td>
<td>Industrial gases</td>
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<td>Specialized inorganic pigments</td>
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<td>2609</td>
<td>Plastic materials, synthetic resins and nonvolatile elastomers</td>
<td>750</td>
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</tr>
<tr>
<td>2610</td>
<td>Synthetic rubber (volatile-base elastomers)</td>
<td>1,000</td>
<td></td>
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<tr>
<td>2611</td>
<td>Cellulose and related products</td>
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</tr>
<tr>
<td>2612</td>
<td>Synthetic organic fibers, except cellulose</td>
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</tr>
<tr>
<td>2613</td>
<td>Pharmaceutical preparations</td>
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</tr>
<tr>
<td>2614</td>
<td>Soap and other detergents, except soaps and detergents</td>
<td>500</td>
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</tr>
<tr>
<td>2615</td>
<td>Specialty cleaning, polishing, and maintenance equipment</td>
<td>600</td>
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</tr>
<tr>
<td>2616</td>
<td>Perfumes, cosmetics, and other toiletries</td>
<td>500</td>
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</tr>
<tr>
<td>2621</td>
<td>Gum and wood chemicals</td>
<td>600</td>
<td></td>
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<tr>
<td>2623</td>
<td>Cyclic (coal tar) pitches and cycle intermediates, dyestuffs, and organic pigments (tars and tars)</td>
<td>750</td>
<td></td>
</tr>
<tr>
<td>2624</td>
<td>Cyclic (coal tar) pitches and cycle intermediates, dyestuffs, and organic pigments (tars and tars)</td>
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<td>2701</td>
<td>Petroleum refining products</td>
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<td>Rubber and related products</td>
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<td>2703</td>
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<td>Varnishes and lacquers</td>
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<td>2802</td>
<td>Synthetic resins</td>
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<td>2902</td>
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</tr>
<tr>
<td>2903</td>
<td>Machinery, except mining</td>
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</tr>
<tr>
<td>2904</td>
<td>Mining machinery, n.e.c.</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>2905</td>
<td>Printing machinery</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>2906</td>
<td>Pumps and pumping equipment</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>2907</td>
<td>Mechanical power transmis-</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>2908</td>
<td>Tyre, rubber, and plastics</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>2909</td>
<td>Chemicals and allied products</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>2910</td>
<td>Mechanical equipment</td>
<td>1,000</td>
<td></td>
</tr>
<tr>
<td>2911</td>
<td>Electrical equipment</td>
<td>1,000</td>
<td></td>
</tr>
</tbody>
</table>

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size classification (number of employees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3813</td>
<td>Engineering, laboratory, medical and research equipment and associated equipment</td>
<td>500</td>
</tr>
<tr>
<td>3825</td>
<td>Instruments for measuring and testing of electricity and electrical signals</td>
<td>500</td>
</tr>
<tr>
<td>3830</td>
<td>Motors, electric, n.e.c.</td>
<td>500</td>
</tr>
<tr>
<td>3835</td>
<td>Electronics, n.e.c.</td>
<td>500</td>
</tr>
<tr>
<td>3840</td>
<td>Telephones and telegraph apparatus</td>
<td>500</td>
</tr>
<tr>
<td>3845</td>
<td>Telecommunications plastic, rubber, iron, steel, and other nonferrous metals</td>
<td>500</td>
</tr>
<tr>
<td>3850</td>
<td>Electric motors and generators</td>
<td>500</td>
</tr>
<tr>
<td>3855</td>
<td>Electric power apparatus</td>
<td>500</td>
</tr>
<tr>
<td>3860</td>
<td>Transformers, industrial and special purpose electron tubes</td>
<td>500</td>
</tr>
<tr>
<td>3870</td>
<td>Semiconductors and related products</td>
<td>500</td>
</tr>
<tr>
<td>3880</td>
<td>Electronic components, n.e.c.</td>
<td>500</td>
</tr>
<tr>
<td>3890</td>
<td>Cinematograph, television, and radar equipment</td>
<td>500</td>
</tr>
<tr>
<td>3900</td>
<td>Radiators</td>
<td>500</td>
</tr>
<tr>
<td>3910</td>
<td>Electrical machinery, equipment and supplies</td>
<td>500</td>
</tr>
</tbody>
</table>

**MAJOR GROUP 27—TRANSPORTATION EQUIPMENT**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size classification (number of employees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3921</td>
<td>Motor vehicle and passenger car bodies</td>
<td>1,000</td>
</tr>
<tr>
<td>3924</td>
<td>Motor vehicle and passenger car chassis</td>
<td>1,000</td>
</tr>
<tr>
<td>3925</td>
<td>Motor vehicles and parts</td>
<td>1,000</td>
</tr>
<tr>
<td>3931</td>
<td>Railway equipment</td>
<td>1,000</td>
</tr>
<tr>
<td>3932</td>
<td>Airplanes and parts</td>
<td>1,000</td>
</tr>
<tr>
<td>3933</td>
<td>Aircraft parts and auxiliary equipment, n.e.c.</td>
<td>1,000</td>
</tr>
<tr>
<td>3941</td>
<td>Railroad equipment</td>
<td>1,000</td>
</tr>
<tr>
<td>3942</td>
<td>Aircraft, n.e.c.</td>
<td>1,000</td>
</tr>
<tr>
<td>3943</td>
<td>Aircraft engines and engines parts</td>
<td>1,000</td>
</tr>
<tr>
<td>3944</td>
<td>Aircraft parts and auxiliary equipment, n.e.c.</td>
<td>1,000</td>
</tr>
</tbody>
</table>

**SCHEDULE B—INDUSTRY EMPLOYMENT SIZE STANDARDS FOR THE PURPOSES OF GOVERNMENT Procurement (Manufacturers)**

<table>
<thead>
<tr>
<th>Census classification code</th>
<th>Industry or class of products</th>
<th>Employment size classification (number of employees)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3800</td>
<td>Field yrs.</td>
<td>750</td>
</tr>
<tr>
<td>3802</td>
<td>Canned specialties</td>
<td>1,500</td>
</tr>
<tr>
<td>3811</td>
<td>Cereal breakfast foods</td>
<td>1,500</td>
</tr>
<tr>
<td>3814</td>
<td>Wht. meal</td>
<td>750</td>
</tr>
<tr>
<td>3816</td>
<td>Cabbage and cabbages</td>
<td>750</td>
</tr>
<tr>
<td>3818</td>
<td>Corn and corn products</td>
<td>750</td>
</tr>
<tr>
<td>3822</td>
<td>Flour</td>
<td>750</td>
</tr>
<tr>
<td>3823</td>
<td>Distilled, rectified, and blended liquors</td>
<td>750</td>
</tr>
</tbody>
</table>
### MAJOR GROUP 23—PRIMARY METAL INDUSTRIES

<table>
<thead>
<tr>
<th>Industry or class of products</th>
<th>Annual sales in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blast furnaces, including coke ovens, steelworks, and rolling-mills</td>
<td>$1,000</td>
</tr>
<tr>
<td>Iron and steel products</td>
<td>$1,000</td>
</tr>
<tr>
<td>Steel pipe and tubes</td>
<td>$1,000</td>
</tr>
<tr>
<td>Primary smelting and refining of copper</td>
<td>$1,000</td>
</tr>
<tr>
<td>Primary smelting and refining of lead</td>
<td>$1,000</td>
</tr>
<tr>
<td>Primary smelting and refining of aluminum</td>
<td>$1,000</td>
</tr>
<tr>
<td>Primary production of aluminum</td>
<td>$1,000</td>
</tr>
<tr>
<td>Primary smelting and refining of nonferrous metals, n.e.c.</td>
<td>$1,000</td>
</tr>
<tr>
<td>Rolling, drawing, and extruding of copper</td>
<td>$1,000</td>
</tr>
<tr>
<td>Aluminum sheets, plates, and foil</td>
<td>$1,000</td>
</tr>
<tr>
<td>Apparatus for recording magnetic tape</td>
<td>$1,000</td>
</tr>
<tr>
<td>Metal heating treatment</td>
<td>$1,000</td>
</tr>
<tr>
<td>Primary metal products, n.e.c.</td>
<td>$1,000</td>
</tr>
</tbody>
</table>

### MAJOR GROUP 24—FABRICATED METAL PRODUCTS, EXCEPT MACHINERY AND TRANSPORTATION EQUIPMENT

<table>
<thead>
<tr>
<th>Industry or class of products</th>
<th>Annual sales in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steel, gas, and turbines</td>
<td>$1,000</td>
</tr>
<tr>
<td>Internal combustion engines, n.e.c.</td>
<td>$1,000</td>
</tr>
<tr>
<td>Construction machinery and equipment</td>
<td>$1,000</td>
</tr>
<tr>
<td>Industrial trucks, tractors, trailers and stockers</td>
<td>$1,000</td>
</tr>
<tr>
<td>Writing materials</td>
<td>$1,000</td>
</tr>
<tr>
<td>Electrical appliances, except for motor vehicles</td>
<td>$1,000</td>
</tr>
<tr>
<td>Air conditioners and air heating equipment and components</td>
<td>$1,000</td>
</tr>
<tr>
<td>Refrigeration equipment</td>
<td>$1,000</td>
</tr>
</tbody>
</table>

### MAJOR GROUP 25—MACHINERY, EXCEPT ELECTRICAL

<table>
<thead>
<tr>
<th>Industry or class of products</th>
<th>Annual sales in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power, distribution, and specialty transformers</td>
<td>$1,000</td>
</tr>
<tr>
<td>Sewing machine</td>
<td>$1,000</td>
</tr>
<tr>
<td>Motors and generators</td>
<td>$1,000</td>
</tr>
<tr>
<td>Agricultural implements</td>
<td>$1,000</td>
</tr>
<tr>
<td>Carbon and graphite products</td>
<td>$1,000</td>
</tr>
<tr>
<td>Home and kitchen equipment</td>
<td>$1,000</td>
</tr>
<tr>
<td>Household refrigerators and household furniture</td>
<td>$1,000</td>
</tr>
<tr>
<td>Household laundry equipment</td>
<td>$1,000</td>
</tr>
<tr>
<td>Electric lighting and fans</td>
<td>$1,000</td>
</tr>
<tr>
<td>Household vacuum cleaners</td>
<td>$1,000</td>
</tr>
<tr>
<td>Sewing machines</td>
<td>$1,000</td>
</tr>
<tr>
<td>Electric lights</td>
<td>$1,000</td>
</tr>
<tr>
<td>Radio and television sets, except communication types</td>
<td>$1,000</td>
</tr>
<tr>
<td>Photographic and motion picture equipment and apparatus</td>
<td>$1,000</td>
</tr>
<tr>
<td>Radios and television type electron tubes, except cathode ray tubes</td>
<td>$1,000</td>
</tr>
</tbody>
</table>

### MAJOR GROUP 26—ELECTRICAL AND ELECTRONIC MACHINERY, EQUIPMENT, AND SUPPLIES

<table>
<thead>
<tr>
<th>Industry or class of products</th>
<th>Annual sales in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cathodes ray television picture tubes</td>
<td>$700</td>
</tr>
<tr>
<td>Transmission, industrial, and special purpose electron tubes</td>
<td>$700</td>
</tr>
<tr>
<td>Electrical insulation, except for electrical equipment, n.e.c.</td>
<td>$700</td>
</tr>
<tr>
<td>Transformers, except for electrical equipment, n.e.c.</td>
<td>$700</td>
</tr>
<tr>
<td>Electric machinery, n.e.c.</td>
<td>$700</td>
</tr>
<tr>
<td>Transformers and switchgear</td>
<td>$700</td>
</tr>
<tr>
<td>Electric motors and generators</td>
<td>$700</td>
</tr>
</tbody>
</table>

### SCHEDULE D—ANNUAL SALES AND STANDARDS FOR CONCERNs PRINCIPALLY ENGAGED IN RETAILING

(For the following size standards, see Act Report, the size standards apply only to the class of product designated.)

### MAJOR GROUP 27—MACHINERY, HOUSEHOLD FURNITURE, AND HOME FIXTURES

<table>
<thead>
<tr>
<th>Industry or class of products</th>
<th>Annual sales in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mobile homes</td>
<td>$1,000</td>
</tr>
</tbody>
</table>

### MAJOR GROUP 28—MEDICAL DEVICES

<table>
<thead>
<tr>
<th>Industry or class of products</th>
<th>Annual sales in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department stores</td>
<td>$1,000</td>
</tr>
<tr>
<td>Vending machines</td>
<td>$1,000</td>
</tr>
</tbody>
</table>

### MAJOR GROUP 29—AUTOMOTIVE DEVICES AND GASOLINE SERVICE STATIONS

<table>
<thead>
<tr>
<th>Industry or class of products</th>
<th>Annual sales in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Motor vehicle dealers (new and used)</td>
<td>$1,000</td>
</tr>
<tr>
<td>Motor vehicle dealers (used only)</td>
<td>$1,000</td>
</tr>
<tr>
<td>Aircraft (not automobiles) dealers</td>
<td>$1,000</td>
</tr>
</tbody>
</table>

### MAJOR GROUP 30—APPAREL AND ACCESSORY GOODS

<table>
<thead>
<tr>
<th>Industry or class of products</th>
<th>Annual sales in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men's and boys' clothing and furnishings stores</td>
<td>$1,000</td>
</tr>
<tr>
<td>Women's clothing stores</td>
<td>$1,000</td>
</tr>
<tr>
<td>Girls' clothing stores</td>
<td>$1,000</td>
</tr>
<tr>
<td>Boys' clothing stores</td>
<td>$1,000</td>
</tr>
</tbody>
</table>
Title 14—Aeronautics and Space
CHAPTER I—FEDERAL AVIATION ADMINISTRATION

PART 39—AIRWORTHINESS DIRECTIVES

Boscoing 707/720 Series Airplanes

Amendment 39-236 EFR 12003, AD 69-18-3 requires inspection of the wing center section upper forward skin panels for cracks and repair as necessary, on Boeing model 707/720 series airplanes.

Recently, the FAA has been requested to provide compliance times in terms of flights as an option to the original compliance times which were stated in the Amendment in terms of hours of total-time-in-service.

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 hearing 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 13077) § 35.13 of Part 39 of the Federal Aviation regulations, Amendment 39-236 EFR 12003, AD 69-18-3 is amended as follows:

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

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

<table>
<thead>
<tr>
<th>Hours of Flight</th>
<th>Equivalency to Flights</th>
</tr>
</thead>
<tbody>
<tr>
<td>600 hours or 300 flights</td>
<td>1200 hours or 600 flights</td>
</tr>
<tr>
<td>1000 hours or 500 flights</td>
<td>2400 hours or 1200 flights</td>
</tr>
<tr>
<td>1500 hours or 750 flights</td>
<td>3600 hours or 1800 flights</td>
</tr>
<tr>
<td>2000 hours or 1000 flights</td>
<td>4800 hours or 2400 flights</td>
</tr>
<tr>
<td>2500 hours or 1250 flights</td>
<td>6000 hours or 3000 flights</td>
</tr>
<tr>
<td>3000 hours or 1500 flights</td>
<td>7200 hours or 3600 flights</td>
</tr>
<tr>
<td>3500 hours or 1750 flights</td>
<td>8400 hours or 4200 flights</td>
</tr>
<tr>
<td>4000 hours or 2000 flights</td>
<td>9600 hours or 4800 flights</td>
</tr>
<tr>
<td>4500 hours or 2250 flights</td>
<td>10800 hours or 5400 flights</td>
</tr>
<tr>
<td>5000 hours or 2500 flights</td>
<td>12000 hours or 6000 flights</td>
</tr>
<tr>
<td>5500 hours or 2750 flights</td>
<td>13200 hours or 6600 flights</td>
</tr>
<tr>
<td>6000 hours or 3000 flights</td>
<td>14400 hours or 7200 flights</td>
</tr>
</tbody>
</table>

For purposes of this paragraph, one flight is defined as one takeoff and landing.

(n) For the purposes 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.


C. B. Wall, Jr.,
Director, Northwest Region.

[FR Doc. 74-23991 Filed 12-23-74; 8:45 am]
RULES AND REGULATIONS

PART 39—AIRWORTHINESS DIRECTIVES

Certain AIResearch Engines.

There have been failures of the high speed pinion (HSP) gear bearing assembly and/or of the pinion gear bearing carrier 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, it is appropriate that these failures be investigated to determine whether or not a modification of the HSP gear bearing carrier bolts and/or failure of the oil transfer tube support bracket. This amendment becomes effective in less than 30 days.

In consideration of the foregoing, and pursuant to the authority delegated to the Administrator of Part 121.360, good cause exists for making this amendment effective in less than 30 days.

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 (turboprop and turboprop) used in operations under Part 121. These amendments also apply to air travel clubs certified under Part 132 and to air taxi operators certified under Part 135, when conducting operations governed by those parts with large turbine-powered airplanes.

Interested persons have been afforded an opportunity to participate in the making of this amendment by a Notice of Proposed Rule Making (Notices 74-32 and 74-33) issued on September 12, 1974 (published in the Federal Register on September 16, 1974; 39 FR 32334), as amended by Notice 74-32A, issued October 1, 1974 (published in the Federal Register on October 7, 1974; 39 FR 30107). Due consideration has been given to all comments presented in response to the notice. Except for editorial changes, and except as specifically discussed hereinafter, these amendments and the reasons therefor are the same as those in Notice 74-32.

Of the 31 public comments received in response to Notices 74-32, 18 favored the adoption of the proposed rule. Some commentators recommended changes that are discussed hereinafter. Several commentators made suggestions that were not within the scope of the notice, and, accordingly, these comments are not discussed, but will be retained by the FAA for future study.

In light of recent air carrier accidents involving large turbine-powered airplanes caused by inadvertent contact with the ground, the FAA believes that present instrumentation, including altitude alerting systems, and appropriate in-flight procedures. The FAA believes that present instrumentation and in-flight procedures provide for safe and adequate terrain clearance as long as proper flight crewmember discipline is maintained and appropriate flight operations procedures are followed. 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 warning of the impending disaster to the flight crew.

Several commentators pointed out that the warning system should operate during non-precision approaches. The FAA agrees, and any system for which approval is sought under § 121.260 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 be required, since it could distract the pilot from taking corrective action. For the reasons stated in Notice 74-32, the FAA believes that a ground proximity warning system should provide automatic and distinct aural and visual warnings with no required input from the flight crew, and that it should operate continuously as long as a terrain
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 capability of 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 and the 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 jet-powered airplanes and 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 indicated that the proposed warning system requirement 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 all other aircraft systems. It was not the intent of the FAA to preclude the integration of such a warning system with other aircraft systems when compatibility exists.

Certain commentators pointed out that the requirement §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 appropriate in the light of the capability of radio altimeters presently in use in large turbopropeller-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. 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 intends to 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 §121.359(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(c) would have prohibited the operation of a large turbopropeller-powered airplane under Part 121 6 months after the effective date of the amendment unless it had been equipped with a radio altimeter 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 shortcomings of such a system, the FAA is of the opinion that such provisions the implementation 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 §121.260 has been added to §121.303(d)(2). This will prohibit the takeoff of any large turbopropeller-powered airplane being operated under Part 121 unless the ground proximity warning system required by §121.360 is in operational condition. However, if §121.360(c) would 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 flights are included in the certificate holder’s manual.

(Secs. 319(a), 601, 603, and 606 of the Federal Aviation Act of 1958; 49 U.S.C. 1354(a), 1421, 1433, and 1436, Sec. 6(c) of the Department of Transportation Act; 49 U.S.C. 1655(e))

In consideration of the foregoing, and for the reasons stated in Nollage 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.

1. By amending paragraph (d) (2) of §121.303 by deleting the phrase “and 121.259” 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 turbopropeller-powered airplane unless it is equipped with an approved ground proximity warning system that is designed, constructed, and installed 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—

(i) Initiate simultaneously and are distinct from each warning provided by any other aural or visual device

(ii) Initiate automatically without any crewmember action; and

(3) Provide warnings based on the—

(i) Rate of descent of the aircraft (including any negative rate of climb after takeoff) in relation to the height of the aircraft above the terrain directly beneath the aircraft;

(ii) Computed height of the aircraft above the terrain along the aircraft’s projected flight path;

(iii) Landing gear and flap positions of the aircraft; and

(iv) Performance capability of the aircraft.

Issued in Washington, D.C., on December 18, 1974.

ALEXANDER P. BUTTERFIELD, Administrator.

[FR Doc.74-20052 Filed 12-23-74; 8:45 am]

CHAPTER II—CIVIL AERONAUTICS BOARD

SUBCHAPTER A—ECONOMIC REGULATIONS

[Reg. ER-691, Amdt. 27]

PART 298—CLASSIFICATION AND EXEMPTION OF AIR TAXI OPERATORS

Revising Form 298-A and Related Instructions for its Use

Adopted by the Civil Aeronautics Board at its office in Washington, D.C., October 31, 1974; effective January 23, 1975.

Subpart E of Part 298 of the Economic Regulations requires air taxi operators to register with the Board, to re-register biennially, and to notify the Board of any change in operations. The within amendment to §298.50 will require the air taxi operator, at the time of registration or reregistration, to list on Form 298-A the address and telephone number of the operator's local FAA office. This amendment to §298.50 will require the operator to use this same Form 298-A in reporting to the Board any change in his name, address or type of operations.

We are also taking this opportunity to effect certain technical changes in §298.50, including deletion of obsolete provisions relating to the reporting of aircraft with maximum payload capacities between 5,000 and 5,500 pounds, and to revise Form 298-A as to reflect such changes and otherwise simplifying it.

Since the amendments provided for herein are rules of agency procedure and practice, and impose no significant burden on any person, the Board finds that notice and public procedure are unnecessary.

In consideration of the foregoing, the Board hereby amends Part 298 of the

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1 Which is no longer required, see ER-691, dated June 21, 1974, 30 FR 23904, June 28, 1974.

2 CAB Form 298-A is filed as part of the original document hereof and can be obtained from the Publications Service Section, Civil Aeronautics Board, Washington, D.C. 20423.
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 certifying officer and the certifying officer’s 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 operate (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 during 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, as the case may be. This 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. 20438, on CAB Form 298-A, of any change in his name or address, or of any change in his type of operations (passenger, cargo, mail, scheduled, etc.) or of his temporary or permanent cessation of operations. Such notification shall be mailed, or otherwise delivered, so as to be 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 33-4A, 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 this 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 JASZ, Director, Bureau of Economic Analysis.

[FR Doc. 74-30005 Filed 12-23-74; 8:45 a.m.]

Title 23—Highways

CHAPTER I—FEDERAL HIGHWAY ADMINISTRATION, DEPARTMENT OF TRANSPORTATION

SUBCHAPTER H—RIGHT-OF-WAY AND PROJECTS

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 23969), the Federal Highway Administration (FHWA) published a notice of proposed rulemaking containing air quality guidelines. These guidelines were required to implement section 138(b) of the Federal-Aid Highways Act of 1956 (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 of 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 the 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 B—Air Quality Guidelines

Sec.

770.220 Purpose.

770.230 Definitions.

770.233 Application.

770.235 Urban Transportation Plans and Programs.

770.237 Highways Sections.

770.239 Construction of Highways.


§ 770.220 Purpose.

To issue policy and procedures covering air quality guidelines for use in planning, location, and construction of highway improvements pursuant to 23 U.S.C. 1857.

§ 770.230 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 Administrator of 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 303(b) of the Clean Air Act of 1970).


(e) Highway 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 multicylar highway improvement program.

(g) Indirect source review agency. The agency designated in an applicable State implementation plan to meet the requirements of 40 CFR 51.15 (38 FR 15834, June 18, 1973).

(h) National Ambient Air Quality Standards. The National Ambient Air Quality Standards.
Quality Standards established pursuant to 42 U.S.C. 1857 (Section 109 of the Clean Air Act of 1970) require the processing of an EIS.

(i) Policy Board (Policy Committee, Coordinating Committee, etc.). That group of Federal, State, and local officials or representatives of agencies or organizations which has been designated by the State to provide policy guidance and direction in the conduct of the urban transportation planning process in an urbanized area.

(k) Urban transportation planning process (3C planning process). The continuing, comprehensive, and cooperative planning process established pursuant to 23 U.S.C. 134.

(i) State implementation plan (SIP). The plan required by 42 U.S.C. 1857 (Section 110 of the Clean Air Act of 1970) to attain and maintain a national ambient air quality standard. For the purpose 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.

(m) Urban transportation plans and programs. Proposed area-wide plans and proposed capital improvement programs developed through the urban transportation planning process.

§ 770.202 Policy.

It is the policy of the Federal Highway Administration (FHWA) that highway agencies responsible for the planning, location, and construction of highways pursuant to 23 U.S.C. consult with the local, State, and Federal air pollution control agencies, as appropriate, and assure that decisions on highways are consistent with approved State implementation plans and that adequate consideration is given to preservation and enhancement of air quality.

§ 770.203 Application.

Land use, air quality, and transportation planning are interdependent. It is, therefore, essential that planning activities be closely coordinated in the conceptual stages and throughout the highway development process. The highway agency shall follow the appropriate procedures outlined in § 770.204 through § 770.206 in order to assure that the planning, location, and construction of highways are consistent with the approved State implementation plan for attainment and maintenance of air quality standards.

(a) The continuing review procedure described in § 770.204 shall be a requirement for each transportation planning process established pursuant to 23 U.S.C. 134.

(b) The procedures for consideration of air quality described in § 770.205 shall apply to the processing of Federal-aid highway proposals.

(c) The procedures described in § 770.205 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 planning conducted pursuant to 23 U.S.C. 134 and air quality planning conducted pursuant to 42 U.S.C. 1857 and the transportation plans resulting therefrom are coordinated, the responsible highway agency in cooperation with each 3C planning agency shall establish a continuing review procedure with the air pollution control agency to:

(1) Assess the consistency of the transportation plan and program with the approved State implementation plan;

(2) Solicit comments annually from the air pollution control agency including its assessment of the consistency of the transportation plan and program with the approved State implementation plan prior to transportation plan approval by the policy board; and

(3) Identify and attempt to resolve differences with the air pollution control agency.

(b) The highway agency shall request the policy board to annually determine the consistency of the current transportation plan and program with the approved State implementation plan. The highway agency shall furnish FHWA a record of this determination along with any written comments received from the air pollution control agency and the policy board's disposition of these comments.

(c) The Regional Federal Highway Administrator, in consultation with the Regional Administrator of the Environmental Protection Agency, shall annually:

(1) Assess the degree of coordination in the planning process between planning for transportation and air quality planning; and

(2) Review the determination on consistency between the transportation plan and program and the approved State implementation plan.

(d) Any deficiencies shall be cited to the highway agency. Significant deficiencies (including major instances of inconsistency) shall be considered by the Regional Federal Highway Administrator as grounds for withholding planning certification.

§ 770.205 Highway 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 both 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 on-site measurements 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 involved in the development of the highway proposal. For highway sections subject to the requirements of 40 CFR 51.18, "Review of New Sources and Modifications," the negative declaration shall also include a record of consultation with the indirect source review agency. The FHWA Division Engineer shall review the air quality information in the negative declaration for adequacy. A negative declaration shall constitute the FHWA determination that the highway is considered to be consistent with the approved State implementation plan.

(3) For highway sections on which a draft EIS is prepared, the draft shall contain:

(1) An identification of the air quality impact of the highway section;

(2) An identification of the analysis methodology utilized;

(3) A brief summary of the early consultation with the air pollution control agency and, where applicable, a brief summary of consultation with the indirect source review agency;

(4) Any comments received from the air pollution control agency and, where applicable, any comments received from the indirect source review agency; and

(5) The highway agency's determination on the consistency of each alternative under consideration with the approved State implementation plan.

(4) Where required by 40 CFR 51.16, 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 as a part of the procedures established pursuant to 40 CFR 51.18 that the highway section will result in a violation of applicable portions of the control strategy or will interfere with the attainment or maintenance of the National Ambient Air Quality Standards.

(5) The final EIS may be adopted by the FHWA only after FHWA has determined that the proposed highway section is consistent with the approved State implementation plan. A determination on consistency shall be made by the Regional Federal Highway Administrator.
(6) 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.

(7) The Regional Federal Highway Administrator shall furnish the results of any consultation with the EPA Regional Administrator on the final EIS and the FHWA determination on consistency in the transmitted information for those final environmental impact statements which require review by FHWA Headquarters.

(b) 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 shall be prepared under the provisions of 12 U.S.C. 757, 39, and 31677 or where a substantial amount of the grade and drain work has been authorized prior to the effective date of this directive.

§ 770.206 Construction of Highways.

(a) The highway agency shall take steps to assure that its current specifications, and any revisions thereof and the use of specific equipment and/or materials associated with construction are consistent with the approved State Implementation Plan. Where the Regional Federal Highway Administrator has made a consistency determination in accordance with the regulations (23 CFR 770, 39, 31677) or where a substantial amount of the grade and drain work has been authorized prior to the effective date of this directive.

(b) The Regional Federal Highway Administrator may request preparation and processing of a revised or supplemental EIS for the highway section where, in his judgment, the air quality issues raised are 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 12 of the “Environmental Impact and Related Statements.”


Effective Date. This amendment is effective December 26, 1974.

Issued on December 16, 1974.

ROBERT T. TIEBEN,
Federal Highway Administrator.

[FR Doc.74-29501 Filed 12-23-74; 8:45 am]

FEDERAL REGISTER, VOL 39, NO. 248—TUESDAY, DECEMBER 24, 1974
Title 26—Internal Revenue
CHAPTER I—INTERNAL REVENUE SERVICE, DEPARTMENT OF THE TREASURY
[TD. 7358]
PART I—INCOME, ESTATE AND INHERITANCE TAXES, TAXES ON EXCESS PROCEEDS OF DEATH, AND SOCIAL SECURITY AND MEDICARE TAXES
CHAPTER 2—SOCIAL SECURITY AND MEDICARE TAXES
SUBCHAPTER A—GENERAL PROVISIONS
Sec. 420, 421), and section 204 (a)
of the Act of 1974,
502(b) of the Social Security Amendments of 1967 (81 Stat. 838, 841, 843, 844, 844), 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, 420, 421), and section 155 (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 certain employees of certain private tax-exempt organizations. After consideration of all relevant matter as was presented by interested persons regarding the rules proposed, certain changes were made.
The proposed amendments to the regulations, as revised, including an amendment to the Income Tax Regulations 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. 838, 841, 843, 844, 844), 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, 420, 421), and section 155 (a) (1) and (b) (1) of the Social Security Amendments of 1972 (86 Stat. 1362, 1363) was published in the Federal Register (38 FR 17727). After consideration of all relevant matter as was presented by interested persons regarding the proposed rules, the amendment of the Income Tax Regulations under sections 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. 955), relating to the rate of tax on self-employment income for purposes of hospital insurance, are adopted by this document.

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(i) 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 a 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 the social security program extend 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 services. To qualify for the exemption an individual must be opposed to, or because of religious principles be opposed to, the acceptance (with respect to service performed by him in his capacity as such minister, member, or (Christian Science practitioner) of any public insurance which makes 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 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 4361, 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 performed 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 performing service for a State or a political subdivision in a position compensated solely on a fee basis. In general, the rules of the proposed regulations on this subject, are identical to the tentative change, except that section 1.1402(c)-2 (a) (2), describing certain covered officials, has been reserved 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 provided they are designed to assure that the payments are bona fide retirement income are met. 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 Tax 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, and the purpose of these changes was to prevent the imposition of a double tax burden on an individual with respect to hospital insurance. Adoption of amendments to the regulations is approved.

On July 3, 1973, a notice of proposed rule making with respect to the Income Tax Regulations (36 FR 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. 838, 841, 843, 844, 844), 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, 420, 421), and section 155 (a) (1) and (b) (1) of the Social Security Amendments of 1972 (86 Stat. 1362, 1363) was published in the Federal Register (38 FR 17727). After consideration of all relevant matter as was presented by interested persons regarding the proposed rules, the amendment of the Income Tax Regulations under sections 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. 954), and section 6(b) (1) of the Act of December 31, 1973 (Pub. L. 93-233, 87 Stat. 955).

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), as set forth in paragraph 9 below, is amended by revising paragraph (b) (1) (1) and (2) (2) and the examples in paragraphs (b) (2) (3) (ii) and (c).

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

Paragraph 6. Section 1.1402(c) (4), 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 7805 of the Internal Revenue Code of 1964 (68A Stat. 917; 26 U.S.C. 7805).)

[TD. 72323]

DONALD C. ALEXANDER,
Commissioner of Internal Revenue.
Approved: December 16, 1974.

FREDERICK RICKMAN,
Assistant Secretary of the Treasury.

[FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974]
§ 1.1402(a)-1 Definition of net earnings from self-employment. 

(a) Subject to the special rules set forth in §§ 1.1402(a)-3 to 1.1402(a)-7, inclusive, and to the exclusions provided in §§ 1.1402(c)-2 to 1.1402(c)-7, inclusive, the term "net earnings from self-employment" means---

(b) Hospital insurance. * * *

(2) In the case of any taxable year beginning after December 31, 1966, and before January 1, 1970, the tax shall be equal to 1.50 percent of the amount of the self-employment income for such taxable year; and

(4) The term "aggregate net earnings," as used in § 1.1402(a)-1, shall be equal to all income from any trade or business, including any income derived from employment as a partner in a partnership, the self-employment income from which is derived from services performed for an employer (as defined in section 1391(c)) and is paid to an individual who is a member of a religious order and is engaged in the performance of religious activities.

(5) In the case of any taxable year beginning after December 31, 1966, and before January 1, 1970, the tax shall be equal to 0.9 percent of the amount of the self-employment income for such taxable year; and

(6) In the case of any taxable year beginning after December 31, 1985, the tax shall be equal to 1.50 percent of the self-employment income for such taxable year.

(7) The term "aggregate net earnings," as used in § 1.1402(a)-1, shall be equal to the total income derived from any trade or business, including any income derived from services performed for an employer (as defined in section 1391(c)) and is paid to an individual who is a member of a religious order and is engaged in the performance of religious activities.

(8) The term "aggregate net earnings," as used in § 1.1402(a)-1, shall be equal to all income from any trade or business, including any income derived from services performed for an employer (as defined in section 1391(c)) and is paid to an individual who is a member of a religious order and is engaged in the performance of religious activities.

(9) The term "aggregate net earnings," as used in § 1.1402(a)-1, shall be equal to all income from any trade or business, including any income derived from services performed for an employer (as defined in section 1391(c)) and is paid to an individual who is a member of a religious order and is engaged in the performance of religious activities.

(10) The term "aggregate net earnings," as used in § 1.1402(a)-1, shall be equal to all income from any trade or business, including any income derived from services performed for an employer (as defined in section 1391(c)) and is paid to an individual who is a member of a religious order and is engaged in the performance of religious activities.

§ 1.1402(a)-2 Computation of net earnings from self-employment.

(a) Aggregate net earnings. Where an individual is engaged in more than one trade or business, the aggregate net earnings from self-employment shall be determined as provided in section 702(a)(9), from any 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 his partnership, see section 703.

(b) 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 1.1402(a)-1 to 1.1402(a)-7, inclusive, and to the exclusions provided in section 1.1402(c)-2 to 1.1402(c)-7, inclusive.

(c) Gross income. For provisions relating to the computation of the taxable income of a partnership, see section 703.

§ 1.1402(a)-3 Special rules for computing net earnings from self-employment.

For the purpose of computing net earnings from self-employment, the gross income derived by an individual from a trade or business carried on by him, the allowable deductions attributable to such trade or business, and the individual's distributive share of the income or loss, described in section 702(a)(9), from any trade or business carried on by a partnership of which he is a member shall be computed in accordance with the special rules set forth in §§ 1.1402(a)-4 to 1.1402(a)-7, inclusive.
§ 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 ending 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 on account of retirement. The exclusion applies only if the payments are made pursuant to a plan which meets the requirements prescribed in paragraph (b) of this section, and, in addition, the conditions set forth 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 retirement. To qualify as payments on account of retirement, the payments must constitute bona fide retirement income. Thus, payments of benefits not customarily included in a pension or retirement plan such as layoff benefits are not payments on account of retirement. Eligibility for retirement generally is established on the basis of age, physical condition, or a combination of age or physical condition and years of service. Generally, retirement benefits are measured by, and based on, such factors as years of service and compensation received. In determining whether the plan of the partnership provides for payments on account of retirement, factors, formulas, etc., reflected in public, and in broad based private, pension or retirement plans in prescribing eligibility requirements and in computing benefits may be taken into account.

(2) The plan of the partnership must provide for payments on account of retirement—

(i) To partners generally or to a class or classes of partners,

(ii) On a periodic basis, and

(iii) Which continue at least until the partner's death.

For purposes of subdivision (i) of this subparagraph, a class of partners may, in an appropriate case, contain only one member. Payments are made on a periodic basis if made at regularly recurring intervals (usually monthly) not exceeding one year.

(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, for purposes of section 1402(a) (10).

(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 except with respect to retirement payments under the plan or rights such as benefits payable on account of sickness, accident, hospitalization, medical expenses, or death; and

(iii) The retired 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 or with his taxable year are excluded or none of the payments are excluded. Subdivision (ii) of this subparagraph has application only to obligations from the other partners as distinguished from an obligation 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 subdivisions (ii) and (iii) of this subparagraph is that the exclusion may apply with respect to payments received by a retired partner during the taxable year of the partnership ending within or with his taxable year only if at the close of the partnership's taxable year the retired partner had no financial interest in the partnership except for the right to retirement payments.

(2) Examples—The application of subparagraph (1) of this paragraph may be illustrated by the following examples.

Example (1). A, who files his income tax returns 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, are not excluded from net earnings from self-employment since A rendered service to the partnership during a portion of the partnership's taxable year (July 1, 1971, through June 30, 1973) which ends within A's taxable year ending on December 31, 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 December 31, 1972 and December 31, 1973. 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 (other than with respect to retirement payments under the plan) from the other partners to D have been liquidated, and D's share of the capital of the partnership has been paid to him in full. Retirement payments received by D pursuant to the partnership's plan in his taxable year ending December 31, 1973, are excluded from 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 percentage of any amounts collected by the partnership from clients of the partnership, paid to him prior to his retirement for clients of the partnership. The amounts collected from clients of the partnership in his taxable year ending December 31, 1973, are not excluded from net earnings from self-employment for taxable years ending after that date which are attributable to services rendered by him prior to his retirement for clients of the partnership. The amount so excluded is treated as a payment under the plan for purposes of subdivision (i) of this subparagraph.
For taxable years ending on or after December 31, 1963, wages as defined in subparagraph (3) (iii) of this paragraph, are taken into account in determining the maximum self-employment income of an individual for purposes of section 1401 (b) (hospital insurance), but not for purposes of the tax imposed under section 1401 (a) (old-age, survivors, and disability insurance). The maximum self-employment income of an individual is paid wages as defined in subparagraph (3) (iii) of this paragraph in a taxable year, his maximum self-employment income for such taxable year for purposes of the tax imposed under section 1401 (b) is the excess of his section 1401 (a) maximum self-employment income over the amount of wages, as defined in subparagraph (3) (ii) of this paragraph, paid to him during the taxable year. For purposes of this subdivision, wages as defined in subparagraph (3) (ii) of this paragraph are deemed paid to an individual in the period with respect to which the payment is made, that is, the period in which the compensation was earned or deemed earned within the meaning of section 3301 (c). For an explanation of the term "compensation" and for provisions relating to when compensation is earned, see the regulations under section 3301 (c) in Part 31 of this chapter (Employment Tax Regulations). The application of the rules set forth in this subdivision may be 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 3301 (a) (see subparagraph (3) (i) of this paragraph) and $1,000 of compensation subject to tax under section 3301 (see subparagraph (3) (ii) of this paragraph). The amount of the tax on the $1,200 of taxable compensation, $1,200 represents compensation for services rendered in 1974 and during the taxable year and the amount of the compensation which pursuant to the provisions of section 3301 (c) is earned or deemed earned during 1974, M's maximum self-employment income for 1974 for purposes of the tax imposed under section 1401 (a) and the tax imposed under section 1401 (b) is $12,200 ($13,200 - $1,000), and for purposes of the tax imposed under section 1401 (b) is $11,200 ($12,200 - $1,000). However, if M compensates $15,000 of his maximum self-employment income for 1974 for purposes of the tax imposed under section 1401 (b) is $12,200 ($13,200 - $1,000), and for purposes of the tax imposed under section 1401 (b) is $11,200 ($12,200 - $1,000). However, if M may compensate his maximum self-employment income for 1974 for purposes of the tax imposed under section 1401 (b) by taking into account the $400 of compensation which is deemed paid in 1973.

(3) Meaning of term "wages". For the purpose of the computation described in subparagraph (2) of this paragraph, the term "wages" includes:

(a) Wages as defined in section 3301 (a); and

(b) Wages as defined in section 3301 (a) (see subparagraph (3) (i) of this paragraph), he has $12,200 ($13,200 - $1,000) of self-employment income for the taxable year.

(3) Special rules. (i) If an individual is paid wages as defined in subparagraph (3) (i) or (ii) of this paragraph in a taxable year, the maximum self-employment income of such individual for such taxable year is the excess of the amounts indicated in subparagraph (1) of this paragraph over the amount of the wages, as defined in subparagraph (2) (i) and (ii) of this paragraph, paid to him during the taxable year. For example, if for his taxable year beginning in 1974, an individual has $15,000 of net earnings from self-employment and during such taxable year is paid $1,000 of wages as defined in section 3121 (a) (see subparagraph (3) (i) of this paragraph), he has $12,200 ($13,200 - $1,000) of self-employment income for the taxable year.

(ii) If an individual is paid wages as defined in subparagraph (3) (i) or (ii) of this paragraph in a taxable year, the maximum self-employment income of such individual for such taxable year is the excess of the amounts indicated in subparagraph (1) of this paragraph over the amount of the wages, as defined in subparagraph (2) (i) and (ii) of this paragraph, paid to him during the taxable year. For example, if for his taxable year beginning in 1974, an individual has $15,000 of net earnings from self-employment and during such taxable year is paid $1,000 of wages as defined in section 3121 (a) (see subparagraph (3) (i) of this paragraph), he has $12,200 ($13,200 - $1,000) of self-employment income for the taxable year.

(iii) For taxable years ending on or after December 31, 1963, wages, as defined in subparagraph (3) (iii) of this paragraph, are taken into account in determining the maximum self-employment income of an individual for purposes of section 1401 (b) (hospital insurance), but not for purposes of the tax imposed under section 1401 (a) (old-age, survivors, and disability insurance). The maximum self-employment income of an individual is paid wages as defined in subparagraph (3) (iii) of this paragraph in a taxable year, his maximum self-employment income for such taxable year for purposes of the tax imposed under section 1401 (b) is the excess of his section 1401 (a) maximum self-employment income over the amount of wages, as defined in subparagraph (3) (ii) of this paragraph, paid to him during the taxable year. For purposes of this subdivision, wages as defined in subparagraph (3) (ii) of this paragraph are deemed paid to an individual in the period with respect to which the payment is made, that is, the period in which the compensation was earned or deemed earned within the meaning of section 3301 (c). For an explanation of the term "compensation" and for provisions relating to when compensation is earned, see the regulations under section 3301 (c) in Part 31 of this chapter (Employment Tax Regulations). The application of the rules set forth in this subdivision may be 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 3301 (a) (see subparagraph (3) (i) of this paragraph) and $1,000 of compensation subject to tax under section 3301 (see subparagraph (3) (ii) of this paragraph). The amount of the tax on the $1,200 of taxable compensation, $1,200 represents compensation for services rendered in 1974 and during the taxable year and the amount of the compensation which pursuant to the provisions of section 3301 (c) is earned or deemed earned during 1974, M's maximum self-employment income for 1974 for purposes of the tax imposed under section 1401 (a) and the tax imposed under section 1401 (b) is $12,200 ($13,200 - $1,000), and for purposes of the tax imposed under section 1401 (b) is $11,200 ($12,200 - $1,000). However, if M may compensate his maximum self-employment income for 1974 for purposes of the tax imposed under section 1401 (b) by taking into account the $400 of compensation which is deemed paid in 1973.

(3) Meaning of term "wages". For the purpose of the computation described in subparagraph (2) of this paragraph, the term "wages" includes:

(a) Wages as defined in section 3301 (a); and

(b) Wages as defined in section 3301 (a) (see subparagraph (3) (i) of this paragraph), he has $12,200 ($13,200 - $1,000) of self-employment income for the taxable year.

(i) If an individual is paid wages as defined in subparagraph (3) (i) or (ii) of this paragraph in a taxable year, the maximum self-employment income of such individual for such taxable year is the excess of the amounts indicated in subparagraph (1) of this paragraph over the amount of the wages, as defined in subparagraph (2) (i) and (ii) of this paragraph, paid to him during the taxable year. For example, if for his taxable year beginning in 1974, an individual has $15,000 of net earnings from self-employment and during such taxable year is paid $1,000 of wages as defined in section 3121 (a) (see subparagraph (3) (i) of this paragraph), he has $12,200 ($13,200 - $1,000) of self-employment income for the taxable year.
§ 1.1402(c)—2 Public office.

(a) In general—(1) General rule. Except as otherwise provided in subparagraph (2) of this paragraph, the performance of the functions of a public office does not constitute a trade or business.

(2) Fee basis public officials. [Reserved]

(b) Meaning of public office. The term "public office" means the office of a public office of the United States or any possession thereof, of the District of Columbia, of a State or its political subdivisions, or of a wholly-owned instrumentality of any one or more of the foregoing. For example, the President, the Vice President, a governor, a mayor, 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 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 title 26) or the Federal Unemployment Tax Act (chapter 23 of title 26), 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 any period in which the functions are performed in a position compensated solely on a fee basis and in which such functions are 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 at the time a fee is received, the service to which such fee relates does not constitute a trade or business. See also paragraph (a) of § 1.1402(c)—2, relating, in part, to the performance of the functions of a public office of a State or a political subdivision thereof by an individual.

(2) Election with respect to fees received in 1965. (1) Any individual who in 1965 receives fees for service as an employee of a State or a political subdivision thereof in a position compensated solely on a fee basis may elect, if the performance of the service for which such fees are received constitutes a trade or business pursuant to the provisions of subparagraph (1) of this paragraph, to have such performance of service treated as excluded from the term "trade or business" for the purpose of the tax on self-employment income, pursuant to the provisions of section 125(c) (2) of the Social Security Act at the time a fee is received in 1965. Such election shall be limited to service to which the fees received in 1965 are attributable but must also be applicable to service (if any) in subsequent years with respect to which an election is made. An election pursuant to the provisions of this subparagraph is irrevocable.

(b) The election referred to in subdivision (1) of this subparagraph shall be made by filing a certificate of election of exemption (Form 4415) on or before the due date of the income tax return (see section 6072), including any extension thereof (see section 6081), for the taxable year of the individual making the election which begins in 1965. The certificate of election of exemption shall be filed with an internal revenue office in accordance with the instructions on the certificate.

Par. 13. The following sections are inserted immediately after § 1.1402(c)—1A.

§ 1.1402(c)—2A 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 (1) a duly ordained, commissioned, or licensed minister, or (2) 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 a Christian Church of the Christian Science faith, may request an exemption from the tax on self-employment income (see §§ 1.1401 and 1.1401—1, 1965) with respect to services performed by him in his capacity as such minister, member, or as a Christian Science practitioner, as the case may be. Such a request shall be made by filing an application for exemption from self-employment income, 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 service performed by a minister, member, or Christian Science practitioner in his capacity as such may not be granted to a minister, member, or practitioner who (in accordance with the provisions of section 1402(e) as in effect before § 1.1402(e)—3A was prescribed in § 1.1402(e)—3A. For provisions applicable to services performed by individuals referred to in this subparagraph, see paragraph (e) of § 1.1402(e)—3 and §§ 1.1402(e)—6 relating to ministers of religious orders, and paragraphs (a), (b), and (c) of § 1.1402(e)—6 relating to Christian Science practitioners.

(2) The application for exemption shall contain, or there shall be filed with such application, a statement to the effect that the individual making application for exemption is conscientiously opposed to, or because of religious principles is opposed to, the acceptance (with respect to services performed by him in his capacity as a minister, member, or Christian Science practitioner) of any public insurance which makes 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 benefits of the Federal Employee's Group Health Insurance System and Medical Care Supplement and the Public Health Service Act). Thus, ministers, members of religious orders, and Christian Science Practitioners requesting exemption from social security coverage must meet either of two alternative tests: (1) A religious principles test which refers to the institutional principles and discipline of the particular religious organization to which he belongs, or (2) a conscientious objection test which refers to the opposition because of religious considerations of individual ministers, members of religious orders, and Christian Science Practitioners (rather than opposition based upon the general conscience of any such individual or individuals). The term "public insurance", as used in section 1402(e) and this paragraph, refers to governmental, as distinguished from private, insurance and does not include insurance carried with a commercial insurance carrier. To be eligible to file an application for exemption on Form 4361, a minister, member, or Christian Science practitioners need not be opposed to the acceptance of all public insurance making payments of this specified type; he must, however, be opposed on religious grounds to the acceptance of any such payment which, in whole or in part, is based on, or measured by, earnings from services performed by him in his capacity as a minister or member (see § 1.1402(c)—5) or in his capacity as a Christian Science practitioner (see paragraph (b) (2) of § 1.1402(c)—6). For example, a minister performing service in the exercise of his ministry may be eligible to file an application for exemption on Form 4361 even though he is not opposed to the acceptance of benefits under the Social Security Act with respect to service performed by him which is not in the exercise of his ministry.

(3) An exemption from the tax imposed on self-employment income with respect to service performed by a minister, member, or Christian Science practitioner in his capacity as such may not be granted to a minister, member, or practitioner who (in accordance with the provisions of section 1402(e) as in effect before § 1.1402(e)—3A was prescribed in § 1.1402(e)—3A. For provisions relating to filing an application for exemption, see §§ 1.1402(e)—1 through 1.1402(e)—3A.

(b) Application for exemption. An application for exemption on Form 4361 shall be filed in triplicate with the Internal revenue officer or the internal revenue office, as the case may be, designated in the instructions relating to the application for exemption. The application for exemption must be 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 before the expiration of the time limitation for filing an application for exemption shows no liability for tax on self-employment income, such return will be treated as an application for exemption, provided that before February 18, 1975 such individual also files a properly executed Form 4361.

(c) Approval of 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 internal revenue officer. See § 1.1402(e)—4A relating to the period for which an exemption is effective.

§ 1.1402(c)—3A Time limitation for filing an application for exemption.

(a) General rule. (1) Any Individual referred to in paragraph (a) of § 1.1402(e)—3 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 whichever of the following dates is later: (i) 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—

(2) In the case of a duly ordained, commissioned, or licensed minister of a church, consists 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 of poverty as a member of such order, consists of remuneration for service performed 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.

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 electing to have his second taxable year both from service performed in such capacity and from the conduct of another trade or business, and the deductions allowed by chapter 1 of the Internal Revenue Code which are attributable to the gross income derived from service performed in such capacity equal or exceed the gross income derived from service 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 service performed in such capacity.

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

Example (1) M, who makes his income tax return on a calendar year basis, was ordained as a minister in January 1963. During each of two or more taxable years ending before 1965 M has not earned income in excess of the poverty level. M has not filed an effective waiver certificate on Form 4361. During each of two or more taxable years ending after 1969 M has earned income in excess of the poverty level. M has not filed an effective waiver certificate on Form 4361.

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 return on a calendar year basis, was ordained as a minister in January 1963. During each of two or more taxable years ending before 1965 M has not earned income in excess of the poverty level. M has not filed an effective waiver certificate on Form 4361.
Example (3). Assume the same facts as in example (2) except that M has net earnings in excess of $400 for each of his taxable years 1967 and 1968 and $600 in 1969. The application for exemption must be filed on or before the due date of his income tax return for 1967. If filed on or before March 15, 1968, M makes his income tax returns on the basis of the calendar year. If M files his returns on a calendar year basis, M derives net earnings in excess of $400 from his activities as a minister. M has net earnings of $300 for the taxable year ending in 1967, $400 of which is earned from service performed by him in the exercise of his ministry. If M desires an extension of 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 1967, or any extension thereof.

Example (4). M, who was ordained as a minister in May 1973, during each of the taxable years 1973 and 1974, M makes his income tax returns on a calendar year basis. During each of these years M receives $410 for service performed in the exercise of his ministry. In addition to his income tax return on the basis of the calendar year, M derives net earnings of $400 from his activities as a minister. M has net earnings of $300 for the taxable years ending in 1973 and 1974. M receives wages of $14,000 from the XYZ Corporation and derives net earnings of $400 from his activities as a minister. M must file an application for exemption from the tax on self-employment income with respect to service performed in the exercise of his ministry. If M desires an extension of 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 1974, or any extension thereof.

Example (5). M, who was ordained as a minister in January 1973, is employed as a tool-maker by the XYZ Corporation for the taxable years 1973 and 1974 and also engages in activities as a minister on weekends. M makes his income tax returns on the basis of the calendar year. M, during each of the calendar years 1973 and 1974 M receives wages of $14,000 from the XYZ Corporation and derives net earnings of $400 from his activities as a minister. M has net earnings of $300 for the taxable year ending in 1973, $400 of which is earned from service performed by him in the exercise of his ministry. If M desires an extension of 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 1974, or any extension thereof. It should be noted that although by reason of section 1402(c) (1) (G) and (H) no part of the $400 represents "self-employment income", nevertheless the entire $400 constitutes "net earnings from self-employment" for purposes of fulfilling the requirements of section 1402(c) (2).

Example (6). M, who files his income tax returns on a calendar year basis, was ordained as a minister in March 1973. During 1973 he receives $410 for service performed in the exercise of his ministry. In addition to his ministerial services, M is engaged during the year 1973 in a mercantile venture from which he derives net earnings from self-employment in the amount of $4,600. The expenses incurred by him in connection with his ministerial services during 1973 and which are allowable deductions under chapter 1 of the Internal Revenue Code amount to $410. During 1974 and 1975, M has net earnings from self-employment of $4,600 and $4,800, respectively, and some part of each of these amounts is from the exercise of his ministry. The deductions allowed in each of the years 1974 and 1975 by chapter 1 which are attributable to the gross income derived by M from the exercise of his ministry in each of such years, respectively, do not equal or exceed such gross income in such year. If M desires an extension of 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.

(b) Effect of death. The right of an individual to file an application for exemption shall cease upon his death. Thus, the husband, administrator, or executor of a decedent shall not be permitted to file an application for exemption for such decedent.

(c) Computation of net earnings—(1) Taxable years ending before 1968. For purposes of this section net earnings from self-employment for taxable years ending before 1968 shall be determined without regard to the fact that, without an election under section 1402(e) (as in effect prior to amendment by section 112 of the Social Security Amendments of 1967, see § 1.1402(e)-1A), the performance of services by a duly ordained, commissioned, or licensed minister of a church in the exercise of 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(c)-3(e) (2) and § 1.1402(c)-5 relating to ministers and members of religious orders, and paragraphs (a) (3) (d) and (b) of § 1.1402(c)-5 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 any part of which was derived from the performance of service in his capacity as a minister, member, or practitioner, and for all succeeding taxable years. See, however, paragraphs (b) (1) paragraphs (d) (2) of § 1.1402(e)-5 relating to ministers and members of religious orders and paragraph (b) (2) of § 1.1402(e)-5 relating to Christian Science practitioners.

(b) Exemption irrevocable. An exemption granted to a minister, a member of a religious order, or a Christian Science practitioner pursuant to the provisions of section 1402(e) is irrevocable.

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Title 32—National Defense

CHAPTER XIV—THE RENEGOTIATION BOARD

PART 1459—COSTS ALLOCABLE TO AND ALLOWABLE AGAINST RENEGOTIABLE BUSINESS

PART 1470—INFORMATION REQUIRED OF CONTRACTORS

Miscellaneous Amendments

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 36533-36534), certain significant changes having been made therein.

Under the proposed amendments as published on October 9, 1974, the Renegotiation Board sought in a two-phase program to require that all financial statements filed with the Renegotiation Board be in conformance with cost accounting standards promulgated by the Cost Accounting Standards Board. The proposed amendments provided that for the first phase (fiscal years beginning after December 31, 1974 but before January 1, 1976), contractors with any renegotiable contracts or subcontracts subject to one or more cost accounting standards would have been required to report all their renegotiable business in conformance with the standards in effect with respect to such renegotiable contracts and subcontracts. For the second phase (fiscal years beginning on or after January 1, 1976), all contractors subject to renegotiation would have been required to file financial statements with the Renegotiation Board in conformance with all cost accounting standards in effect, even those contracts or subcontracts subject to such standards. The remaining portion of the contractor's renegotiable business would be reported in the financial statements subject to such standards.

Significant changes in the proposed amendments are reflected in the final 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.

The 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 systems.

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...
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. Except with respect to allocations made pursuant to such paragraph (b) (2), nothing in this preceding sentence shall affect the authority of the Board under section 103 (1) and (1) of the Act to determine the income received or accrued or the costs paid or incurred by the contractor with respect to renegotiable business in a fiscal year in accordance with such method of accounting as, in the opinion of the Board, properly reflects such income or costs, if the method of accounting required by the contractor in determining net income for Federal income tax purposes does not, in the opinion of the Board, 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, 351.2, 4 CFR 351.2, issued under Pub. L. 91-379, 84 Stat. 706, approved August 31, 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 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 subcontracts subject to one or more 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 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) (i), (ii), (iii), (iv), (v) and (vi) 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) of this section, may extend the application 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 (as defined in § 351.30 of the Cost Accounting Standards Board regulations, 4 CFR 351.30) in accordance with such cost accounting standards. 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, or any renegotiable business reported as provided in paragraph (b) (2) (ii) (a) of this section, contractors, with Board approval, may report any other renegotiable business in accordance with such standards.

(c) Financial statements filed with the Renegotiation Board pursuant to paragraphs (b) (2) (i) (4) or (5) 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) (1)); and the contractor shall comply with any renegotiation practice followed pursuant to paragraphs (b) (2) (ii) (a) or (b) (2) (ii) (b) of this section or the renegotiation practice followed pursuant to paragraph (b) (2) (ii) (d) of this section.

(2) Allocation of costs. For fiscal years beginning after December 31, 1974, contractors subject to cost accounting standards may adopt a different method of accounting for the purpose of determining all amounts received or accrued and costs paid or incurred in a fiscal year, as in the case of a change from a cash receipts and disbursements method of accounting to an accrual method of accounting, or it may adopt a different method of accounting for a particular item or cost or for a particular class of items of cost which would result in recognizing such item or items in one fiscal year rather than another.

(3) Allocating profit. A contractor employs, for the purposes of a renegotiation proceeding relating to the year under review, a method of accounting different from that which it 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) (2) 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 expenses as are established in the accounting method if that method reflects recognized accounting principles and practices. If 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 such costs because there are insufficient or improper allocations of items of cost in the accounting records or in the

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reports or statements filed for the purpose of renegotiation, costs will be allocated in accordance with such method as in the opinion of the Board does properly reflect such costs. The fact that all receipts and accruals during a fiscal year are classified as revenue (which does not necessarily mean that all items of cost estimated to be deductible in that year are allocable to renegotiable business.

(5) Tax deductions. When an item of cost is allocable in whole or in part to renegotiable business, the Board will estimate the amount allowable 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 allocable 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 or in excess of that estimated to be in 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 self assessment or otherwise provided in this paragraph (b). When it is clear that a contractor's deductions and exclusions under the Internal Revenue Code result in allowable costs of renegotiable business which are in the aggregate either high or low on a comparative basis, this circumstance will be considered in connection with the factor 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 allowable 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 of the Internal Revenue Service on matters of calculation which are in the aggregate either high or low on a comparative basis, this circumstance will be considered in connection with the factor 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 allowable 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 of the Internal Revenue Service on matters of calculation which are in the aggregate either high or low on a comparative basis.

(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 with respect to recognition of such costs for income tax purposes. The Board will exercise independent judgment in connection with the fact that all amounts allowable as deductions or exclusions under the Internal Revenue Code result in allowable costs of renegotiation purposes. Similarly, an item allowable as a "cost" by such regulation or by specific contractual agreement will not be allowed unless it is a proper Federal income tax deduction. Furthermore, a specific agreement that additional proper costs incurred in performing a contract will not be claimed as an addition to the contract price will not result in the non-recognition of such cost for renegotiation purposes.

(7) Conditional allowance of cost. If an item of cost is allocable in whole or in part to renegotiable business, the Board will exercise independent judgment in connection with the fact that all amounts allowable as deductions or exclusions under the Internal Revenue Code result in allowable costs of renegotiation purposes. Similarly, an item allowable as a "cost" by such regulation or by specific contractual agreement will not be allowed unless it is a proper Federal income tax deduction.

(8) Costs previously allowed in renegotiation. No item will be allowed as a cost of renegotiable business in the year under review the item is material as of January 31, 1975.

(9) Replacement of inventory involuntarily liquidated.

44452

RULES AND REGULATIONS

This amendment changes the regulations for the drawbridges located across the C/MW 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 obtained 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 need 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.

Title 33—Navigation and Navigable Waters

CHAPTER I—COAST GUARD, DEPARTMENT OF TRANSPORTATION

[CGD 74 285]

PART 117—DRAWBRIDGE OPERATION REGULATIONS

GIWW, Mile 57.6 Through Mile 59.8, West of Harvey Lock, Houma, La.

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(b) These regulations shall be revoked as of January 31, 1975.


R. L. Parce,
Rear Admiral, U.S. Coast Guard, Chief, Office of Marine Environment and Systems.
RULING AND REGULATIONS

§ 1-5.902 Authorization to contractors.

(a) Copies of each authorization shall be forwarded to the Federal Supply Service of the General Services Administration regional office serving the geographical area in which the facilities of the authorized contractor are located.

(1) Copies of each authorization shall be forwarded to the Federal Supply Service of the General Services Administration regional office serving the geographical area in which the facilities of the authorized contractor are located.

(2) (Sec. 205(c), 63 Stat. 390; (40 U.S.C. 486(c))

Effective date. This amendment is effective January 27, 1975, but may be observed earlier.

Dated: December 17, 1974.

Arthur F. Sampson,
Administrator of General Services.

[FR Doc.74-20917 Filed 12-23-74;8:45 am]

SPECIAL AND DIRECTED SOURCES OF SUPPLY, ILLUSTRATION OF FORMS, OFFICE SYMBOLS

Miscellaneous Amendments

The revision to AECPR 9-5.5205-5 is being made in order to cancel the moratorium imposed 1-3-5.902-3 on the purchase of steel filing cabinets by either AEC or cost-type contractors, and to delete the requirement for obtaining GSA approval of such direct AEC procurements. These changes are being made to bring AECPR into accord with FPMR Amendment 1-144 dated June 19, 1974. The revision to AECPR 9-5.5205-5 is intended to bring AECPR 5.16.9 is intended to bring AECPR 9-16.951-2 (AEC 103a) Purchase Order Terms, in line with the latest organizational changes, as well as with AEC and Federal Procurement Regulation requirements. The remaining change is being made for the purpose of updating AECPR 9-5.202 to reflect the assignment of the symbol "DR" to identify purchase orders issued by the Director of Regulation in accordance with the recent delegation to him of contractual authority.

PART 9-5—SPECIAL AND DIRECTED SOURCES OF SUPPLY

1. Paragraphs (a) and (b) of § 9-5.5205-5 are revised as follows:

§ 9-5.5205-5 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 101-16.951-5. 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 bases 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 shall be retained in the appropriate purchasing office files.

PART 9-16—PROCUREMENT OF FORMS

§ 9-16.951-2 (AEC 103a) Purchase Order Terms.

10. Contract Work Hours and Safety Standards Act—Overtime Compensation. See the clauses set forth in FPR 1-12.302, including the revision to paragraph (c) thereof as required by AECPR 9-12.302.

3. In § 9-16.951-2, paragraph 13 is revised as follows:

§ 9-16.951-2 (AEC 103a) Purchase Order Terms.

13. Priorities, Allocations, and Allotments. The contractor shall follow the provisions of DMS Regulation 1 and all other applicable regulations and orders of the Domestic and International Business Administration, Department of Commerce in obtaining controlled materials and other products and materials needed to fill this order.

PART 9-53—NUMBERING AND DISTRIBUTION OF CONTRACTS AND ORDERS

4. Section 9-53.202, is revised as follows:


The symbols assigned for the purpose of identifying AEC procurement offices on purchase orders issued by them are set forth as follows:

Procurement office: Order prefixes

Albuquerque -------------- AL
Brookhaven -------------- BR
Chicago ------------------ CH
Dayton -------------------- DA
Grand Junction ------------ GD
Idaho Falls -------------- ID
Kancas City ----------- KX
Los Alamos -------------- LA
New Brunswick --------- NB
Nevada ----------------- NV
Oak Ridge ----------- OR
Pendleton --------- PD
Pittsburgh --------------- PK
Pueblo --------------- PY
Richland ---------------- RL
Sun Francisco ---------- SF
Savannah River ------- SW
Headquarters Services -- WA

Director of Regulation

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.74-40095 Filed 12-29-74;8:45 am]
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 80, 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.

[Sec. 205(c), 63 Stat. 390 (40 U.S.C. 486(c))] Effective date. This regulation is effective December 24, 1974.

Dated: December 12, 1974.

ARTHUR F. SAMSON,
Administrator of General Services.
[FR Doc.74-22918 Filed 12-23-74; 8:45 am]
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 22385). 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 not 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 making corrections and adjustments in the marketing quotas for the 1974-75 marketing year for which marketing quotas are in effect under this section, the Secretary and regulations covered by this notice may be made available for public inspection.

The amount of the national marketing quota determined under sub-section (e) (less the national reserve) by the sum of the farm marketing quotas for the immediately preceding year for all farms for which burley tobacco marketing quotas will be determined: Provided, That such national factor shall not be less than 0.05 percent.

Section 319(d) provides, in part, that if the Secretary, in his discretion, determined it is desirable to encourage additional marketing of any grades of burley tobacco during any marketing year to insure traditional market patterns to meet the normal demands of export and domestic markets, he may authorize the marketing of such grades without the payment of penalty or deduction from subsequent quotas to the extent of 5 percent of the farm marketing quota for the farm on which the tobacco was produced and such marketing shall be eligible for price support.

Section 319(b) 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(d) to encourage additional marketing of any grade 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 4:45 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.

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**PROPOSED RULES**

**with the other fiduciary responsibility provisions of the Act.**

**Interested persons are invited to submit 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 25 of Part 2 of Title I 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.**

Authority: (Sec. 505, Pub. L. 93-406, 88 Stat. 1132), and also as specifically noted.

§ 2552.1 Exemption from trust requirements for unfunded welfare benefit plans.

(a) Under the authority of section 403(b)(4) of the Employee Retirement Income Security Act of 1974 (the Act), 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 who established the plan is hereby exempted from the requirements of section 403(a) of the Act, which generally requires that assets of employee welfare benefit plans be held in trust by one or more trustees.

(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 4 of Title I of the Act. Any person who is a fiduciary with respect to an unfunded welfare benefit plan must still comply with the other fiduciary responsibility provisions of the Act.

Signed at Washington, D.C., this 19th day of December, 1974.

Paul J. Passer, Jr.,
Assistant Secretary of Labor, for Labor-Management Relations.

**[FR Doc.74-30007 Filed 12-23-74; 8:45 am]**

**[Docket No. OBE-58]**

**PROPOSED RULES**

**EMPLOYMENT RELATED HOUSING (TEMPORARY LABOR CAMPS)**

**Notice of Hearing**

On September 23, 1974, pursuant to section 6(b) of the Williams-Steiger Occupational Safety and Health Act of 1970 (84 Stat. 1594, 29 U.S.C. 655), Secretary of Labor's Order No. 12-71 (36 FR 8754), and 29 CFR Part 111, a proposal was published in the Federal Register (39 FR 34057) to revise § 1910.142 of Title 29, Code of Federal Regulations, which concerns employment related housing.

In accordance with the provisions of the proposal, and with the notice which appeared in the Federal Register (39 FR 40655, November 18, 1974) extending the period for submitting written comments, numerous comments and requests for informal hearings were received.

There were numerous objections to the proposal by employees, employers and their respective representatives. Objections by or on behalf of employees asserted that the proposed regulations would not provide a safe and healthful place of employment, while objections by or on behalf of employers alleged that in many instances the regulations would be too stringent. Some of the major issues raised in the comments dealt with bathing facilities, electricity, windows, screening, shelter structures, space requirements for beds and living areas, toilet facilities, cooking facilities, and adequacy of the water supply.

Some commenters asserted that the scope of the proposed regulations exceeded the authority of the Occupational Safety and Health Administration because some regulations would be neither necessary nor appropriate for the protection of employees. It was also asserted that the regulations should not apply to marine housing or to housing provided by an employer which is used by an employee as a permanent residence. Others commented that the protection which would be afforded by the proposed regulations would not extend to non-employee occupants and, in addition, would place the burden upon the employee to prove that occupancy of the housing facility was a condition of employment.

In view of the interest shown during the written comment period and pursuant to section 6(b) of the Act (84 Stat. 1594, 29 U.S.C. 655) and 29 CFR Part 111, I have directed that an informal hearing be held in four locations concerning the proposed regulations. Numerous comments and requests for informal hearings were received. A prehearing conference commencing at 9:39 a.m. local time will be held at each location, in order to establish the order and time for the presentation of statements and to settle any other procedural matters relating to the proceeding. The hearings will begin immediately thereafter and will be held as follows:


Jan. 23, 1975 Federal Office Building, room 418, 354 Senate St., Toledo, Ohio.

Jan. 28, 1975 Galt Ocean Mile Hotel, Board Rooms A and B, 3250 Gulf of Mexico Dr., Fort Lauderdale, Fla.


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INTERESTED PARTIES

Proposed Rules

DEPARTMENT OF TRANSPORTATION

Urban Mass Transportation Administration

Extension of Comment Period

This notice extends the period for comments to the notice published October 9, 1974 (39 FR 36350) proposing urban area boundary regulations, and the notices published on November 8, 1974 (39 FR 36659, 36665), 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. 93-509). 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. Tummin, Federal Highway Administrator.

Frank C. Herringer, Urban Mass Transportation Administrator.

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. 93-113, volunteer sponsors enter into an agreement with ACTION to reimburse ACV for the direct cost of volunteer support, i.e. allowances, stipend and other direct benefits.

The 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 duration 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. 93-113).

Notice is hereby given that the Director of ACTION proposes to amend Chapter XII of Title 48, 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, 806 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 readmission.

1213.2-4 Living conditions.

1213.2-5 Role of volunteer.
Subpart C—ACTION Provided Volunteer Support

Sec.

1213.1-1 Financial support.

1213.1-2 Transportation.

1213.1-3 Health support.

1213.1-4 Allowances.

1213.1-5 Insurance.

1213.1-6 Leave.

1213.1-7 Federal service.

1213.1-8 Lost property.

Subpart D—Sponsor Provided Volunteer Support

1213.4-1 Training.

1213.4-2 Provisional volunteers.

1213.4-3 Job-related transportation.

1213.4-4 Supplies and equipment and office facilities.

1213.4-5 Emergencies.

Subpart E—Administrative Hold—Grievance, Removal, Resignation, Suspension, and Termination

1213.5-1 Administrative hold.

1213.5-2 Volunteer grievances.

1213.5-3 Resignation.

1213.5-4 Sponsor request for removal of volunteer.

1213.5-5 Suspension and termination.

Subpart F—Special Conditions Affecting Volunteer Service

1213.6-1 Provisional volunteers.

1213.6-2 Nonappropriateness.

1213.6-3 Nonappropriate assignments.

1213.6-4 Political activities and limitation of lawful activities.

1213.6-5 Discrimination.

1213.6-6 Religious activities.

1213.6-7 Evaluation.

1213.6-8 Limitation on labor and anti-labor activity.

1213.6-9 Weapons.

1213.6-10 Impairment of capacity.

1213.6-11 Racial and ethnic discrimination.

1213.6-12 Special personal protection.

1213.6-13 Provisions for religious observance.

1213.6-14 Funds for general support.

1213.6-15 Other direct benefits.

1213.6-16 Political activities and limitation of lawful activities.

1213.6-17 Limitation on labor and anti-labor activity.

1213.6-18 Special personal protection.

1213.6-19 Funds for general support.

1213.6-20 Special personal protection.

1213.6-21 Political activities and limitation of lawful activities.

1213.6-22 Limitation on labor and anti-labor activity.

1213.6-23 Special personal protection.

1213.6-24 Funds for general support.

1213.6-25 Special personal protection.

1213.6-26 Political activities and limitation of lawful activities.

1213.6-27 Limitation on labor and anti-labor activity.

1213.6-28 Special personal protection.

1213.6-29 Funds for general support.

1213.6-30 Special personal protection.

1213.6-31 Political activities and limitation of lawful activities.

1213.6-32 Limitation on labor and anti-labor activity.

1213.6-33 Special personal protection.

Subpart G—Miscellaneous

1213.7-1 Student loan deferrals.

1213.7-2 Death benefits.

1213.7-3 Student loan deferrals and death benefits.


Subpart A—General

§ 1213.1-1 Introduction.

(a) Section 122(a), Part C, of the Domestic Volunteer Service Act of 1973 (the Act), Pub. L. 93-113, 87 Stat. 401, authorizes the Director of ACTION to con- duct and to make contracts for special volunteer programs to encourage wider volunteer participation on a full-time basis to strengthen and supplement efforts to meet a broad range of human, social, and environmental needs, particularly those related to poverty. The ACTION Cooperative Volunteer Program (ACV) is one of these special volunteer programs. It provides full-time volunteer service opportunities for individuals in assignments with nonprofit and public agency sponsors involving a broad range of human, social, and environmental needs, particularly those related to pov- erty.

Organizations wishing to become sponsors enter into an agreement with ACTION to share expenses associated with ACV volunteer assignments. The sponsor’s obligations consist of reimbursing ACTION for the direct costs of volunteer support, f.o. allowances, stipend and other direct benefits.

(b) Section 122(b) requires that the assignments of ACV volunteers be on such terms and conditions as the Director shall determine.

(c) 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 duration 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. 93-113).

Subpart B—Description of Volunteer Service

§ 1213.2-1 Enrollment and duration of service.

ACTION enrolls an individual in ACV during the preservice processing it provides. Such enrollment is for a period comprising the time of such processing, ACTION preservice orientation, and a one-year assignment to a project.

§ 1213.2-2 Provisional volunteers.

Individuals are considered to be provisional volunteers during the period of pre-service processing and ACTION preservice orientation. They have all the rights and benefits and are subject to all the duties of volunteers, except as expressly provided in these regulations or where it would appear from the language of a section of the regulations to be inapplicable.

§ 1213.2-3 Extension of service and reenrollment.

In certain situations, a volunteer may have his period of volunteer service extended for not more than one year, at the request of a sponsor and the concurrence of the appropriate ACTION Regional Director.

A volunteer may only be reenrolled for a period of at least one year. A sponsor must request the reenrollment for a period of at least one year.

§ 1213.2-4 Living conditions.

To the extent practicable volunteers are expected to make a personal commitment to live among and at the economic level of the people served by the project in which the volunteer works. The sponsor will insure that this commitment is observed.

§ 1213.2-5 Role of the volunteer.

The volunteer’s assignments are carried out under the supervision of the sponsor. The volunteer assumes a “live-in” obligation carrying his work into all facets of community life and social activity. He is available for service without regard to regular working hours seven days a week, except for periods of approved leave.

§ 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 residents of the community to which he is assigned. The rate of the allowance is determined by the Regional Office after consultation with the sponsor.

(b) Personal living allowance. ACTION also provides each volunteer a personal living allowance of $76 per month. It is intended to cover incidental expenses and local travel.

(c) Adjustment allowances. At the beginning of service, a volunteer may receive from ACTION an adjustment allowance when necessary to cover the initial cost of securing and setting up living quarters. Such an allowance is usually provided only to those who serve outside their home area. It is not usually available to volunteers recruited locally for an assignment in their home communities.

(d) Stipend. At the conclusion of the term of service, each volunteer receives a stipend of $50 for each month of service on an ACV project. Volunteers may be authorized to make bi-weekly allotments from the stipend, not in excess of $125, in extraordinary circumstances. These may include allotments for obligations incurred prior to service for family support, insurance, or loan payments and income taxes.

(e) Provisional volunteers. Provisional volunteers do not receive any allowances other than those which accrue on the basis of stipend and personal allowance.

(f) Emergencies. In case of emergencies, ACTION may provide the volunteer with assistance and support to prevent injury or hardship to him, including a $500 advance against allowances and stipends due the volunteer or to be paid subsequently to him during his volunteer service.

§ 1213.3-2 No dependent support. ACTION assumes no financial responsibility for a non-volunteer spouse, a volunteer’s children or other dependents.

§ 1213.3-3 Transportation.

ACTION will be responsible for providing the volunteer with needed transportation for the following purposes:

(a) To, and when appropriate, from volunteer/sponsor site.

(b) To the pre-service processing site, whether it is the ACTION 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 terms 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 area.
area to which he has been assigned when he does so at the request of the Government.  

(1) 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's parent or legal guardian if the volunteer had been residing with the parent or legal guardian immediately prior to entering ACTION service, or if the volunteer was a full-time student whose permanent residency 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 or designee.  

§ 1213.3-3 Health support  

ACTION provides ACV volunteers with a health-based program at no cost to the volunteer.  

Coverage includes most medical and surgical costs, hospitalization, prescription drugs, and emergency dental care.  

ACTION reserves the right to alter the extent, or the method of providing health care for volunteers. In nonemergency situations, the Regional Office must clear hospitalization of other serious (in excess of $150) treatments.  

§ 1213.3-4 Legal support  

ACTION will pay certain legal expenses where volunteers are involved in criminal or civil judicial or administrative proceedings to the extent provided in Part 1216.  

§ 1213.3-5 Insurance  

(a) ACV volunteers are covered by the Federal Employees Compensation Act. This provides a broad-based workmen's compensation-type coverage for volunteer job-related accidents and occupational sickness.  

(b) ACV volunteers are also Federal employees for the purpose of the Federal Tort Claims Act. Any third-party claims for injury or damage to property arising out of the volunteer's job-related activities will be treated as claims against the United States.  

§ 1213.3-6 Leave  

(a) Vacation leave. Once on the job for four months, an ACV volunteer earns one day of leave for every full month of service up to a maximum of seven days, including one weekend. No leave is to be granted during the last month of service, unless for emergencies. During leave, the volunteer's regular support allowances are continued. No leave may be taken without the approval of the sponsor.  

(b) Emergency leave. Should a member of a volunteer's immediate family—spouse, mother, father, sister, brother, child or guardian—become critically ill or die, emergency leave granted by the sponsor for a period of up to one week. Any additional time requires the approval of the ACTION Regional Office.  

It does not count against vacation leave. The volunteer is responsible for transportation by the fastest scheduled carrier to and from the emergency site and for actual travel expenses incurred, but not in excess of those in standard government travel regulations.  

§ 1213.3-7 Federal service  

Section 415(c) of the Act provides that should an ACV volunteer subsequently enter Federal service, his period of volunteer service counts as a period of Federal service for certain purposes, including job security and retirement benefits.  

§ 1213.3-8 Lost property  

(a) The Regional Director may at his discretion, reimburse volunteers or trainees for or replace lost, damaged, or stolen clothing and personal belongings, and certain other allowances, such as health insurance, transportation and per diem, and living allowances; and equipment and supplies if, (1) reimbursement is essential to the volunteer's ability to perform 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. No reimbursement is essential to the volunteer's ability to perform effectively in his particular assignment.  

(c) No reimbursement will be made for luxury items, such as photographic or phonographic 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 volunteer 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 vehicles 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 compliance with all state and local laws 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  

The sponsor is responsible for providing most job-related support involving materials, supplies, and equipment needed for the volunteer's work. The sponsor shall provide equipment, facilities, and other materials and supplies needed by the volunteer, including telephone and secretarial support.  

§ 1213.4-5 Emergencies  

In case of emergencies in which it is not possible for ACTION to provide a volunteer with the necessary assistance and support in time to prevent injury or hardship to him, the sponsor may furnish the needed assistance, including an advance of up to $500 from its own funds to the volunteer. Such advances, however, should be cleared in advance by telephone with the ACTION Regional Director or designee.  

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.  

(b) Absence from project site without authority of the sponsoring organization.  

(c) During termination action.  

(d) Arrest and placement in jail without bail or on parole on charges the sponsor determines to be job-related.  

(e) Removal from site at request of sponsoring organization, pending decision on transfer to new assignment.  

(f) 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
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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 unfairly affected by a decision of the Regional Director, or has not been treated fairly 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 informal mechanism allows 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 allowances, 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 in any way. Before resorting to a formal request for removal the sponsor should contact the appropriate ACTION state 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;

Procedures for the suspension and termination of volunteers are contained in Part 1212.

(b) Suspension. Volunteers may be suspended for up to 30 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 renew ACTION/sponsoring organization agreement. If the Memorandum of Agreement between ACTION and a sponsoring organization is terminated or not renewed, a volunteer who is removed from employment as a result of such a termination 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 reinstatement as soon as an appropriate slot is open.
3. 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) De-selection of a provisional volunteer. The Regional Director may de-select 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 de-selection are contained in Part 1212.

Subpart F—Special Conditions Affecting Volunteer Service

§ 1213.6-1 Sponsor’s employment of volunteer.

ACTION volunteers make a commitment to one full year of ACTION service. Similarly, ACTION asks that the sponsor on his part honor the spirit of that commitment and refrain from offering fully paid employment to volunteers during their first year of service. Volunteers may not perform services or duties or engage in activities for which the sponsor receives or requests any compensation. Volunteers may not receive any other compensation, directly or indirectly, from a sponsor while serving as a volunteer.

§ 1213.6-2 Nondisplacement of employees and impairment of contracts of service.

An ACTION volunteer’s assignment is limited to activities that would otherwise be performed by employed workers and which will not supplant the hiring of or result in the displacement of employed workers, or impair existing contracts for service. (Part 1216 implements this provision.)

§ 1213.6-3 Nonappropiate assignments.

(a) An assignment is not appropriate for a volunteer if:

1. The service, duty, or activity is principally administrative or clerical,
2. The volunteer is not directly in contact with groups or individuals who are to be served by the project or is not performing services, duties, or engaged in activities which are authorized under section 123a of the Act.

§ 1213.6-4 Political activities and limitation of unlawful activities.

(a) ACTION volunteers are covered by the Hatch Act to the same extent as Federal employees. This Act prohibits volunteers from engaging in partisan or nonpartisan political activities of any sort at any and all times during their terms of service, including periods of official leave.

(b) Section 403 of Pub. L. 93–113 requires that a sponsor’s project be operated in such a manner as to avoid involvement of ACTION volunteers in any partisan or nonpartisan political activity in an election for public or party office, voter transportation during elections, and voter registration drives.

(c) While engaged in carrying out their duties volunteers may, as a part of the project, participate in lawful and nonpolitical demonstrations and protest activities which are approved by the sponsor as a part of its project activity and which are not in violation of any ACTION policies.

§ 1213.6-5 Nondiscrimination.

Part 1208 provides regulations concerning nondiscrimination in ACTION programs and activities.

(a) No person with responsibilities in the operation of an ACTION project shall discriminate with respect to such program because of race, creed, belief, color,
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§ 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 representatives of 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 the results of the evaluation with the sponsor.

§ 1213.6-8 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 legal debts promptly to avoid creating a situation which would impair the volunteer to furnish meals 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 from repayment 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 a volunteer should submit the form to Headquarter 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) Regular college loans may also be deferred. These repayments, however, are deferred at the discretion of the lender. If the lender is willing to defer payment, volunteers must obtain the necessary forms from the lender and forward them to the Regional Office for certification. If forms are not available from the lender, a letter to the university or lender may be prepared certifying the dates of the volunteer's service.

§ 1213.7-2 Death benefits.

In case of the death of a volunteer away from the volunteer's home of record, certain costs associated with transportation of the body are reimbursable either under the Federal Employees Compensation Act or ACTION policy. Volunteers whose death results from personal injury or illness sustained in the performance of his project duties are eligible for reimbursement of certain 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 possession or use of firearms 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 (49 CFR 52.220).

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 of Fuel in Direct Heat Exchangers." The amendment, in effect, would allow sulfur oxides to be added to a combustion unit exit gas stream for the purpose of improving control equipment efficiency on existing fuel burning units.

2. Amendments to Regulation VII, "To Prevent and Control Particulate Air Pollution from Combustion of Fuel in Indirect Heat Exchangers." The essential change would allow the primary aluminum reduction polllines which are equipped with fluidized bed reactors or other similar gas cleaning devices to comply with the provisions presently governing process waste operations, provided that at least 99 percent of the gaseous fluoride is removed from the exit gas stream, and that the particulate loading not be greater than 0.01 grains 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 the requirements provided in the Administrator's existing regulations. This particular proposal was previously submitted by the State of West Virginia on June 17, 1974. Accordingly, the Administrator announced receipt of the submission and provided for a public comment period (39 FR 33986).

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 proof that public hearings regarding these proposed changes, with the appropriate 30 day notice took place at the following times:

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This notice is to advise the public of the receipt of these proposed amendments, and to request public comment 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 50.

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; 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.

[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 § 73.606(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 21, 1974, 39 F.R. 19329. 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, 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 KEBS-TV, 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 and in view of this request the Administrator, on November 11, 1974, 39 F.R. 40170, requested that the date for filing comments and reply comments be extended to December 19, 1974, and January 7, 1975, respectively. Counsel states that intervening holiday and vacation schedules of various individuals preclude the completion of engineering and demographic studies being made by East Coast Broadcasting Corporation to be made in this proceeding.

3. It appears that the requested extension is warranted. Accordingly, it is ordered, that the date for filing comments and reply comments be extended to and including January 27 and February 14, 1974, respectively.

NATIONAL CREDIT UNION ADMINISTRATION

[12 CFR Part 701]

SUPERVISORY COMMITTEE AUDITS

Notice is hereby given that the Administrator of the National Credit Union Administration, pursuant to the authority conferred by section 123, 73 Stat. 763, 12 U.S.C. 1766, and section 209, 84 Stat. 1014, 12 U.S.C. 1764, proposes to amend part 701 (12 CFR pt. 701) by revising § 701.12 as set forth below.

The proposed revision is necessitated by the recent amendment to § 115 of the Federal Credit Union Act (12 U.S.C. 1761(d)).

Interested persons are invited to submit written comments, suggestions, or objections regarding the proposed amendment to the Administrator, National Credit Union Administration, 2035 M St., NW., Washington, D.C. 20450. Comments received prior to January 15, 1975, will be considered before final action is taken on this proposed rule. Copies of all written comments received will be available for public inspection during normal business hours at the foregoing address.

R. W. FORM, Regional Administrator.

[FR Doc.74-30080 Filed 12-23-74;8:45 am]

FEDERAL COMMUNICATIONS COMMISSION

[47 CFR Part 73]

FEDERAL BROADCASTING STATIONS

Table of Assignments; Order Extending Time for Filing Comments

In the matter of amendment of § 73.202(b), table of assignments, FM broadcast stations. (Southold, Center Moriches, and Westhampton Beach, New York).

1. On November 5, 1974, the Commission adopted a Notice of Proposed Rule Making in the above-entitled proceeding. Publication was given in the Federal Register on November 11, 1974, 39 F.R. 40170. The date for filing comments and reply comments are December 19, 1974, and January 7, 1975, respectively.

2. 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 intervening holiday and vacation schedules of various individuals preclude the completion of engineering and demographic studies being made by East Coast Broadcasting Corporation to be made in this proceeding.

3. It appears that the requested extension is warranted. Accordingly, it is ordered, that the date for filing comments and reply comments be extended to and including January 27 and February 14, 1974, respectively.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974

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. 1213(a). In section 103(g) (1), cited above, 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 proposed 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 under a prime contract or subcontract included. 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 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. Dated: December 19, 1974.

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: (1) The sale or processing of an end product which is to be delivered under a renegotiable prime contract; or (ii) the sale or processing of materials to be physically incorporated in such end product; or (iii) the sale, furnishing or installation of machinery, equipment or other materials used in the processing of such end product or materials incorporated therein; or (iv) the sale, furnishing or installation of materials incorporated in machinery, equipment or other materials used in the processing of such end product or materials incorporated therein; or (v) the sale, processing, furnishing or installation of materials, or the performance of work, required for the performance of a renegotiable prime contract or subcontract for work or services; or (vi) 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, and other items of a consumable character, as well as related items of a relatively short life and minor cost, such as pens, pencils, paper clips, staples, and other items of similar character; 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.

(SEC. 103, 65 STAT. 22; 50 U.S.C.A., APP. SEC. 1219)

[FR Doc. 74-3008 Filed 12-23-74; 8:45 am]
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 December 18, 1974 (39 FR 43413, 39 FR 43437), will be continued on December 30, 1974, at 11:00 a.m. in the Secretary's Conference Room in the Treasury Department, Washington, D.C. 20220.

Dated: December 20, 1974.

[SEAL]

W. F. BEECH, Assistant Secretary for Administration.

[F.R. Doc. 74-30112 Filed 12-23-74; 8:44 am]

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 74-71]

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 Drewel Avenue, Miami Beach, Florida 33139, as to why his Certificate of Registration (DEA Registration No. AR0148406) should not be revoked.

The Administrator finds it especially significant to note that the Administrator's registration for a period of nine months would be clearly inadequate in duration to ensure protection of the public health and safety. After evaluating the entire record, it is the opinion of the Administrator that the suspension of respondent's registration be for a period of two years from the date of this opinion.

In reaching this conclusion, the Administrator finds

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of respondent's registration for a period of nine months. The Administrator finds, with 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. However, 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 only nine months would be clearly inadequate in duration to ensure protection of the public health and safety. After evaluating the entire record, it is the opinion of the Administrator that the suspension of respondent's registration be for a period of two years from the date of this opinion.

In reaching this conclusion, the Administrator finds it especially significant to note that the Administrator's registration for a period of nine months would be clearly inadequate in duration to ensure protection of the public health and safety. After evaluating the entire record, it is the opinion of the Administrator that the suspension of respondent's registration be for a period of two years from the date of this opinion.

In summary, due to the seriousness of the nature of Dr. Robbins' conviction for the unlawful dispensing of a controlled substance, and after reviewing the transcript of testimony of the hearing, the facts and conclusions of law recommended by the Administrative Law Judge, the Administrator hereby adopts the recommended decision of the Administrative Law Judge, provided that the suspension of the subject Certificate of Registration be for a period of two years from the date of this order.

Therefore, in accordance with the provisions of § 316.66, 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 § 0.100, as amended, Title 26, 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.

[FR Doc.74-29921 Filed 12-23-74;8:45 am]

IMPORTER OF CONTROLLED SUBSTANCES

Notice of Application

By Notice dated October 21, 1974, and published in the Federal Register on October 25, 1974; (39 FR 38009) Cord Laboratories, Inc., 19191 Eiler, Detroit, Michigan 48234, made application to the Drug Enforcement Administration to be registered as an Importer of Amobarbital, a basic class controlled substance listed in schedule II.

No comments or objections having been received, and pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and in accordance with 21 CFR 1311.42, the above firm is granted registration as an Importer of Amobarbital.

Dated: December 18, 1974.

John R. Bartels, Jr.,
Administrator.

[FR Doc.74-29924 Filed 12-23-74;8:45 am]

IMPORTATION OF CONTROLLED SUBSTANCES

Notice of Application

Pursuant to section 1008 of the Controlled Substances Import and Export Act (21 U.S.C. 958b(h) ), the Attorney General shall, prior to issuing a registration under this section to abulk manufacturer of a controlled substance in schedules I or II, and prior to issuing a registration under section 1002(a) authorizing the importation of such a substance, provide manufacturers holding registrations for the bulk manufacture of the substance an opportunity for a hearing.

Therefore, in accordance with §1311.42 of Title 21, Code of Federal Regulations, notice is hereby given that on December 2, 1974, McNeil Laboratories, Inc., Camp Hill Road, Fort Washington, Pennsylvania 19034, made application to the Drug Enforcement Administration to be registered as an Importer of Codeine, a basic class controlled substance listed in schedule II.

Any person registered to manufacture Codeine in bulk may, on or before January 23, 1975 file written comments on or objection to the issuance of the proposed registration and may, at the same time, file written request for a hearing on the application (stating with particularity the objections or issues, if any, concerning which the person desires to be heard and a brief summary of his position on those objections or issues).

Comments and objections may be addressed to the Hearing Clerk, Office of Administrative Law Judge, Drug Enforcement Administration, Room 1130, 1405 Eye Street, NW, Washington, D.C. 20537.

Dated: December 18, 1974.

John R. Bartels, Jr.,
Administrator.

[FR Doc.74-29923 Filed 12-23-74;8:45 am]

MANUFACTURE OF CONTROLLED SUBSTANCES

Notice of Application

By Notice dated September 17, 1974, and published in the Federal Register on September 30, 1974; (39 FR 35188-9) Effer Corporation Ltd., Carreira 132, Km 23.8, P.O. Box 4108, Ponce, Puerto Rico 00731, made application to the Drug Enforcement Administration to be registered as a bulk manufacturer of Phenmetrazine, a basic class controlled substance listed in schedule I.

No comments or objections having been received, and pursuant to section 303 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, and in accordance with 21 CFR 1301.43, the above firm is granted registration as a bulk manufacturer of Phenmetrazine.

Dated: December 18, 1974.

John R. Bartels, Jr.,
Administrator.

[FR Doc.74-29920 Filed 12-23-74;8:45 am]

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

ANCIL JOHNSON

Issuance of Permit Marine Mammals

On September 16, 1974, a notice was published in the Federal Register (39 FR 33246-47) 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 seal 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. Barton,
Chief, Division of Law Enforcement, Fish and Wildlife Service.

[FR Doc.74-29923 Filed 12-23-74;8:45 am]
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-R-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, So. Agriculture Bldg, Room 2330, 12th St., and Independence Ave. SW, Washington, D.C. 20250.

USDA, Forest Service, 11177 West 6th 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 6th 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 6th Avenue, P.O. Box 25127, Denver, Colorado 80225. Comments must be received by February 18, 1975, in order to be considered in the preparation of the final environmental statement.

CLAYTON B. PEREY,
Director, Multiple Use and Environmental Quality Coordination.
December 18, 1974.

TIMBER MANAGEMENT PLAN, MODOC NATIONAL FOREST
Availability of Draft Environmental Statement

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, Modoc National Forest, California USDA-FS-R-DES (Adm) 75-6.

The environmental statement concerns a proposed timber management plan for the management of the timber resources on the forest.

This draft environmental statement was transmitted to CEQ on December 17, 1974.

Copies are available for inspection during regular working hours on the following locations:


USDA, Forest Service, 630 Sansome Street, San Francisco, California 94111.

USDA, Forest Service, 441 North Main Street, Alturas, California 96101.

A limited number of single copies are available upon request to Douglas R. Leisz, Regional Forester, USDA Forest Service, 50th Street, San Francisco, California 94111.

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 Douglas R. Leisz, Regional Forester, 630 Sansome Street, San Francisco, California 94111. Comments must be received by February 17, 1975, in order to be considered.
In the preparation of the final environmental statement.

GLENN P. HANBY, Deputy Regional Forester.

DECEMBER 17, 1974.

[SFR Doc.74-29988 Filed 12-23-74;7:45 am]

SOIL CONSERVATION SERVICE

NOTICE OF NEGATIVE DECLARATION

Pursuant to section 102(2)(C) of the National Environmental Policy Act of 1969; § 1508.5(c) of the Council on Environmental Quality guidelines (38 FR 20550 August 1, 1973; and § 1508.5(b)(3) of the Soil Conservation Service Guidelines (39 FR 19651 June 3, 1974; the Soil Conservation Service, U.S. Department of Agriculture, gives notice that an environmental impact statement is not being prepared for the Upper Elk River Watershed Project, Ellis Butler, and Greenwood Counties, Kansas.

The environmental assessment of this federal action indicates that the project will not create significant adverse local, regional, or national impacts on the environment and that no significant controversy is associated with the project. As a result of these findings, Mr. Robert K. Griffin, State Conservationist, Soil Conservation Service, USDA, First National Bank Building, Temple, Texas 76501, has determined that the preparation and review of an environmental statement is not needed for this project.

The project concerns a plan for watershed protection and flood prevention. The planned works of improvement remaining to be built include conservation land treatment supplemented by 22 floodwater retarding structures.

The environmental assessment file is available for inspection during regular working hours at the following locations: Soil Conservation Service, USDA, First National Bank Building, Temple, Texas 76501, has determined that the preparation and review of an environmental impact statement is not needed for this project.

The proposal concerns an independent portion of the remaining works of improvement consisting of 16 miles of multiple-purpose channel work for flood prevention and drainage on intermittent and ephemeral streams and about 112 pipe drop structures.

No administrative action on implementation of the proposal will be taken until 15 days after the date of this notice.

S. The following are notices of the receipt of applications for duty-free entry of scientific articles

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 1968 (Public Law 89-651; 80 Stat. 897). Interested persons may present their views with respect to the question of whether an instrument or apparatus of equivalent scientific value for the purpose 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, 1974, 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: 75-00213-33-90000. Applicant: University of Wisconsin Center for Health Sciences, Dep't of Radiology, 1300 University Avenue, Madison, Wisconsin 53706. Article: Scanning Electron Microscope, Model JSM U-S. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used to carry out sophisticated studies of metallic, nonmetallic, biological materials. Specific projects will include:

1. Large strain rate deformation of materials.
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. Calcium tissue research.
8. Drug release rate of polymers.

The article will also be used for educational purposes in graduate and undergraduate level courses, including nontechnical people in health sciences. Application received by Commissioner of Customs: November 19, 1974.

Docket Number: 75-00213-05-60000. Applicant: State University of New York at Buffalo, 345 Main Street, Buffalo, New York 14214. Article: Scanning Electron Microscope, Model JSM U-S. Manufacturer: JEOL Ltd., Japan. Intended use of article: The article is intended to be used to carry out sophisticated and detailed studies of metallic, nonmetallic, biological materials. Specific projects will include:

1. Large strain rate deformation of materials.
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. Calcium tissue research.
8. Drug release rate of polymers.

The article will also be used for educational purposes in graduate and undergraduate level courses, including nontechnical people in health sciences. Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00213-01-11000. Applicant: Yale University, Purchasing

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Dep t, 260 Whitney Avenue, New Haven, Connecticut 06520. Article: Gas Chromatograph-Mass Spectrometer, Model 5400, MAT GmbH. Manufacturer: Varian MAT, Cincinnati, Ohio. Intended use of article: The article is intended to be used for the study of metabolites in the blood and urine from patients with metabolic disease and from control subjects. The materials analyzed will be complex mixtures of compounds extracted from blood or urine. The objectives of the investigations that will require use of the article are threefold: 1) to detect and characterize metabolic disorders which have not yet been described; 2) to establish the diagnosis of known diseases in new patients; 3) to study such disorders, both known and newly discovered, in greater detail in order to gain insight into their biochemical origins and implications.

Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00215-33-46500.

Applicant: West Virginia University Medical Center, Medical Center Campus, Morgantown, West Virginia 26506. Article: Ultramicrotome, Model LKB 8800A. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to section materials for high resolution light and electron microscope examination of renal tubules from rats 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: 75-00219-33-46500.

Applicant: Yale University, Purchasing Dept., 20 Ashmun Street, New Haven, Conn. 06520. Article Ultramicrotome, Model LKB 8800A. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to section materials for high resolution light and electron microscope examination of kidney tubules from rats 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: 75-00220-33-46500.

Applicant: County of Los Angeles, John Wesley Hospital, 2625 S. Hope Street, Los Angeles, Calif. Article: Ultramicrotome, Model LKB 8800A. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used to section specimens of human blood and bone marrow for investigation aimed at understanding the normal maturation process of human bone marrow cells and aberrations of this process which occur in neoplastic diseases. The article will also be used to train physicians in techniques for electron microscopy. Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00221-33-46000.

Applicant: Delaware Valley Neurosurgical Association—Episcopal Hospital, 1115 N. 30th Street and Lehigh Avenue, Philadelphia, Pa. 19125. Article: EMI Scanner System. Manufacturer: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used to study the brain, bone, and soft tissues 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, isotope brain scan versus CTT and ultrasound versus CTT. CTT is also intended to be used to train neurological, neurosurgical and radiological residents, as well as medical students and physicians in the use of CTT. Application received by Commissioner of Customs: November 20, 1974.

Docket Number: 75-00224-33-46000.

Applicant: Philadelphia College of Osteopathic Medicine, 4150 City Avenue, Philadelphia, Pa. 19114. Article: Electron Microscope, Model LKB 8800A. Manufacturer: LKB Produkter AB, Sweden. 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 concerned with the effect of the oviductal constituents of various hormones on the capillary permeability and vascular changes associated with pregnancy.
2. The structural organization of skeletal and cardiac muscle in normal and pathological material from man and animals.
3. Experiments in the important process of genetic activity and genetic replication that occur in normal and virally infected cells, including protein-nucleic acid interactions during adenovirus 2 virus infection. The article will also be used to familiarize medical students with electron microscopy and to make the transition from light microscopy to electron microscopy. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00226-33-40010.

Applicant: Trenton State College, Trenton, New Jersey 08628. Article: Electron Microscope, Model HS-S. Manufacturer: Hitachi, Ltd., Japan. Intended use of article: The article is intended to be used in the following research:

1. The effects of drugs and ion imbalance on mitochondrial ultrastructure of Purkinje fibers of canine heart.
2. The origin and development of C-bodies and C-bodies in mutant and normal oocytes of Drosophila melanogaster and Drosophila virilis.
3. An ultrastructural analysis of green and blue-green algae of New Jersey: Taxonomic differentiation.
4. The ultrastructure of amoebocytes and lymphocytes isolated from hard clam, Mercenaria mercenari in polluted and non-polluted environments.
5. Electron microscopio visualization of DNA isolated from E. Coli during AX174 infection.

The article will also be used to introduce the undergraduate Biology major to the theory and practical operation of the electron microscope. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00227-33-90000.

Applicant: University of Michigan, 1405 East Ann Street, Ann Arbor, Michigan 48104. Article: Electron Scanning System. Manufacturer: LKB Produkter AB, Sweden. Intended use of article: The article is intended to be used for training graduate students in the modern aspects of neuroradiology and related sciences. The article is intended to be used for training graduate students in the modern aspects of neuroradiology and related sciences. In addition, the article will be used to present the modern aspects of neuroradiology to residents, neuroradiology fellows, medical students and x-ray technology students. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00228-90-40040.

Applicant: Ohio 45701. Article: Electron Microscope, Model HS-L. Manufacturer: Hitachi, Ltd., Japan. Intended use of article: The article is intended to be used for training graduate students in its...
use in the course Botany 735L, "Electron Microscopy." Students will be taught (1) basic procedures for preparing plant material for examination by transmission electron microscopy, and (4) photoelectron optics and related alignment procedures for transmission electron microscopy, (3) examination and evaluation of specimen image in the electron microscope, and (4) photographic recording of information. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00250-33-46500. Applicant: Veterans Administration Hospital, Long Beach, Calif. Article: 1400 V.F.W. Parkway, West Roxbury, Mass. 02123. Article: Ultramicrotome, Model LKB 8000A. Manufacturer: LKB Produktor AB, Sweden. Intended use of article: The article is intended to be used for studies of cardiac muscle from animals (cats, dogs, rats) and from human tissues removed at surgery. The article will also be used to copy histological sections of human liver and muscle to use the electron microscope for examination of normal and diseased tissues, in order to provide new information about diseases. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00230-33-36900. Applicant: The Pennsylvania State University College of Medicine, Department of Microbiology and Immunology, 224 Hidley, Hershey, Pa. 17033. Article: Electron Microscope, Model EM 201. Manufacturer: Philips Electronic Instruments, NVD, The Netherlands. Intended use of article: The article is intended to be used in the graduate course "Electron Microscope Techniques" to teach the basic techniques in specimen preparation, use of the electron microscope and photographic competence in developing and printing of electron micrographs, to graduate students, medical students and post-doctoral fellows, who intend to examine DNA or to use the ultrathin section technique in a phase of their research. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00231-75-68495. Applicant: University of California, Los Alamos Scientific Laboratory, P.O. Box 990, Los Alamos, New Mexico 87544. Article: Pump: Electric Drive. Manufacturer:Stansted Eng. Co. Ltd., United Kingdom. Intended use of article: The article is intended to be used to conduct P-V-T data on the molecular hydrogens. Application received by Commissioner of Customs: November 22, 1974.

Docket Number: 75-00229-33-46500. Applicant: Veteran's Administration Hospital, Long Beach, Calif. Article: Electronic Drive. Manufacturer: Stansted Eng. Co. Ltd., United Kingdom. Intended use of article: The article is intended to be used in an investigation carried out by the Department of Health, Education, and Welfare in cooperation with the University of California, Los Angeles, for the development of techniques which may be used in the conventional carotid angiography and pneumoencephalography. This may include the performing of X-rays using and subsequently found operative information. The article will be used to screen large numbers of patients, the results of which will be compared with the conventional carotid angiography and pneumoencephalography. Application received by Commissioner of Customs: August 28, 1974. Advice submitted by the Department of Health, Education, and Welfare: November 21, 1974.


Docket Number: 75-00232-33-46500. Applicant: Children's Hospital Research Foundation, 1000 East North Avenue, Pittsburgh, Pa. 15212. Article: EMI Limited, United Kingdom. Intended use of article: The article is intended to be used in an investigation carried out by the Department of Health, Education, and Welfare in cooperation with the University of California, Los Angeles, for the development of techniques which may be used in the conventional carotid angiography and pneumoencephalography. This may include the performing of X-rays using and subsequently found operative information. The article will be used to screen large numbers of patients, the results of which will be compared with the conventional carotid angiography and pneumoencephalography. Application received by Commissioner of Customs: August 28, 1974. Advice submitted by the Department of Health, Education, and Welfare: November 21, 1974.


Article: 2000-BeV accelerator which is to be used in the construction of a 200 BeV accelerator which is to be used in a large variety 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.

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.

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 EMU-95-2 differs considerably from the domestically manufactured instrument, The

2. The electron microscope 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 than the EMU-4C microscope, thus requiring a much higher degree of sophistication in its operation. By comparison, the EMU-95-2 was designed for biological applications, overall ease of foolproof operation and safer performance for students with little, or even without, previous experience.

3. 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.

4. A semi-automatic "beam finder" enabling rapid beam location even when the condenser aperture and the gun are completely disaligned;

5. Thin film metal objective apertures (three discs with seven holes each); it is possible to obtain "true" tilt, plus or minus 6°, by using the normal specimen holder, thus obviating the necessity of a tilting stage.

6. A fully automatic photographic system. The operation of a single lever activates a spot-reading timing system; negatives are transported automatically with double exposure excluded; provision for manual override is included and an "empty magazine" indicator is present.

7. Unique specimen airlock system in which the specimen holder and the handling rod are one unit. Thus, accidental separation and loss of the specimen during transfer operation is impossible.

8. Low number of controls at the column and console of the EMU-95-2.
advised that it knows of no additional domestic manufacture or availability of magnets considered comparable to the foreign article.

In response to Question 8(c) of the present submission, the applicant claims 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 (such domestic manufacturers as National Electric Coil, Westinghouse Electric Corporation and Almen Temescal) could not meet the specified delivery date because of prior contractual obligations and/or the capacity at which such magnets were being manufactured in the United States. Reasons: Examination of the applicant's research purposes. Applicant advises that the foreign article (those which offered proposals, were willing and able to produce the article) were manufactured in the United States. Reasons: Examination of the applicant's research purposes.

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 accelerators 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 a daily production capacity absorbed by domestic 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 excessive within the meaning of § 701.11(c).

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 additional domestic manufacturers 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.

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.).

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, which is being manufactured in the United States.

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.).

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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, which is being manufactured in the United States.

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.).

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, which is being manufactured in the United States.
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 used by many people, some of them in training, and others in research and education.

2. A range of magnification from very low to medium high, while not disturbing the specimen or losing the field of view.

3. Adequate resolution at higher magnification for differential of small particles and cellular organelles.2

4. Capability of using 70 mm camera for large number of simple oriented, sequential pictures in quantitative studies.

5. Ready availability of contract manufacturer's service and maintenance, and


At the time the article was ordered, two domestically manufactured electron microscopes were available. The Model EMU-4C is a relatively simple low resolution instrument designed for use by beginners with a minimum of supervision, manufactured by Elektron Incorporated. The Model EMU-4C, supplied by Adam David Company, HEW advises 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 camera or condenser (characteristics 4 and 6, respectively). Projected service needs (characteristic 5) and other conveniences cited (such as simplicity in operation characteristic 3) 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(c) 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 which purpose as 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(e) 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 response to the application form, if the delay in obtaining such domestic instrument, apparatus, or accessory (as indicated by the delivery times of foreign manufacturer) Is seriously impeding the accomplishment of the applicant's purposes.

We find that the difference between the delivery time for the article and the delivery time quoted for the domestic instrument is excessive within the meaning of § 701.11(c) since the longer delivery time of the domestic instrument would seriously impair the accomplishment of the applicant's purposes.

(Richard M. Seppa, Acting Director, Special Import Programs Division.

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(a) of the National, Scientific, and Cultural Materials Importation Act of 1969 (Pub. L. 83-651, 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. 20235.

Docket number: 76-00057-55-17000.

Applicant: University of Washington, Department of Oceanography, Seattle, Washington 98195. Article: Two Recording Current Meters, Model 4/4. Manufacturer: Ivar Aamod, Norway. Intended use of article: The article is intended to be used in experiments involving continuous detailed monitoring of currents and thermal fields in the Arctic Ocean.

Reasons: The article provides measurements of current speed, direction, water temperature, and other relevant electrical properties of the foreign article, for such purposes as this article is intended to be used, is being manufactured in the United States.

Comments: No comments have been received with respect to this application.

Decision: Application denied. An instrument or apparatus of equivalent scientific value to the foreign article, for such purpose as this article is intended to be used, is being manufactured in the United States.

We find that the difference between the delivery time for the article and the delivery time quoted for the domestic instrument is excessive within the meaning of § 701.11(c) since the longer delivery time of the domestic instrument would seriously impair the accomplishment of the applicant's purposes.

(Richard M. Seppa, Acting Director, Special Import Programs Division.

Decision on Application for Duty-Free Entry of Scientific Article

The foreign article was ordered December 7, 1973, with a quoted delivery time of six months. The quoted delivery time of the Varian Model Clime 35 was 700 days (approximately 25 months). We are advised by the Department of Health, Education, and Welfare (HEW) in its memorandum dated December 11, 1974 that the delivery time for the Clime 35 is excessive. The Department advises the applicant that research and educational programs would be delayed by approximately one year if the domestic article was to be utilized. Accordingly, we find that the difference between the delivery time for the article and the delivery time quoted for the domestic instrument is excessive within the meaning of § 701.11(c) since the longer delivery time of the domestic instrument would seriously impair the accomplishment of the applicant's purposes.

(Richard M. Seppa, Acting Director, Special Import Programs Division.)
to the applicant's purposes within the meaning of § 701.22(n) of the regulations. The most closely comparable domestic instrument is the Model VACM vector averaging current meter manufactured by AMF Sea-Link Systems. The VACM provides measurement of current speed, current direction, and water temperature (−2 to 30 °C) with internal data recording. It utilizes the vector averaging technique which continuously samples current velocity every 1/2 turn from minimum to maximum velocity, and in addition, the VACM, has a 11.5 x 10^6 bit data storage capacity which is equivalent to or better than that of the article and, which permits sampling frequencies 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 Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppe,
Acting Director,
Special Import Programs Division.

[FR Doc.74-29966 Filed 12-23-74;8:45 am]

YALE UNIVERSITY, ET AL.

Consolidated Decision on Application for Duty-Free Entry of Scientific Articles

In the notice of consolidated decision on application for duty-free entry of scientific articles appearing at page 42334 in the Federal Register of Monday, December 9, 1974, the following docket should be deleted:

Docket number: 74-00437-00-42600.
Applicant: National Aeronautics and Space Administration, Langley Research Center (MS 145), Hampton, Virginia 23685.
Article: Alpha-numeric Display Device Made from a Two-Color-Multi-Array of Light-Emitting Diodes.
Manufacturer: Bowmar Canada Limited, Canada. Dated of denial without prejudice to resubmission: July 2, 1974.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials.)

Richard M. Seppe,
Acting Director,
Special Import Programs Division.

[FR Doc.74-29967 Filed 12-23-74;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 saccharin as sweetening agents. The Food and Drug Administration has also received information, as yet unconfirmed, that other food manufacturers may be using mixtures of saccharin and nutritive 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(g), 402(a)(2)(C) and 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g), 342(a)(2)(C), 348) and may not be used in food except under the conditions of use set forth in 21 CFR 121.400, 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 nutritive sweeteners and saccharin or its salts in ‘diet beverages’ or diet beverage bases are also subject to additional requirements set forth in 21 CFR 3.72. Both regulations set forth restrictions upon use and regulation to which they apply and to labeling requirements.

The purpose of this notice is to emphasize the existence of the above-referenced regulations and to inform all beverage and other food manufacturers that upon 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 activity. Illegal use of saccharin or its salts in beverages products involved and the responsible companies and individuals to potential regulatory action, including seizure, injunction, and criminal prosecution.

Dated: December 18, 1974.

William F. Randolph,
Acting Associate Commissioner
for Compliance.

[FR Doc.74-29305 Filed 12-23-74;8:45 am]

ADVISORY COMMITTEES

Notice of Renewal

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776; 5 U.S.C. App.), the Food and Drug Administration announces the renewal by the Secretary, Department of Health, Education, and Welfare, of the Panel on Review of Dentifrices and Dental Care Products, and the responsible companies and individuals to potential regulatory action, including seizure, injunction, and criminal prosecution.


William F. Randolph,
Acting Associate Commissioner
for Compliance.

[FR Doc.74-30046 Filed 12-23-74;8:45 am]

FEDERAL REGISTER, VOL. 39, NO. 246—TUESDAY, DECEMBER 24, 1974

NATIONAL ADVISORY FOOD AND DRUG COMMITTEE

Notice of Establishment

Pursuant to the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776; 5 U.S.C. App.), the Food and Drug Administration announces the establishment by the Secretary, Department of Health, Education, and Welfare, on November 15, 1974, of the following advisory committee:

Designation. National Advisory Food and Drug Committee.

Purpose. The committee will review and evaluate agency programs and provide advice and guidance to the Secretary, Assistant Secretary for Health, and the Commissioner of Food and Drugs on policy matters of national significance as they relate to policy matters of national significance as they relate to FDA's statutory mission in the following areas: Food, drugs, cosmetics, medical devices, biological products, and electronic products.

Authority for this committee will expire November 15, 1976, unless the Secretary formally determines that continuation is in the public interest.

Concurrent with this action, the Secretary also establishes the following committees under the National Advisory Committee Act of October 6, 1972 (Pub. L. 92-463, 86 Stat. 770-776; 5 U.S.C. App.):

(1) Health, Education, and Welfare, the National Advisory Review Committee, the National Advisory Food Committee, and the National Advisory Veterinary Medicine Committee.


WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc.74-30047 Filed 12-23-74;8:45 am]

TOXICOLOGY ADVISORY COMMITTEE

Notice of Establishment


WILLIAM F. RANDOLPH,
Acting Associate Commissioner
for Compliance.

[FR Doc.74-30048 Filed 12-23-74;8:45 am]
NOTICES

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 308, 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 report matters. 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 a.m. 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 other technical information; financial data, such as salaries; and personal information concerning individuals associated with the applications and proposals.

Dr. Luis A. Froehlich, Executive Secretary, Allergy and Immunology Research Committee, Extramural Programs, National Institute of Allergy and Infectious Diseases, Westwood Building, Room 703, Bethesda, Maryland, telephone (301) 496-7131, will furnish substantive program information.

Suzanne L. Fremeau, Committee Management Officer, National Institutes of Health.

December 12, 1974.

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 30 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 30 from 12 noon to 5 p.m.

Suzanne L. Fremeau, Committee Management Officer, National Institutes of Health.

December 12, 1974.
NOTICES

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, NIGMS, Building 31, Room 4A46, Bethesda, Maryland 20014, Telephone: 301-496-6676, will provide a summary of the meeting and a roster of committee members.

Dr. Robert S. Melville, Executive Secretary, Automation in the Medical Laboratory Sciences Review Committee, Westwood Building, Room 954, Bethesda, Maryland 20014, Telephone: 301-496-7081, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program No. 18-660, National Institute of General Medical Sciences, National Institutes of Health)

SUSANNE L. FREEMAN,
Committee Management Officer,
National Institutes of Health.

DECEMBER 12, 1974.

[FR Doc.74-29942 Filed 12-23-74; 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 20-22, 1975, at the El Tropicano Motor Hotel, River Room, San Antonio, Texas.

The meeting will be open to the public from 8 a.m. to 10:30 a.m. on January 20, 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 Chilen, Blair Building, Room 716A, National Cancer Institute, National Institutes of Health, Bethesda, Maryland 20014, (301) 427-1748.

SUSANNE L. FREEMAN,
Committee Management Officer,
National Institutes of Health.

DECEMBER 17, 1974.

[FR Doc.74-29932 Filed 12-23-74; 8:45 am]

BIOMEDICAL LIBRARY REVIEW COMMITTEE
Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Biomedical Library Review Committee, National Library of Medicine, on February 5-6, 1975, from 8:30 a.m. to 5:00 p.m. each day, in the Board Room of the National Library of Medicine, 8600 Rockville Pike, Bethesda, Maryland.

This meeting will be open to the public from 8:30 a.m. to 10:30 a.m. and from 2 p.m. to 5 p.m. 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 grants 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, Telephone Number: 301-496-4191, will furnish summaries of the meeting, rosters of committee members, and substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13-349, National Institute of General Medical Sciences, National Institutes of Health)

SUSANNE L. FREEMAN,
Committee Management Officer,
National Institutes of Health.

DECEMBER 12, 1974.

[FR Doc.74-29945 Filed 12-23-74; 8:45 am]

BREAST CANCER EPIDEMIOLOGY COMMITTEE
Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of the meeting of the Breast Cancer Epidemiology Committee, National Cancer Institute, February 11, 1975, Tropicana Hotel, Central American Room, San Antonio, Texas. This meeting will be open to the public from 10:30 a.m. to 1 p.m. on February 11, 1975 from 12:30 p.m. to 1 p.m. to discuss miscellaneous committee matters. 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 11, 1975 from 1 p.m. until adjournment at 2 p.m. for review of contract proposals. The contracts 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 contracts.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 3A16, National Institutes of Health, Bethesda, Maryland 20014 (301) 496-5708, will furnish summaries of the meeting and rosters of committee members.

Dr. Bernice T. Radovich, Executive Secretary, Tandau Building, Room E-404, National Institutes of Health, Bethesda, Maryland 20014 (301) 496-5775, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program No. 13-662, National Institutes of Health)

SUSANNE L. FREEMAN,
Committee Management Officer,
National Institutes of Health.

DECEMBER 17, 1974.

[FR Doc.74-29950 Filed 12-23-74; 8:45 am]

BREAST CANCER NETWORK MEETING
Notice of Meeting

Notice is hereby given of the meeting of the Breast Cancer Network Meeting, National Cancer Institute, January 15, 1975, Building 31, Conference Room 5.

This meeting will be open to the public from 8:30 a.m. to adjournment on January 15, 1975 to discuss the details of management plans for the operation of the Breast Cancer Networks. Attendance by the public will be limited to space available.

For additional information please contact: Dr. Roger Halterman, Blair Building, Room 6A09, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, (301) 427-1747.

SUSANNE L. FREEMAN,
Committee Management Officer,
National Institutes of Health.

DECEMBER 17, 1974.

[FR Doc.74-29952 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 to be held in Building 31, C-Wing, Conference Room 7.

This meeting will be open to the public on January 31, 1975, from 9 a.m. to 10:15 a.m. for a report on the evaluation of dental research institutes and centers. 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. Rigg, Special Assistant for Institutes and Centers, National Institute of Dental Research, National Institutes of Health, Westwood Building, Room 507, Bethesda, Maryland 20014 (telephone 301-496-7419) will provide summaries of meetings; rosters of committee members, and will furnish substantive program information.

Suzanne L. Freneau, Committee Management Officer, National Institutes of Health.

December 16, 1974.

[FR Doc.74-29945 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 31, Rm. 6, Bethesda, Md., but has been changed to the United Inn, 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.

Suzanne L. Freneau, Committee Management Officer, National Institutes of Health.

December 18, 1974.

[FR Doc.74-29977 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, Bldg. 31-C, Conference Room 8, Bethesda, Maryland.

This meeting will be open 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 32-49, Bethesda, Maryland 20014, phone 301-496-6955, 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 Project Committee, National Heart and Lung Institute, January 31–February 1, 1975, National Institutes of Health, Building 31, Conference Room 8. This meeting will be open to the public on January 31, 1975, from 8:30 a.m. to approximately 9:30 a.m. to discuss administrative details and to hear a report of the current status of the Division of Lung Diseases. 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 9:30 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, Landow Building, Room 1005, phone (301) 496-7506, will furnish substantive program information.

(Catalog of Federal Domestic Assistance Program Nos. 13.837, 13.838, and 13.839 National Institutes of Health)

SUSANNE L. FREMAU, Committee Management Officer, National Institutes of Health.

DECEMBER 12, 1974.

[FR Doc.74-29944 Filed 12-23-74; 8:45 am]

INFECTION DISEASE COMMITTEE
Notice of Meeting

Pursuant to Public Law 92-463, 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.

This meeting will be open to the public from 9 a.m. to 3 p.m. on January 16, 1975 to review and discuss the hepatitis collaborative program and from 8:30 a.m. to 3 p.m. on January 17, 1975 to review and discuss 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 section 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 from 9 a.m. to 5 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 adjournment on January 17, 1975 for the review, discussion, and evaluation of the Ara-A collaborative study. These contracts 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.

SUSANNE L. FREMAU, Committee Management Officer, National Institutes of Health.

DECEMBER 12, 1974.

[FR Doc.74-29944 Filed 12-23-74; 8:45 am]
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NOTICES

MATERIAL AND CHILD HEALTH RESEARCH COMMITTEE

Notice of Meeting

Pursuant to Pub. L. 92-465, notice is hereby given of the meeting of the Material and Child Health Research Committee, National Institute of Child Health and Human Development, on December 24, 1974, in Room C418, Landow Building, 1010 Woodmont Avenue, Bethesda, Maryland.

The meeting will be open to the public on December 24, 1974, from 9 a.m. to 11 a.m., to discuss general business of the Committee and reports from the Acting Associate Director for Extramural Programs, Program Director for Perinatal Biology and Infant Mortality Branch, Acting Program Director for Growth and Development Branch, and the Executive Secretary of the 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) of Title 5, U.S. Code and section 10(d) of Pub. L. 92-465, the meeting will be closed to the public on December 24, 1974, from 11 a.m. until 3 p.m., to adjourn for 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.

Mrs. Marjorie Neff, Committee Management Officer, NICHD, Landow Building, Room C-603, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496-1756, will provide summaries of the meeting and rosters of committee members. Dr. Patsy H. Sampson, Executive Secretary of the Maternal and Child Health Research Committee, NICHD, Room C717, Landow Building, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496-5556, will furnish substantive program information.

NEUROLOGICAL DISEASES AND STROKE SCIENCE INFORMATION PROGRAM ADVISORY COMMITTEE

Notice of Meeting

Pursuant to Public Law 92-465, 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 29-31, 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 29-30, and from 9 a.m. to 10:30 a.m. on January 31, 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 by the Director, NINDS to the Congress, which in its second supplemental appropriation of 1974 for the DHHS, required reconsideration of a previous decision regarding the information centers in this 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 meeting and rosters of committee members.

Mr. Alfred Weissberg, Executive Secretary of the Committee, Room 706, Federal Bldg., Phone: 49-6004, will provide substantive program information.

NEUROLOGY A STUDY SECTION

Amended Notice of Meeting

Notice is hereby given of a change in the meeting date of the Neurology A Study Section, Division of Research Grants, which was published in the Federal Register on November 29, 1974 (39 FR 41971).

The Neurology A Study Section was to have convened at 9:30 a.m. on January 8-11, 1975, but has been changed to 9:00 a.m. January 8-11, 1975 at Building 1, Bethesda, Maryland, the location for which it was originally scheduled.

The 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.


SUZANNE L. FREEMAN
Committee Management Officer, National Institutes of Health.

[FR Doc.74-29940 Filed 12-23-74; 8:45 am]

POPULATION RESEARCH COMMITTEE

Notice of Meeting

Pursuant to Pub. L. 92-463, notice is hereby given of the meeting of the Population Research Committee, National Institute of Child Health and Human Development, on January 30-31, 1975, in Room C-418, Landow Building, 1010 Woodmont Avenue, Bethesda, Maryland.

This meeting will be open to the public on January 20, 1975 from 9 a.m. to 10:30 a.m. to discuss the program status, new developments and projections for population research centers and program projects. 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) of Title 5, U.S. Code and section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on January 20, 1975 from 10:30 a.m. until adjournment, 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.

Mrs. Majorie Neff, Committee Management Officer, NICHD, Landow Building, Room C-603, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496-6616, will furnish summaries of meetings and rosters of committee members.

Dr. William A. Sadler, Executive Secretary of the Population Research Committee, NICHD, Room C-733, Landow Building, National Institutes of Health, Bethesda, Maryland, Area Code 301, 496-6616, will furnish substantive program information.


SUZANNE L. FREEMAN
Committee Management Officer, National Institutes of Health.

[FR Doc.74-29903 Filed 12-23-74; 8:45 am]

FEDERAL REGISTER, VOL. 39, NO. 245—TUESDAY, DECEMBER 24, 1974
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 occurred at the Connecticut Inn Motel, Washington, D.C., but has been moved to the Bethesda Motor Hotel, 7740 Wisconsin Avenue, Bethesda, Maryland at 9 a.m. January 18, 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 Hilton Inn, Cheverly, Maryland, the same location for which it was originally scheduled.

These meetings will be open to the public for approximately one hour at the beginning of the first session of the first day of the meeting.


Suzanne L. Freneau,
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 the authority contained in the Cooperative Research Act, Pub. L. 83-531, as amended, 20 USC 331, applications are being accepted for non-competing continuation grants under the Right to Read State Grants Program. No new grants will be awarded under this program.

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 it is due the following business day, as evidenced by the U.S. Postal Service postmark on the wrapper or envelope, or on the original receipt from the U.S. Postal Service.

(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.

Hand delivered applications 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 8:30 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 D); and the Regulations for the State Grants Program which are being separately published in the Federal Register in proposed form (45 CFR Part 151, Subpart D).

Program information and forms. Information 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 U.S.C. 331a(a) (1))

Dated: December 17, 1974.

Suzanne L. Freneau,
Committee Management Officer,
National Institutes of Health.

NOTICES

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, Building 31, National Institutes of Health, Bethesda, Maryland.

The entire meeting will be open to the public on February 1, 1975, from 8:30 a.m. until 5 p.m. to discuss the Division of Lung Diseases programs relative to contracts and Specialized Centers of Research. Attendance by the public will be limited to space available.

Mr. York Cannon, Chief, Public Inquiries and Reports Branch, National Heart and Lung Institute, Building 31, Room 5A21, National Institutes of Health, Bethesda, Maryland.

The meeting will be closed to the public from 12 p.m. to 1:30 p.m. to adjournment for review and discussion of the proposed fiscal year 1975 budget in accordance with the provisions set forth in section 552(b) (6) of Title 5 U.S. Code and 10(d) of Pub. L. 92-463.

Mrs. Marjorie F. Early, Committee Management Officer, NCI, Building 31, Room 3A18, National Institutes of Health, Bethesda, Maryland 20204 (301/496-5708) will furnish transcripts of the open meeting and roster of committee members.

Dr. Richard A. Tjalsma, Executive Secretary, Building 31, Room 3A18, National Institutes of Health, Bethesda, Maryland 20204 (301/496-5854) will provide substantive program information.

Dated: December 18, 1974.

Suzanne L. Freneau,
Committee Management Officer,
National Institutes of Health.

[FR Doc. 74-59933 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.

Discussion of Roles of Vocational Education, Career Education, Career Counseling, and GSEA.

Discussion of Council Priorities and Concerns for FY 76.

The proposed agenda includes:

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, located at 43 Federal Plaza, Room 400, Suite 413, 425-13th Street, NW, Washington, D.C. 20004.

Signed at Washington, D.C., on December 16, 1974.

Calvin Dellefield, Executive Director.

[FR Doc No. 74-29006 Filed 12-30-74; 8:45 a.m.]

**DEPARTMENT OF TRANSPORTATION**

National Highway Traffic Safety Administration

[Docket No. 74-10; Notice 09]

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. 74-74-10-1 of the docket.) Specifically, the requirement that trailer-trailers be capable of meeting the braking test requirements without lockup of wheels, except in certain limited circumstances, has been questioned as unduly designating 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 maintaining and the degree to which the vehicle's directional stability and controllability remain uncompromised by brake application. (b) Minimum safe levels of deceleration capability are assured by prescribing maximum distances within 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 constraints 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 cannot be compensated by the typical driver, and (b) that all wheels continue rolling until the vehicle's speed falls below 10 mph.

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.


Issued on December 18, 1974.

James B. Gregory, Administrator.

[FR Doc No. 74-29006 Filed 12-30-74; 10:36 a.m.]

**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 discussion of which, if written, would fall within exemption (5) of 5 U.S.C. 552b. Any factual material that may be presented during the meeting will be inextricably interwoven with such exempt material, and no separation of this material is considered practicable. 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 No. 74-29019 Filed 12-23-74; 4:45 a.m.]

ADVISORY COMMITTEE ON REACTOR SAFEGUARDS WORKING GROUP ON IMPER 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

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 and, in some cases, to delineate techniques used by the staff in evaluating specific protective designs 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 present revisions necessary to make a portion of the Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, Revision 1, October 1972 (Regulatory Guide 1.70), consistent with the appropriate Standard Review Plan. Standard Review Plans (SRPs) are being prepared by the Regulatory staff for the guidance of staff reviewers who perform the detailed safety review of applications to construct or operate nuclear power plants. A primary purpose of SRPs is to improve the quality and uniformity of staff reviews and to provide a well-defined basis from which they can evaluate proposed changes in the scope and requirements of reviews. A complete Revision 2 of the Standard Format is contained in this 1.70.X series and 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: Decking and Service Section.

Regulatory Guides are available for inspection at the Commission's Public Document Room, 111 H Street NW, Washington, D.C. 20545, for single copies of issued guides which may be reproduced or for placement on an automatic distribution 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. Regulatory Guides are not copyrighted and Commission approval is not required to reproduce them.

(6 U.S.C. 522(a))

Dated at Rockville, Maryland this 17th day of December 1974.

For the Atomic Energy Commission.

LESTER ROGERS,
Director of Regulatory Standards.

[FR Doc.74-30020 Filed 12-23-74;3:45 am]

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. 2039, 2223b), the Advisory Committee on Reactor Safeguards will hold a meeting on January 9-11, 1975 in Room 1046, 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, 5:30 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 the review of the request for a construction permit for this station. Portions of this meeting will be closed if required to hear presentations and discuss security arrangements for this plant.

With respect to public participation in the open portion of the meeting, the following requirements shall apply:

The Potomac Electric Power Company 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 Commission's Public Document Room, 1717 H Street, Washington, D.C. 20545, and as follows:

RIVERBEND STATION, Units 1 & 2
Audubon Library, West Feliciana Branch, St. Francisville, Louisiana 70775.

DOUGLAS POINT NUCLEAR GENERATING STATION
St. Charles County Library, Garretts and Charles Street, La Place, Maryland 20648.

WASH-1400, REACTOR SAFETY STudy
AEC's field information office in Albuquerque, Chicago; King of Prussia, Pennsylvania; Idaho Falls, Idaho; Las Vegas, Nevada; Grand Junction, Colorado; Oak Ridge, Tennessee; Richland, Washington; San Francisco; Alken, 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 in accordance with 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 telephone call on January 8, 1975, to the Office of the Executive Secretary of the Committee (Telephone: 202-334-1571) 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 ACRS 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 made 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 Management Officer.

[FR Doc.74-30097 Filed 12-23-74;8:46 am]

JERSEY CENTRAL POWER AND LIGHT CO.
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 2768, 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 17260). The comments received from Federal, State, local and interested members of the public have been included as appendices to the Final Environmental Statement.

Single copies of the Final Environmental Statement may be obtained by writing the U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Deputy Director for Reactor Projects, Directorate of Licensing.

Dated at Bethesda, Maryland, this 20th day of December 1974.

For the Atomic Energy Commission.

Wm. H. REAGAN, Jr.,
Chief, Environmental Projects Branch 4, Directorate of Licensing.

[FR Doc.74-30097 Filed 12-23-74;8:46 am]

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 Operating License No. DPR-34, dated October 19, 1973, 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, Amendment No. 5 to License No. DPR-34, with any attachments, and (2) 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—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.74-30098 Filed 12-23-74;8:46 am]
NOTICES

[Docket Nos. 50-445 & 50-446]
TEXAS UTILITIES GENERATING CO. ET AL. (COMANCHE PEAK STEAM ELECTRIC STATION, UNITS 1 AND 2)
Assignment of Members of Atomic Safety and Licensing Appeals 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 Appeals Panel has assigned the following panel members to serve as the Atomic Safety and Licensing Appeals Board for these proceedings:

Ailan S. Rosenthal, Chairman
Michael G. Ferrar, Member
Dr. Lawrence B. Quaries, Member

Dated: December 17, 1974.
MARGARET E. DU FLEO,
Secretary to the Appeal Board.

[Docket No. 50-189]
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-105 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 revise provisions in the Technical Specifications to increase the maximum allowable energy release rate from 15 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 proceeding may file a request for a public hearing in the form of a petition to the Chairman of the Board to intervene in accordance with Section 2.787 of the Federal Energy Regulations (FERC 10, Part 2, of the Commission’s regulations). Petitions for leave to intervene must be filed under oath or affirmation and in accordance with the provisions of §2.714 of 10 CFR Part 2 of the Commission’s regulations. Petitions for leave to intervene must set forth the interest of the petitioner in the proceeding and whether the amendment to the facility operating license should be issued.

A petition for leave to intervene must be filed under oath or affirmation and in accordance with the provisions of the Federal Register Notice and §2.714, and must be filed with the Secretary of the Commission, U.S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Deputy Director for Reactor Projects, Directorate of Licensing—Regulation.

Dated at Bethesda, Maryland, this 13th day of December, 1974.
For the Atomic Energy Commission.
GEORGE LEX,
Chief, Operating Reactors Branch No. 3, Directorate of Licensing—Regulation.

[Civil Aeronautics Board]
CIVIL AERONAUTICS BOARD
[Docket No. 32753; Order 74-12-71]
AIRLIFT INTERNATIONAL, INC.
Surcharge Per Shipment of Restricted Articles, Order of Suspension and Investigation
Airlift International, Inc. (Airlift) proposes 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 tariff rule requiring that restricted articles be tendered outside of containers under container charges has resulted in Airlift's absorbing additional costs; that these costs, which are adequately identified and classified, are additional direct labor costs per shipment plus certain non-labor costs; that the proposal would generate $35,400 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 Hazards presents a complaint requesting rejection, or alternatively, suspension and investigation. In support of its request for rejection, COSTHA alleges, inter alia, that the proposal is penalizing transportation of non-labor costs in accordance with the tariff restriction on acceptance of containerized restricted articles, and that tariff non-acceptance is a matter outside the authority of the Board to consider. In support of a request for suspension and investigation, COSTHA alleges, among other things, that the proposal is based on purported costs incurred by the carrier in voluntary action to contravene a common carrier obligation; that the direct labor cost comparison submitted by Airlift is inadequate to support the claim assessed, since it is a comparison without indication as to methodology or identification of services performed in consuming 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, and that COSTHA has essentially complied with the Board's Economic Regulations on filing tariffs (10 CFR Part 221), and, consequently, we find no basis for rejection.

Upon consideration of all relevant matters, however, the Board finds that Airlift's proposal may be unjust, 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 partial list of non-labor costs, not quantified. The man-minute study indicates that a restricted article shipment requires an average of 50 man-minutes at $5.59 per man-minute.

We believe that the foregoing submission has significant effects. There is no indication of the size of the sample upon which the man-minute data are based; without such indication, it is impossible
to evaluate the accuracy of the figures. Moreover, we believe that terminal handling costs for restricted article shipments may vary by the number of pieces per shipment, as well as by the number of shipments. For example, Airlift claims that over half of the man-hours, 26.5 out of a total of 50, are required for an item that includes "inspection of packaging, marking, and labeling; confirmation of quantity limitations," as well as certain other items. It is apparent that the requirements indicated above vary with the number of pieces per shipment. Consequently, Airlift's submission raises a serious question as to whether a surcharge applied on a per-shipment basis, regardless of the number of pieces per shipment, is unreasonable or unjustly discriminatory.

Our suspension action herein is consistent with those actions taken with respect to proposals establishing a $3.00 surcharge per shipment in Orders 74-1-100 for Braniff Airways, Inc. (Braniff) and 75-12-12 for Air Interpol, Ltd. (United). Investigation of these surcharges was consolidated into the Domestic Freight Rate Investigation, Docket 23885.

Accordingly, pursuant to the Federal Aviation Act of 1958, and particularly sections 204(a), 403, 404, and 1002 thereof,

It is ordered, That: 1. An investigation is instituted to determine whether the charge and provisions in Rule No. 51(C) on 26th and 27th Revised Pages 18-B of Airline Tariff Publishers, Inc., Agent, Tariff C.A.B. No. 96, and rules, regulations, or practices affecting such charge and provisions, are or will be unjust, unreasonable, unjustly discriminatory, unduly preferential, unduly prejudicial, or otherwise unlawful, and if found to be unlawful, to determine and prescribe the lawful charge and provisions, and rules, regulations, or practices affecting such charge and provisions;

2. Pending hearing and decision by the Board, the charge and provisions in Rule No. 51(C) on 26th and 27th Revised Pages 18-B of Airline Tariff Publishers, Inc., Agent, Tariff C.A.B. No. 96, are suspended and their use deferred to and including March 19, 1975, unless otherwise ordered by the Board, and that no changes be made therein during the period of suspension except by order or special permission of the Board;

3. The proceeding herein designated Docket 27283, be assigned before an Administrative Law Judge of the Board at a time and place hereafter to be designated;

4. Except to the extent granted herein, the complaint of the Council for Safe Transportation of Hazardous Articles in Docket 27218 is dismissed; and

5. Copies of this order shall be filed with the tariff and served upon Airlift International, Inc., and the Council for Safe Transportation of Hazardous Articles, which are hereby made parties to Docket 27283.

This order will be published in the Federal Register.

By the Civil Aeronautics Board.

[SEAL] EDMIN Z. HOLLAND, Secretary.

[FR Doc.74-29985 Filed 12-23-74;8:45 am]

[Docket Nos. 27001 and 27003]

EASTERN AIRLINES, 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 1601 North Universal Building, 1875 Connecticut Avenue, NW, 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 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 will 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.


[FR Doc.74-29981 Filed 12-23-74;8:45 am]

[Docket No. 26280; Agreement C.A.B. 24815; Order 74-12-75]

INTERNATIONAL AIR TRANSPORT ASSOCIATION

Order Regarding North Atlantic 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, embedded in the resolutions of the Joint Traffic Conferences of the International Air Transport Association (IATA). The agreement, requested at a North Atlantic Cargo Policy Meeting held November 4-8, 1974, has been approved by mail vote, has been designated Agreement C.A.B. 24810.

The agreement would extend the existing North Atlantic (except Africa) cargo rates structure, due to expire December 31, 1974, by one month to January 31, 1975. The IATA carriers consider this action necessary so they may have additional time to consider a proposal under development which would amend the entire North Atlantic rates structure as of February 1, 1976. In that case, the provisions of the agreement would expire December 31, 1976 or such other date as the agreement provides.
light we will approve the instant agreement. At this time, we will also approve a mail vote agreement establishing bulk utilization charges for rate classifications three and five from Jersey to New York at levels representing a differential seven cents higher than existing rates between New York and London.

The Proposed Additions to sections 102, 204(a), and 412 of the Act, does not find resolutions JT12(Mail 856) 002 and JT12(Mail 854) 534a, incorporated in Agreements C.A.B. 24819 and 24835 respectively, to be adverse to the public interest or in violation of the Act provided that approval is subject, where applicable, to conditions previously imposed by the Board.

Accordingly, it is ordered, That: 1. Agreements C.A.B. 24819 and 24835 be and hereby are approved subject, where applicable, to conditions previously imposed by the Board;

2. The carriers and affected indirect air carriers are hereby authorized to file tariffs implementing or reflecting the provisions of Agreement C.A.B. 24819 on not less than one day's notice for effectiveness not earlier than January 1, 1975. The authority granted in this paragraph expires on January 31, 1975; and

3. Tariffs implementing the agreements shall be marked to expire on their respective expiry dates.

This order will be published in the Federal Register.

By the Civil Aeronautics Board.

Edwin E. Holland, Secretary.

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

COTTON TEXTILES

Products Produced or Manufactured in the Republic of China

DECEMBER 18, 1974.

On January 4, 1974, there was published in the Federal Register (39 FR 11629), a letter dated December 27, 1973 from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs, establishing levels of restraint applicable to certain specified categories of cotton textiles and cotton textile products produced or manufactured in the Republic of China and exported to the United States during the twelve-month period beginning January 1, 1974. As set forth in that letter, the levels of restraint are subject to adjustment pursuant to paragraph 6 of the Bilateral Cotton Textile Agreement of December 30, 1971, as amended, between the Governments of the United States and the Republic of China, which provides that within the aggregate and applicable group limits, limits on certain categories may be exceeded by not more than five (5) percent.

Accordingly, at the request of the Government of the Republic of China and pursuant to the provision of the bilateral agreement referred to above, there is published below a letter of December 18, 1974, from the Chairman of the Committee for the Implementation of Textile Agreements to the Commissioner of Customs amending the levels of restraint applicable to cotton textile products in selected categories for the twelve-month period which began on January 1, 1974. ALAN POLANSKY, Acting Chairman, Committee for the Implementation of Textile Agreements, and Acting Deputy Assistant Secretary for Resources and Trade Assistance, Commissioner of Customs, Department of the Treasury, Washington, D.C. 20229

DEAR MR. COMMISSIONER: On December 30, 1973, the Chairman, Committee for the Implementation of Textile Agreements, directed you to prohibit entry during the twelve-month period beginning January 1, 1974 of cotton textiles and cotton textile products in certain specified categories to be produced or manufactured in the Republic of China in excess of designated levels of restraint. The Chairman further directed that the levels of restraint are subject to adjustment. Certain of these levels were previously amended by directive of September 25, 1974.

Pursuant to paragraph 6 of the Bilateral Cotton Textile Agreement of December 30, 1971, as amended, between the Governments of the United States and the Republic of China, and in accordance with the provisions of Executive Order 11651 of March 3, 1972, you are directed further to amend, effective December 23, 1974, the levels of restraint established in the aforesaid directive of December 27, 1973 for cotton textile products in the following categories for the twelve-month period which began on January 1, 1974:

Amended 12-month level of restraint

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The term “adjustment” refers to those provisions of the Bilateral Cotton Textile Agreement of December 30, 1971, as amended, between the Governments of the United States and the Republic of China which provide, in part, that within the aggregate limit, the limits for Groups I and II may be exceeded by not more than five (5) and ten (10) percent, respectively; for limited carryover of shortfalls in certain categories to the next agreement year; and for administrative arrangements.

3. These levels have not been adjusted to reflect any entries made on or after January 1, 1974.

The actions taken with respect to the Government of the Republic of China and with respect to imports of cotton textiles and cotton textile products from the Republic of China have been determined by the Committee for the Implementation of Textile Agreements to involve foreign affairs functions of the United States. The recommendations to the Commissioner of Customs, being necessary to the implementation of such actions, fall within the foreign affairs exception to the rule-making provisions of 5 U.S.C. 553. This letter will be published in the Federal Register.

Sincerely, 

ALAN POLANSKY, Acting Chairman, Committee for the Implementation of Textile Agreements, and Acting Deputy Assistant Secretary for Resources and Trade Assistance.

[FR Doc.74-29385 Filed 12-23-74; 8:45 am]

COMMITTEE FOR PURCHASE FROM THE BLIND AND OTHER SEVERELY HANDICAPPED

PROCUREMENT LIST 1975

Proposed Additions

Notice is hereby given pursuant to section 24(a) (2) of Public Law 92-28; 85 Stat. 72, of the proposed addition of the following commodities and service to Procurement List 1975, November 12, 1974 (39 FR 39364).

COMMODITIES

Ballpoint pen, plastic type, RAD-1918

Ballpoint pen, ink type, RAD-1907

INSTRUMENT CLASS 7249

Juvenile/Child Service, Non-Commissioned Officer's Club, Building 512, Home-Head Air Force Base, Florida.

Comments and views regarding these proposed additions may be filed with the Committee not later than 30 days after the date of this Federal Register. Communications should be addressed to the Executive Director, Committee for Purchase from the Blind and Other Severely Handicapped, 2009 Fourteenth Street North, Suite 610, Arlington, Virginia 22201.

By the Committee.

C. W. FLETCHER, Executive Director.

[FR Doc.74-30071 Filed 12-23-74; 8:45 am]

ENVIRONMENTAL PROTECTION AGENCY

[FR Doc.71-5107]

PLUTONIUM AND THE TRANSURANIUM ELEMENTS

PUBLIC HEARING

In the September 23, 1974 issue of the Federal Register, 39 FR 34698, the Environmental Protection Agency published a notice of intent to evaluate the environmental impact of plutonium and
NOTICES

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 of the public health from potential contamination of the environment by radionuclides of the transuranium elements. Notice will be given to 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 continuation 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, 1823 Stout Street, Denver, Colorado.

Persons wishing to present an oral statement at this hearing shall give written notice to the Director, Criteria and Standards Division (AW-569), Office of Radiation Programs, U.S. Environmental Protection Agency, 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 STRELOW,
Assistant Administrator for Air and Waste Management.

December 18, 1974.

[FR Doc.74-28977 Filed 12-23-74; 7:45 am]

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) an 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 summary of 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 developed and submitted to EPA on or after October 21, 1974, is being used to support an application described in this section, (c) desires to assert a claim for compensation under Section 3(c)(1)(D) for such use of his data, and (d) wishes to preserve his right to have the Administrator determine the reason- able compensation to which he is entitled for such use of the data, must notify the Administrator and the applicant named 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 (WZ-569), Office of Pesticide Programs, 401 M Street SW., Washington, D.C. 20460. Every such claimant must include, at a minimum, the information listed in the interim policy of November 19, 1973.

Application submitted under 2(a) or 2(b) of the interim policy will be processed according to the method of Support: Application proceeds under 2(c) of interim policy.

Application submitted under 2(c) or 2(b) of the interim policy will be processed according to the method of Support: Application proceeds under 2(c) of interim policy.

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NOTICES

FEDERAL COMMUNICATIONS COMMISSION

[Report No. 733]

COMMON CARRIER SERVICES INFORMATION

Domestic Public Radio Services
Applications Accepted for Filing

December 10, 1974.

Pursuant to §§ 1.27(b) (3) and 32.30 (b) of the Commission’s rules on application, in order to be considered with any domestic public radio station applications appearing on the list below must be substantially complete and tendered for filing by whichever date is earlier (a) the date of this notice, or (b) within 60 days after the date of this notice. Thereafter, the following items represent a correction appearing under the Commission’s rules for provisions governing the time for filing and other requirements relating to such pleadings.

Federal Communications Commission,

[Seal]

Vincent J. Marzilli,

Secretary.

Applications Accepted for Filing

Domestic Public Land Mobile Radio Service

20850-CD-P-(2)-75, General Telephone Company of the Northwest, Inc. (KOCN15). C.P. to change antenna system operating on 454.425 & 454.625 MHz, located at 420 Casino Road, Everett, Washington.

20851-CD-P-(4)-75, Pago A Fono Corporation (KXNA01). C.P. to relocate facilities and change antenna system operating on 454.025, 454.075, 454.175, & 454.300 MHz, to be located at Fort Worth National Bank Building, 500 Threechomst Street, Fort Worth, Texas.

20852-CD-P-(7)-55, Algonquin of Colorado, Inc. (KZCW76). C.P. for a new station to operate on 35.58 MHz to be located at Cheyenne Mountain, Manitou Springs, Colorado.

20853-CD-P-(7)-55, Tel-Illinois, Inc. (KBEW94). C.P. to add Transmitter Loc. #2 operating on 152.00 MHz to be located at Existing WSBN (FM) Tower, Edwardsville, Illinois.

20854-CD-P-(7)-55, Tel-Illinois, Inc. (KUSC56). C.P. to add Transmitter Loc. #3 operating on 215.4 MHz to be located at Existing WSBN (FM) Tower, Edwardsville, Illinois.

20855-CD-P-(2)-75, Tel-Page, Inc. (KXMD35). C.P. for additional facilities to operate on 43.68 MHz at Loc. #3: Summit of Roundtop Peak, east of Oakland, California; and same facilities at Loc. #4: 1200 Lakehore Avenue, Oakland, California.

20856-CD-P-(7)-55, Mobile Radio Telephone Service, Inc. (KXHBO1). C.P. to increase power operating on 162.24 MHz, to be located at Ensign Park, Salt Lake City, Utah.

20857-CD-P-(7)-55, Mobile Radio Telephone Service, Inc. (KAAA76). C.P. for additional control facilities to operate on 2175.2 MHz at Loc. #1: 1016 Glenmore Place, Denver, Colorado; and repeater facilities to operate 2113.4 MHz at Loc. #1: 22.2 miles due south from Golden, Lookout Mountain, Colorado.

20858-CD-P-(7)-55, Mobile Radio Telephone Service, Inc. (KOE264). C.P. to relocate facilities on 152.05 MHz at Loc. #1: 310 Southwest 4th Avenue, Portland, Oregon.

20859-CD-P-(4)-75, Summit Mobile Radio Company (KOEZ04). C.P. for additional control facilities on 152.65 & 152.12 MHz, to be 452.255 MHz, Repeater on Loc. #1: 21,cream Mountain, 2.5 miles SW. of Buckaroo, Maine; and additional facilities operating on 454.255 MHz, Control on Loc. #1: 22.3 Coast Station, Auburn, Maine.

20860-CD-P-(7)-55, Mobile Radio Telephone Service, Inc. (KOEZ02). C.P. to add facilities operating on 162.24 MHz at Loc. #1: 1020 Industrial Road, Boulder City, Nevada.

20861-CD-P-(4)-75, Mobile Radio Telephone Service, Inc. (KOEZ02). C.P. to relocate facilities from KXGM72 operating on 152.05 MHz, and change antenna system operating on 152.05, 152.15, 152.45, & 454.225 MHz, to Loc. #1: 14337 Range, 5.3 mi. SW. of Girdle, Utah.

20862-CD-P-(7)-55, Metrotec, Inc. (KTZS23). C.P. to add antenna Loc. #3 on operating on 35.25 MHz to be located at 630 NE. of Bolivar, Ohio.

20863-CD-P-(7)-55, Vegas Instant Page (KESL41). C.P. to add antenna operating on 35.58 MHz to be located at 1020 Industrial Road, Boulder City, Nevada.

20864-CD-P-(12)-75, (KXDM02), South Central Bell Telephone Company, New Orleans, Louisiana. Amend to add base frequencies on 454.375 & 454.525 MHz. Also, add test frequencies on 452.975 and 452.925 MHz. All other particulars to remain as reported on FN #721 dated September 30, 1974.

Corrections

20864-CD-P-(7)-55, Comex, Inc. - (KXCC77), should read: C.P. to add antenna operating on 35.58 MHz to be located on 1020 Industrial Road, Boulder City, Nevada.

20865-CD-P-(2)-75, Mobile Radio Telephone Service, Inc. (KXHBO1), Correction to delete Call Sign KR560. File number should read: 20867-CD-P-(7)-55. All other particulars to remain as reported on FN #731, dated December 9, 1974.

20867-CD-P-(2)-75, Mobile Radio Telephone Service, Inc. (KXHBO1), Correction to delete Call Sign KR500. File number should read: 20867-CD-P-(7)-55. All other particulars to remain as reported on FN #731, dated December 9, 1974.

20867-CD-P-(2)-75, Mobile Radio Telephone Service, Inc. (KXHBO1), Correction to delete Call Sign KR500. File number should read: 20867-CD-P-(7)-55. All other particulars to remain as reported on FN #731, dated December 9, 1974.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
NOTICES

It appears that the following applications may be mutually exclusive and subject to the Commission's rules regarding 47 CFR as presented by reasons of potential electrical interference.


RURAL RADIO

60211-CF-P-7S, Continental Telephone Company of Texas (new), C.P. for a new rural subscriber to operate on 157.80 MHz to be located at 44.5 miles South Southwest of Pecos, Texas.

60125-CF-P-7S, Continental Telephone Company of Texas (new), C.P. for a new rural subscriber to operate on 158.00 MHz to be located at 24.6 East Southeast of Van Horn, Texas.

POINT-TO-POINT MICROWAVE RADIO SERVICE

1729-CF-P-7S, Continental Telephone Company of Texas (XUV05), Van Horn, Texas. Renewal of Development License expiring December 20, 1974. Applicant requests authority to change from Developmental to Regular service on 11015V MHz towards Lobo, Texas, on azimuth 163 degrees/43 minutes; formerly licensed to American Telephone and Telegraph Company (EBW15), 405 North Broadway Avenue, Oklahoma City, Oklahoma. Lat. 35°29'16" N., Long. 97°39'53" W. C.P. to add 6564.5V MHz change polarity from Horizontal to Vertical on 11365, and change 6526.2H MHz and 6544.9H MHz towards Guthrie, Oklahoma, to 6562.5V MHz and 6544.5V MHz and change the station to Yukon, Oklahoma, on azimuth 229 degrees/46 minutes.

1876-CF-P-7S, Same (KMW37), 22.3 MHz SSY of Mineola, Oklahoma. Lat. 38°16'58" N., Long. 97°57'32" W. C.P. to change points of communication, power, replace transmitter and antenna to 6526.3Y MHz and 6544.8Y MHz towards a new point of communication at Cement, Oklahoma, on azimuth 136 degrees/39 minutes.

1797-CF-P-7S, Same (KMW37), 1703 Gore Street, Lawton, Oklahoma. Lat. 34°36'50" N., Long. 98°00'62" W. C.P. to add 6526.2H MHz and 6544.9H MHz towards a new point of communication at Guthrie, Oklahoma, on azimuth 119 degrees/33 minutes; formerly licensed to The Pacific Telephone and Telegraph Company (WDE 7).

1998-CF-P-7S, Samo (ESN41), 2.5 miles SSE of Rosemont, New York. Lat. 37°52'54" N., Long. 75°15'16" W. C.P. to replace transmitter and antenna, relocate at 44.5 miles South Southwest of Pecos, Texas, on azimuth 132 degrees/46 minutes.

1972-CF-P-7S, Same (WHT15), Lobo, Texas. Renewal of Development License expiring December 20, 1974. Applicant requests authority to change from Developmental to Regular service on 11175V MHz towards Lobo, Texas, on azimuth 315 degrees/49 minutes; formerly licensed to American Telephone and Telegraph Company (EBW15), 405 North Broadway Avenue, Oklahoma City, Oklahoma. Lat. 35°29'16" N., Long. 97°39'53" W. C.P. to add 6564.5V MHz change polarity from Horizontal to Vertical on 11365, and change 6526.2H MHz and 6544.9H MHz towards Guthrie, Oklahoma, to 6562.5V MHz and 6544.5V MHz and change the station to Yukon, Oklahoma, on azimuth 229 degrees/46 minutes.

1989-CF-P-7S, Same (WTR98), Sierra Blanca, Texas. Renewal of Developmental License expiring December 20, 1974. Applicant requests authority to change from Developmental to Regular service on 11175V MHz towards Lobo, Texas, on azimuth 132 degrees/46 minutes.

1973-CF-P-7S, Same (WET17), Lobo, Texas. Renewal of Development License expiring December 20, 1974. Applicant requests authority to change from Developmental to Regular service on 11175V MHz towards Lobo, Texas, on azimuth 315 degrees/49 minutes; formerly licensed to American Telephone and Telegraph Company (EBW15), 405 North Broadway Avenue, Oklahoma City, Oklahoma. Lat. 35°29'16" N., Long. 97°39'53" W. C.P. to add 6564.5V MHz change polarity from Horizontal to Vertical on 11365, and change 6526.2H MHz and 6544.9H MHz towards Guthrie, Oklahoma, to 6562.5V MHz and 6544.5V MHz and change the station to Yukon, Oklahoma, on azimuth 229 degrees/46 minutes.
NOTICES

1974-CF-P-75, Same (KEL61), 2.8 miles South of Warwick, New York. Lat. 41°12'29" N., Long. 74°21'53" W. C.P. to add frequencies 11265 kHz and 11704 kHz toward New York, New York, on azimuths 147°02' and frequency 11585 kHz toward Vernon, New Jersey, on azimuth 152°24'.

1975-CF-P-75, Same (KN72), 5 miles WSW. of Corona, California. Lat. 33°31'01" N., Long. 116°50'51" W. to add frequencies 3750 kHz and 3995 kHz toward Los Angeles, California, on azimuths 293°47' and 315°06', and 315°06' kHz toward Parris, California, on azimuths 99°56'.

1976-CF-P-75, Same (WQ4S0), 1.7 miles SW. of Vernon, New Jersey. Lat. 41°10'38" N., Long. 74°29'51" W. C.P. to add frequencies 10918 kHz and 10993 kHz toward Warwick, New York, on azimuths 73°41' and 10975 kHz toward Glenwood, New Jersey, on azimuth 04°27'.

1977-CF-P-75, Same (WQ4C1), 1.1 miles NW. of Vernon, New Jersey. Lat. 41°12'44" N., Long. 74°23'36" W. C.P. to add frequencies 11546 kHz and 11666 kHz toward Vernon, New Jersey, on azimuths 184°27'.

1978-CF-P-75, Same (WQ520), 0.3 miles SW. of Fort Worth, Texas. Lat. 32°17'56" N., Long. 117°18'56" W. C.P. to add frequency 11625 kHz toward Parris, California, on azimuth 03°47'.

1979-CF-P-75, Same (WQ3S1), 2.3 miles West of Parris, California. Lat. 33°48'00" N., Long. 117°43'50" W. C.P. to add frequencies 10809 kHz and 11151 kHz toward Steele Valley, California, on azimuth 182°49' and 4950 kHz on azimuth 268°07'.

1980-CF-MP-75, Southern Pacific Communications Company (U5W449), 0.15 miles West of State Route 64, 2.2 miles South of Shamrock, Texas. Lat. 35°03'55" N., Long. 103°46'20" W. C.P. to change antenna location resulting in change in coordinates as stated above; change in azimuth on frequency 6149 kHz toward Greenwich, Ohio, to 84°10' and toward Maple Grove, Ohio, to 031°59'.

1981-CF-P-75, West Texas Microwave Company (KEL87), Las Banas, 3.8 miles North of Pueblo, Texas. Lat. 32°30'02" N., Long. 106°48'88" W. C.P. to add point of communication on frequencies 3900 kHz, 5995.7 kHz, and 6176.6 kHz toward Table Mountain, Texas, on azimuths 189°50' and 192°15'.

1982-CF-P-75, Southwest Texas Transmission Company (WFPF93), Table Mountain, 21.0 miles NE. of Ballinger, Texas. Lat. 31°09'29" N., Long. 100°10'16" W. C.P. to add frequencies 5995.7 kHz, 6176.6 kHz, and 6176.6 kHz toward Ballinger, Texas, on azimuths 5785'57' and 5805.7 kHz toward Miles, Texas, on azimuth 229°15'.

1983-CF-P-74, Same (WSI424), Miles, Texas. Lat. 31°10'19" N., Long. 100°10'16" W. C.P. to add point of communication on frequencies 2641.7 kHz, 6001.0 kHz, and 6920.3 kHz toward Miles, Texas, on azimuths 229°15' and 230°15'. A waiver of section 81.701 is requested by West Texas and Southwest Transco.

1976-CF-MP-75, Midwestern Relay Company (WQ455), Fischo Tower, S. 9th St., Shenley, Montana. Lat. 49°34'29" N., Long. 109°21'17" W. C.P. (1) to increase transmitter power for frequency 11626 kHz on corrected azimuth 80°03' toward Arden Hills (WQ4S5), Minnesota; (2) to increase transmitter power for frequencies 11265 kHz and 11704 kHz on corrected azimuth 236°04' toward Golden Valley (Studios of WITCN), Minnesota; and (3) to increase transmitter power for frequencies 11450 kHz and 11508 kHz on corrected azimuths 151°05' and 11508 kHz and add power by corrected frequency 11265 kHz toward corrected azimuth 119°35' toward Eden (Studios of KMP3), Minnesota.

1977-CF-MP-75, Same (WTV491), 1298 W. Colonial Drive, Orlando, Florida. Lat. 28°33'04" N., Long. 81°35'37" W. C.P. (1) to add by power split frequency 10769 kHz and 10769 kHz toward Saint Paul (Studios of KSTP), Minnesota; (2) to change polarization and point of communication from 3111 kHz and 3113 kHz and to increase power on frequencies 10775 kHz, 10935 kHz, and 11095 kHz toward Phoenix (WTV494), Minnesota; and (3) to increase frequency 10795 kHz on corrected transmitter power for frequencies 10769 kHz and 10769 kHz toward Folsom Tower (WTV494), Minnesota.

1978-CF-MP-75, American Television & Telecommunications Corporation (WWFD04), 2.5 Miles SW. of Delray Beach, Florida. Lat. 29°02'56" N., Long. 80°35'34" W. Mod. of C.P. (1123-C1-02-75) to relocate station to foregoing coordinates.

1978-CF-MP-75, Same (WIL280), 2.0 miles West of Mike, Florida. Lat. 27°55'25" N., Long. 80°39'12" W. Mod. of C.P. (1429-C1-02-75) to correct coordinates to foregoing.

1979-CF-MP-75, Eastern Microwave, Inc. (KCKI71), Beech Hill, 7.0 miles E. of Marlboro, New Hampshire. Lat. 43°43'41" N., Long. 72°04'11" W. C.P. to add 4382 kHz toward Manchester, New Hampshire (new), on azimuth 78°22'.

1980-CF-MP-75, Same (WIL251), (non), Wood Hill, 2.3 miles SW. of Lawrence, Massachusetts. Lat. 42°39'17" N., Long. 71°13'52" W. C.P. to add (a) frequency 11255 kHz toward Lawrence, Massachusetts, on azimuth 84°61' (b) frequency 11255 kHz toward point of communication Woburn, Massachusetts, on azimuth 172°34'.

1981-CF-P-75, Same (KCKI71), Beech Hill, 7.0 miles E. of Marlboro, New Hampshire. Lat. 43°43'41" N., Long. 72°04'11" W. C.P. to add 6300.7 kHz toward Florida Mt. (N. Adams), Massachusetts on azimuth 82°34'. A waiver of section 81.701 is requested.

1981-CF-P-75, Same (WTV941), 800 Main Street, Grand Junction, Colorado. Lat. 39°04'59" N., Long. 108°37'00" W. C.P. to add 2180.7 kHz toward a new point of communication at Rangely, Colorado, on azimuth 103°29'29" from 2185.4 kHz toward Rangely, Colorado, on azimuth 189°89'03".

1982-CF-P-75, Same (new), Riven Hill, 8 miles West Northwest of Rangeley, Colorado. Lat. 40°07'40" N., Long. 108°57'00" W. C.P. for a new station on 2178.5 kHz toward a new point of communication at Rangely, Colorado, on azimuth 103°29'29" from 2185.4 kHz toward Rangely, Colorado, on azimuth 189°89'03".

1983-CF-P-75, Same (new), 112 North White Avenue, Kayenta, Colorado. Lat. 39°50'17" N., Long. 108°46'16" W. C.P. for a new station on 2123.6 kHz toward Rangely, Colorado, on azimuth 293°32' from 2125.9 kHz toward Rangely, Colorado.

Correction

1915-CF-XL-75, American Telephone and Telegraph Company (KESP71), Correct station to read 12.1 miles SE. of Volunteers, Illinois. (Best same as reported on Public Notice dated November 25, 1971.)

[FR Doc.74-2392 Filed 12-23-74; 8:45 am]

[Report No.720]

COMMON CARRIER SERVICES INFORMATION

Domestic Public Radio Services Applications Accepted for FY 1974

December 2, 1974.

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 services application appearing on the attached 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 on the previously filed application; or (b) within 60

1 All applications listed below are subject to further consideration and review and may be returned and/or disclaimed by the Commission to be in accordance with the Commission's rules, regulations, and other requirements.

The above alternative cutoff rules apply to those applications listed below as having been accepted in Domestic Public Land Mobile Radio, Rural Radio, Point-to-Point Microwave, and Low Power Radio Transmission Services (part 21 of the rules).
NOTICES

DOMESTIC PUBLIC LAND MOBILE RADIO SERVICE:

20795-CF-P-75, John R. Wilcox, dba Wilcoex Communications (KIJ996), C.P. to reinstate expired license operating on 152.12 MHz located at U.S. Highway #41, Lake City, Florida.

20796-CF-P-75, Industrial Communications, Inc., dba Port Arthur Mobile Phone (KRS642), C.P. to relocate facilities operating on 152.21 MHz to be located at Church House Rd, a mile S. of Vidor, Texas.

20797-CF-P-75, Services Unlimited, Inc. (KIN996), C.P. to add standby facilities to operate on 152.24 MHz at Loc. #1: Wachovia Building, Winston-Salem, North Carolina.

20798-CF-P-75, Northeast Louisiana Telephone Company, Inc. (new), C.P. for a new 3-way station to operate on 152.27 MHz to be located at Lot 123, near corner of Third Avenue and Fifth Street, Collinston, Louisiana.

20799-CF-P-75, Wilkes Telephone and Electric Company (KIM996), C.P. and License to reinstate expired facilities operating on 152.27 MHz located 400 feet N. of 516 E. Robert Toombs Avenue, Washington, Georgia.

20800-CF-P-75, Amelia Telephone Corporation (new), C.P. for a new 2-way station to operate on 152.66 MHz to be located at intersection of Routes 661 & 930, 2.5 miles NE of Amelia, Virginia.

20801-CF-P-75, Dodge County Telephone Company (new), C.P. for a new 2-way station to operate on 152.68 MHz to be located 1.8 mile SW of Reeseville, Wisconsin.

20802-CF-P-75, Hawaiian Telephone Company (KAU216), C.P. for a new 3-way station to operate on 152.76 & 152.78 MHz to be located at Loc. #1: 2.9 miles NE of Honolulu, Mt. Tantalus, Hawaii; and change antenna system operating on 152.76 & 152.78 MHz to be located 3.8 mile S. of Hawaii Kai P.O., Koko Head, Hawaii.

20803-CF-P-75, Salinas Valley Radio Telephone Company (KRX981), C.P. for additional facilities to operate on 154.025 & 154.175 MHz at Loc. #1: Mt. Toro, 10.3 miles SSE of Salinas, California.

20804-CD-P-75, Salinas Valley Radio Telephone Company (KMA837), Mod. Permit to change antenna system and relocate facilities operating on 154.025 MHz at Loc. #2: 690 Valenzuela Road, Monterey, California.

20805-CF-P-75, Summit Mobile-Radio Company (KGG984), C.P. to relocate facilities operating on 154.075 MHz at Loc. #2: 109 Cook Street, Auburn, Maine, control.

FEDERAL COMMUNICATIONS COMMISSION,
VINCENT J. MULLINS,
Secretary.

APPLICATIONS ACCEPTED FOR FILING:

RURAL RADIO SERVICE:

60165-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 25.0 miles SSE of Pecos, Texas.

60166-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 SSW of Pecos, Texas.

60167-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.

60168-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:

1531-CF-P-75, American Telephone and Telegraph Company (KRX981), C.P. for a new point-to-point microwave system to be located in Montana.

1532-CF-P-75, The Mountain States Telephone and Telegraph Company (KDC981), C.P. for a new point-to-point microwave system to be located in Montana.

1533-CF-P-75, The Mountain States Telephone and Telegraph Company (KDC981), C.P. for a new point-to-point microwave system to be located in Montana.

FEDERAL REGISTER, VOL 39, NO. 248—TUESDAY, DECEMBER 24, 1974

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Table of Canadian Television Channel Allocations Within 250 Miles of the Canada-U.S. Border

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Notes:
- Limitations to protect CBUAT-3 Crawford Bay, B.C.
- Limitations to protect CKSA-TV Lloydminster, Sask. and CHCT-TV Calgary, Alberta.
- Limitation 18 dbk and 500 feet EIAAT.
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I—Limitation to protect CHBC-TV-1, Penticton, B.C.
I—Limitation to protect CFWB-TV-1, Drumheller, Alberta.
I—Limitation to protect CHBC-TV-4, Salmon Arm, B.C.
I—Limitation of 8.9 kW ERP, 493 feet EHAAT specified directional pattern, to protect KOTS, Seattle, Wash.
I—1 kW ERP and 100 feet EHAAT.
I—Limitation to protect CJOJ-TV-3, Burmis, Alberta, and 700 watts maximum ERP and 2,000 feet EHAAT.
I—Limitation of 1,000 watts maximum ERP and 1,604 feet EHAAT.
I—Limitation to protect CBUDT, Bonnington, B.C., and CHBC-TV-1 Penticton, B.C.
I—Limitation to protect CHEK-TV, Victoria, B.C.
I—To protect CFOR-TV-6, Mount Timothy, B.C., and CBUAT-3, Crawford Bay, B.C.
I—Limitation to protect CBUBAT, Trail, B.C.
I—Limitation to protect GIILTV-3, Burmis, Alberta
I—Limitation 1.97 kW ERP, 1,409 feet EHAAT, to protect KCFW-TV, Kalispell, Mont.
I—Limitation to protect CBUBAT, Cranbrook, B.C.
I—To protect CBUT-2, Chilliwack, B.C.
I—Limitation to protect CBUT-1, Nelson, B.C.
I—Limitation to protect CBUBAT-1, Canal Flats, B.C.
### NOTICES

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L—Limitation to protect CKX-TV-1, Foxwarren, Manitoba.
L—Limitation to protect CKBI-TV-3, Greenwater Lake, Sask.
L—Limitation to protect CKBQ-TV-5, Melfort, Sask., and an allocation at Brandon, Manitoba.
L—Limitation to protect CKX-TV-2, Melita, Manitoba, CBKAV, Regina, Saskatchewan, and an allocation at Winnipeg, Manitoba.
L—Limitation to protect CKSS-TV, Dauphin, Manitoba, and CBWAT, Kenora, Ontario.
L—Limitation to protect allocations at Dryden, Ontario, and Brandon, Manitoba.
L—Limitation to protect CKX-TV, Brandon, Manitoba, and CWBCT, Fort Frances, Ontario.
L—Limitation to protect Channel 9—at Regina, Saskatchewan, and Channel 9—at Winnipeg, Manitoba.
L—Limitation to protect CKY-TV, Winnipeg, Manitoba, and CFSS-TV, Carlyle Lake, Saskatchewan.
### NOTICE

#### NEW BRUNSWICK

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**LI**—Limitation 18 dbk and 500 feet EHAAT and Toward Channel 7, CKRT-TV, Riviere du Loup, P.Q.

**L**—Limitation to protect CICH-TV, Halifax, Nova Scotia, CHAU-TV, Carleton (New Carlisle), Quebec, and WABI-TV, Bangor, Maine.

**L**—Limitation to protect CHSJ-TV, Saint John, N.B., CFCH-T, Quebec, P.Q., and a cochannel allocation at Ste. Anne des Monts, P.Q.

**L**—Limitation to protect cochannel allocation at Woodstock, New Brunswick.

**L**—Limitation to protect Channel 5, CHIP-TV, Rimouski, P.Q.
### NOTICES.

#### NORTHWEST TERRITORIES

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#### NOVA SCOTIA

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#### ONTARIO

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FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
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<td>Woodstock</td>
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**NOTICES**

L 1—Limitation to protect cochannel assignment at Wiarton, Ontario. Limitation to protect WGR-TV, Buffalo, N.Y. Danceroff assignment to be located no less than 170 miles from WGR-TV.

L 2—Limitation to protect CBFOT-2, Hearst, Ontario.

L 3—The transmitter site of a television broadcast station authorized to operate pursuant to this allocation shall not be located less than 700 feet from the transmitter site of cochannel station WMTW-TV, Poland Springs, Maine. The effective radiated power from the Cornwall station over a sector encompassing the northern and southern limits of Lake Champlain will not exceed the equivalent of 60 kilowatts from an antenna 500 feet above average terrain.

L 4—Limitation 20 dbk and 1,000 feet EIAAT.

L 5—Limitation to protect CFCL-TV-6, Chapleau, Ontario; CBFST, Surogue Falls, Ontario and a cochannel limited allocation at Timmins, Ontario.

L 6—Limitation of 310 watts maximum radiated power and 100 watts equivalent nondirectional power, with specified directional antenna pattern at 140 feet EIAAT. Also, limitation to protect WNTZ-TV, North Pole, N.Y., and WIENT-TV, Syracuse, New York.

L 7—Limitation to protect Channel 11, CKWS-TV, Kingston, Ontario.

L 8—Limitation to protect Channel 8, CKNX-TV, Wingham, Ontario, and Channel 8, ROC-TV, Rochester, New York.

L 9—Limitation to protect CHIC-TV, Hamilton, Ontario, CKWS-TV, Kingston, Ontario, and CBOF-1, Chapleau, Quebec.

L 10—Limitation to protect CFCL-TV-2, Kirkland Lake, Ontario.

L 11—Limitation to protect CKRN-TV, Rouyn, Quebec and CGBT, Ottawa, Ontario.

L 12—Limitation to protect CBMT, Montreal, Quebec and Channel 6, Belleville, Ontario.

L 13—Limitation to protect Channel 13, CKTM-TV, Three Rivers, P.Q.

L 14—Limitation to protect CKSO-TV, Sudbury, Ontario.

L 15—Limitation to protect CBFOT, Timmins, Ontario.

L 16—Limitation to protect CKOS-TV-1, Elliot Lake, Ontario.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
NOTICES

L*—Limitation to protect CFCL-TV-6, Chapleau, CBFOT-2, Hearst and CBFST, Sturgeon Falls.
L*—Limitation to protect WHEN-TV, Syracuse, New York.
L*—Limitation to protect CBFOT, Timmins, Ontario.
L*—Limitation to protect CBFOT-1, Kapuskasing, Ontario.
L*—Limitation to protect CBFOT-2, Hearst and CBFST.

Approximate site locations:
* 44°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°31'00" North Latitude, 81°26'49" West Longitude.
* 43°06'00" North Latitude, 82°00'00" West Longitude.
* 44°09'00" North Latitude, 81°02'00" West Longitude.
* 42°57'15" North Latitude, 81°15'59" West Longitude.
* 43°43'21" North Latitude, 82°10'00" West Longitude.
* 43°08'00" North Latitude, 82°45'42" West Longitude.
* 42°17'42" North Latitude, 83°03'00" West Longitude.
* 42°09'09" North Latitude, 82°37'05" West Longitude.
* 43°08'28" North Latitude, 82°51'40" West Longitude.

PRINCE EDWARD ISLAND

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QUEBEC

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<tr>
<td>Chicoutimi-Arvida</td>
<td>2+ Li, Li²</td>
<td>70, 82-</td>
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<tr>
<td>Clermont-La Malbaie</td>
<td>23+</td>
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</tr>
<tr>
<td>Coaticook</td>
<td>75</td>
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<tr>
<td>Cowansville</td>
<td>75</td>
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<tr>
<td>Dolbeau</td>
<td>75</td>
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<tr>
<td>Donnacoma</td>
<td>24+</td>
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<tr>
<td>Dorchester County</td>
<td>19, Li²</td>
<td>41+</td>
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<tr>
<td>Estcourt</td>
<td>43</td>
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<tr>
<td>Forestville</td>
<td>75</td>
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<tr>
<td>Fox River</td>
<td>1 Li</td>
<td></td>
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<tr>
<td>Granby</td>
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<tr>
<td>Hull (see Ottawa, Ontario)</td>
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<td>Jolliette</td>
<td>65+</td>
<td>14, 20- , 30-</td>
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<td>Jenguere-Kenogami</td>
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<td>Lac Etchemin</td>
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<td>Lac Magantic</td>
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<td>Manicouagan</td>
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<tr>
<td>Marieville</td>
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<td>Matane</td>
<td>6+ Li, 9-</td>
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<td>Mont Clunet</td>
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<td>Mont Joli</td>
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<tr>
<td>Mont Laurier</td>
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<tr>
<td>Mont Tremblant</td>
<td>1 Li, 10 Li³</td>
<td>12, 23, 30</td>
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<td>Montreal-Verdun</td>
<td>2, 10, 12 Li²</td>
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<td>Montmagny</td>
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<tr>
<td>Perce</td>
<td>15+</td>
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<td>Plessiville</td>
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<tr>
<td>Port Alfred-Bagotville</td>
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<tr>
<td>Quebec-Levis</td>
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<tr>
<td></td>
<td>19, 64+</td>
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<tr>
<td></td>
<td>15, 21, 22 Li</td>
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<tr>
<td></td>
<td>5 Li, Li²</td>
<td>77+, 83+</td>
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FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
<table>
<thead>
<tr>
<th>City</th>
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<tr>
<td>Rapides des Jouchims</td>
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<tr>
<td>Rimouski</td>
<td>S</td>
<td>10, 51</td>
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<tr>
<td>Riviere du Loup</td>
<td>7+</td>
<td>39—21</td>
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<tr>
<td>Roberval</td>
<td>8+</td>
<td>20+</td>
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<tr>
<td>Ste. Adele</td>
<td>9+</td>
<td>50+</td>
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<td>Ste. Anne des Aix</td>
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<td>65</td>
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<td>Ste. Anne de la Pocatiere</td>
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<td>47</td>
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<td>St. Felicien</td>
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<td>St. Georges de Beauce</td>
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<tr>
<td>Ste. Hyacinthe</td>
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<td>St. Jean-Iberville</td>
<td>75</td>
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<tr>
<td>Sept Iles</td>
<td>2—17</td>
<td>14, 20+</td>
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<td>Shawinigan Falls</td>
<td>16—23, 63</td>
<td>14—20, 50</td>
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<td>Sherbrooke</td>
<td>13—19</td>
<td>74, 59</td>
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<td>Three Mines</td>
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<tr>
<td>Trois Pisteles</td>
<td>13—37, 69+</td>
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<tr>
<td>Trois Rivieres</td>
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<td>Verchères</td>
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<tr>
<td>Verdun (see Montreal)</td>
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<tr>
<td>Victoriaville</td>
<td>20—60+</td>
<td></td>
</tr>
</tbody>
</table>

L—Limitation to protect CHAU-TV, Carleton (New Carlisle).
L—Limitation to protect CKWS-TV, Kingston, Ontario, and CBFT-1, Mont Tremblant, P.Q.
L—Limitation to protect a cochannel allocation at Quebec City, Quebec.
L—Limitation to protect CKCD-TV, Campbellton, N.B.
L—Limitation to protect CBFT-2, Mont Laurier, Quebec.
L—Limitation to protect CBOT, Ottawa, Ontario, and CFQM-TV, Quebec, P.Q.
L—Limitation to protect CHISJ-TV-1, Bon Accord, N.B., and CJFM-TV, Chicoutimi, P.Q.
L—Limitation ERP 1,23 dBK EIAAT 732 feet with specified antenna pattern.
L—Limitation toward Channel 2—, CHAU-TV-1, Ste. Marguerite-Marie, P.Q.
L—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.
L—Limitation to protect CKVR-TV-2, Huntsville, Ontario, CJSS-TV, Cornwall, Ontario, and CJDG-TV, Lithium Mines, P.Q.
L—Limitation to protect CJBR-TV, Rimouski, Quebec.
L—Limitation to protect CBOFT, Ottawa, Ontario, and WMUR-TV, Manchester, New Hampshire. Assignment to be located no less than 170 miles from WMUR-TV, Manchester, New Hampshire.
L—Limitation 18 dBK and 860 feet EIAAT and specified radiation pattern.
### SASKATCHEWAN

<table>
<thead>
<tr>
<th>City</th>
<th>VHF channel No.</th>
<th>UHF channel No.</th>
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<tr>
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<tr>
<td>Biggar</td>
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<tr>
<td>Broadview</td>
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<tr>
<td>Canora</td>
<td></td>
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</tr>
<tr>
<td>Carlyle Lake</td>
<td>(7^+), (L^+)</td>
<td></td>
</tr>
<tr>
<td>Colgate</td>
<td>(L^+)</td>
<td></td>
</tr>
<tr>
<td>Estevan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Estey</td>
<td>(7)</td>
<td></td>
</tr>
<tr>
<td>Fort Qu'Appelle</td>
<td>(7)</td>
<td></td>
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<tr>
<td>Gravelbourg</td>
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<tr>
<td>Greenwater Lake</td>
<td>(4), (L^+)</td>
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<tr>
<td>Humboldt</td>
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<tr>
<td>Indian Head</td>
<td>(7)</td>
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<tr>
<td>Kamsack</td>
<td>(3)</td>
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<tr>
<td>Kindersley</td>
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<td>Maple Creek</td>
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<tr>
<td>Melville</td>
<td>(4)</td>
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<tr>
<td>Moose Jaw</td>
<td>(4), (7)-</td>
<td>(10), (29), (45)</td>
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<td>Moosomin</td>
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<td>Oxbow</td>
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<td>Regina</td>
<td>(2), (9)-, (13)-</td>
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<tr>
<td>Riverhurst</td>
<td>(10)-, (L^+)</td>
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<tr>
<td>Rosetown</td>
<td>(8)+, (11)</td>
<td>(17), (23), (33), (54)</td>
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<tr>
<td>Saskatoon</td>
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<tr>
<td>Shaunavon</td>
<td>(7), (L^+)</td>
<td>(7)</td>
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<tr>
<td>Stranrae</td>
<td>(3)-, (9)-</td>
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<td>Swift Current</td>
<td>(5)-, (12)-</td>
<td>(40)+, (54)</td>
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<tr>
<td>Unity</td>
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<td>(80)</td>
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<td>Watrous</td>
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<td>(78)</td>
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<td>Weyburn</td>
<td>(48)</td>
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<tr>
<td>Willow</td>
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<tr>
<td>Willow Bunch</td>
<td>(6)-, (L^+), (10)-</td>
<td>(5)</td>
</tr>
<tr>
<td>Wynyard</td>
<td>(6), (12)+, (L^+)</td>
<td>(31)+</td>
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<tr>
<td>Yorkton</td>
<td>(5), (10)</td>
<td>(20), (33)+</td>
</tr>
</tbody>
</table>

\(L^+\)—Limitation 20 dbk and 500 feet EHAAT and toward CKMJJ-TV, Marquis (Moose Jaw) Saskatchewan.

\(L\)—Limitation to protect CHAB-TV, Moose Jaw, Saskatchewan.

\(L^+\)—Limitation to protect Channel 10+, CKBL-TV-1, Alricane, Sask.

\(L\)—Limitation to protect CKMJJ-TV, Channel 7-, Marquis (Moose Jaw) Saskatchewan.

\(L^+\)—Limitation to protect Channel 6, CKOS-TV-3, Wynyard, Sask.

\(L\)—Limitation to protect CJFB-TV-3, Riverhurst, Saskatchewan.

\(L^+\)—Limitation to protect Channel 12, CEGK-TV-1, Colgate, Saskatchewan, and an allocation at Swift Current, Sask.

### YUKON TERRITORY

<table>
<thead>
<tr>
<th>City</th>
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<tr>
<td>Clinton Creek</td>
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<tr>
<td>Dawson</td>
<td>(3), (10)</td>
<td>(14), (20)</td>
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<tr>
<td>Elsa</td>
<td>(9)</td>
<td></td>
</tr>
<tr>
<td>Faro</td>
<td>(13)</td>
<td></td>
</tr>
<tr>
<td>Mayo</td>
<td>(7)</td>
<td></td>
</tr>
<tr>
<td>Watson Lake</td>
<td>(8)+</td>
<td></td>
</tr>
<tr>
<td>Whitehorse</td>
<td>(2)+, (6)</td>
<td>(14), (20)</td>
</tr>
</tbody>
</table>

\(\text{12}, \text{4}, \text{6}, \text{25}\) 1123344556677899000

WALLACE E. JOHNSON,
Chief, Broadcast Bureau,
Federal Communications Commission.

[FR Doc.74-29818 Filed 12-23-74;8:45 am]

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
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 (CH&V); 497.6 feet; Willson Broadcasting Company, Hanford, California; Requests: 103.7 mHz; Channel No. 279; 50 kW (CH&V); 500 feet; For construction permits.

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 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 ever, 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(e) of the Communications Act of 1934, as amended, the applications are designated for a hearing in a consolidated proceeding, a time and place to be specified in a subsequent order, upon the following issues:

   (1) To determine which of the proposals would, on 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 § 1.231(c) 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 on the date fixed for 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) (c) 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 § 1.584(g) of the rules.

Adopted: December 9, 1974.

Released: December 13, 1974.

FEDERAL COMMUNICATIONS COMMISSION

[SEAL] WALTER E. WILSON,
Chief, Broadcast Bureau.

[FR Doc 74-50076 Filed 12-23-74; 8:45 a.m.]

STANDARD BROADCAST APPLICATION

Availability for Processing

The following application, seeking the issuance 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 KAVE License expiring 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-19837, NEW, Carlsbad, New Mexico, Zia Telecommunications, Inc., Req: 1250 kW, 250 W, 1 kW-LW, U. S.

Pursuant to the provisions of §§ 1.227 (b) (1) and 1.591 (b) of the Commission's rules, an application, in order to be considered with this application must be received no later than January 1, 1975. Any request for joint interim operation must be filed no later than March 3, 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, as amended, is directed to § 1.580(d) 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 74-50077 Filed 12-29-74; 8:45 a.m.]
NOTICES

e.d.t., January 3, 1975 and must submit 50 copies of this statement to Executive Communications, FEA, Room 322, Federal Building, Washington, D.C. 20461, before 4:30 p.m., e.d.t., on 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 theretoe to the individual petitions under consideration. Accordingly, 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 of the Special Rule itself or of the FEA's policy regarding the use of petroleum feedstocks in the manufacture of SNGS, except to the extent that such comments appear to 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 be heard.

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 of the rebuttal statements. 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 must submit the question, in writing, to the person who made the oral statement. The FEA reserves the right to select the persons to be heard at these hearings and to establish the procedures governing the conduct of the hearings. Any interested person may 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.

PROCEDURES FOR THE SYMPOSIUM

Persons selected to address the symposium have been asked to limit their oral presentation to about twenty minutes, and five 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, 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 exploring and developing reserves 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 hearings 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 affecting exploration and development.
(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.

 ALLOCATION 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

.....
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FEDERAL REGISTER

Vol. 39, No. 248—Tuesday, December 24, 1974

Report), which are the required reports for the month of November 1974 under FEA's Old Oil Entitlements Program (39 FR 42246; December 4, 1974), to the firms listed in the Appendix to this notice.

If a firm not listed in the Appendix hereof believes that it qualifies as an eligible firm under the program, it should contact FEA at (202) 693-7610 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. Johnson
American Petroleum, Inc.
APCO Oil Corporation
Arizona Fuels Corporation
Ashland Oil Company
Atlantic Richfield Company
Bay Refining Company
Bayou State Oil Company
Beacon Oil Company
Belcher Oil Company
Blia Ridge Fuel Company
C&G Farmands Industries, Inc.
Calumet Refining Company
Canal Refining Company
Caribou Four Corners Oil Co.
Castle Coal & Oil Company, Inc.
Central Petroleum Corporation
C & R Refinery
Champion Petroleum Company
Chattanooga Industrial Oil Co.
Chirillo Brothers Oil Company
Citgo Service Oil Company
Clanborn Gasoline Company
Clark Oil & Refining Corporation
Coastal States Gas Corporation
Colonial Oil Co., Inc.
Colonial Oil Industries, Inc.
Commonwealth Oil Refining Co., Inc.
Continental Oil Company
Cross Oil & Refining Co., of AR
Crow Central Petroleum Corporation
Crystal Refining Company
Cryotol Oil Company
Deepwater Oil Terminals, Inc.
Delta Refining Company
Diamond Shamrock Corporation
Dingman Oil & Refining Co., Inc.
Dorchester Gas Producing Co., Eo.
Eastern of New Jersey, Inc.
Eddy Refining Company
Edgington Oswald Refinery
Elm Oil Refining Stations, Inc.
Evanfield Refining Co., Inc.
Exxon Corporation
Famarise Oil & Refining Co.
Edgington Oil Company
Farmers Union Central Exchange
Fletcher Oil & Refining Co.
Pilot Chemical Company
Fort Neck Oil Terminals Corp.
Gary Operating Company
George Hall Corporation
Getty/Elkins Oil Co. of the U.S.
Giant Industries Inc.
Gladiators Refining Company
Goetz Oil Corporation
Golden Eagle Refining Co., Inc.
Good Hope Refineries, Inc.

Guam Oil & Refining Co., Inc.
Gulf Oil Corporation
Gulf States Gas Co., Inc.
H. M. Hartwell & Son, Inc.
Hawaiian Independent Refinery, Inc.
Howard Oil Company
Ewell Corporation
Hunt Oil Company
Husky Oil Company
Indiana Farm Bureau Cooperative Association
Irrving Oil Corporation
J. W. Ruttan Inc.
Jet Fuel Refinery
The Kaiser Trading Co.
Kentucky & Indiana Refining Co.
Kerr-McGee Corporation
The King Service, Inc.
Koch Refining Co.
LaGloria Oil & Gas Company
Lakeside Refining Co.
Laketon Asphalt Refining, Inc.
Little America Refining Co.
Macon Oil & Refining Co., Inc.
Mid-Missouri Ring-Free Oil Co., Inc.
Marathon Oil Company
Marion Corporation
Meehan Oil Co., Inc.
Mid-America Refining Co., Inc.
Midland Cooperatives, Inc.
Mid-Tex Refinery
Mohawk Oil Company
Northern Industrial Refining Co., Inc.
Murphy Oil Corporation
National Co-operatives Refining Association
National Oil Recovery Corp.
Navajo Refining Company
New Energy Petroleum Corporation
Newhall Refining Company
R. B. Newman Fuel Corporation
North American Petroleum Corp.
Northeast Petroleum Industries Inc.
Northern Illinois & Refining Company
Northland Oil & Refining Co.
North Fork Industries Corporation
Monsanto Company
Morrison Petroleum Company
Oakland Refining Company
Oleo Refining
Paco Oil Company
Pasco Incorporated
Pathogue Oil Terminal Corp.
Patterson Fuel Oil Co., Inc.
Pennzoil Company
Petroleum Coke & Power Co., Inc.
Philco, Pa.
Phillips Petroleum Company
Pioneer Refining Company
Pitsion Co., Inc.
Platuse, Incorporated
Power Service Corporation
Fido Refining
Quaker State Oil Refining Corp.
The Refinery Corporation
Remington Fertilizer Co.
Rico Petroleum Corporation
Road Oil Sales, Inc.
Rock Island Refining Corporation
OKO Refining, Incorporated
Rockway Fuel Oil Corporation
Royal Petroleum Corporation
Sabre Petroleum Corporation
Sage Creek Refining Company, Inc.
San Joaquin Refining Co.
Sears Oil Co. & Sears Petroleum & Transport Corp.
Seminole Asphalt Refining Co.
Shanahian Natural Resources Co.
Shell Oil Company
Sigmar Corporation
Signal Company, Inc.
Somerset Refining Company
Sound Refining Inc.
Southern Terminal & Transport Co.

South Hampton Company
Southland Oil Company
Southwestern Refining Company
Standard Oil Company of CA
Standard Oil Company of Ohio
Stephen International Corp.
Stewart Petroleum Company
Stillings Petroleum Corporation
Sunland Refining Corporation
Sun Oil Company
Swan Oil Company
A. Tubb
Tennessee Oil
Texaco Petroleum Corporation
Texaco Incorporated
Texas Asphalt & Refining Co.
Texas Fuel & Asphalt Co., Inc.
Texas City Refining Inc.
Thaggard Oil
Thriftway Oil Co.
Thunderbird Resources Inc.
Tomokawa Refining Co.
Total Leonard Incorporated
U.S. Oil & Refining Co.
Union Oil Company of Cal.
Union Petroleum Corporation
Union Texas Petroleum
United Independent Oil Co.
United Refining Company
Van-Fuel Inc.
Vickers Petroleum Corporation
VIC Oil Company
Vulcan Asphalt Refining Co.
Wallace & Wallace Fuel Oil Co.
Warrior Asphalt Corporation
Webber Tanks
Welton Oil Inc.
Wether coast Oil Company
Western Refining Co.
Widcott Refining Company
Toro Petroleum Corporation
Welch Corporation
Wesback Oil Co.
Willo Chemical Corporation
Wyatt, Inc.
Yeter Oil Company
Young Refining Company

[FR Doc. 74-30021 Filed 12-20-74; 9:42 am]

FEDERAL MARITIME COMMISSION

[Docket No. 74-51]

INTERNATIONAL FREIGHT SERVICES, LTD. INC.

Order of Hearing on Petition for License

On November 30, 1973, pursuant to section 44, Shipping Act, 1916 (46 U.S.C. 841b), International Freight Services, Ltd. Inc., 6316 Eastland Road, Cleveland, Ohio, filed an application for a license as an independent ocean freight forwarder. The Commission's investigation of International Freight Services, Ltd. Inc. revealed apparently that:

(1) The experience of one of the employees who was to be made the qualifying officer pursuant to § 510.5(a) (2) (iii) of the Commission's General Order 4 (46 CFR 510.5(a) (2) (iii)), was falsely enlarged so that it would appear that the employee was fully qualified to perform ocean freight forwarding services. This employee was also induced by the applicant's President and sole stockholder, Mr. Swift, to make false and misleading
NOTICES

CONSUMERS POWER CO.

Filing of Contract for Electric Service

DECEMBER 17, 1974.

Take notice that on December 9, 1974, Consumers Power Company (Consumers), acting as agent for the Federal Power Commission in 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-7983, 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 in its discretion determines all work required to provide the reserve capacity of 5000 kw from its said 46000-24000/4160 volt station. Consumers estimates this accomplishment to occur during the first week of January, 1975. Consumers states that copies of the filing 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, 825 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. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants party to the proceeding. Any person wishing to become a party must file a petition to intervene. Alabama’s filing is on file with the Commission and available for public inspection.

KENNETH F. PLUMB, Secretary.

FEDERAL POWER COMMISSION

[Docket No. E-9165]

ALABAMA POWER CO.

Filing of Service Agreement

DECEMBER 17, 1974.

Take notice that on December 9, 1974, Alabama Power Company filed in Docket No. E-9165 a proposed service agreement dated July 1, 1974, providing for service by Alabama to Tallapoosa River Electric Cooperative, Inc, under Alabama’s Tariff Schedule RPA-1 at the aggregated delivery points, Lafayette and Providence, Alabama.

Any person desiring to be heard and to make any protest with reference to the rates to be charged under the terms of the Contract as proposed, is invited to file a petition to intervene or protest with the Federal Power Commission, 825 North Capitol Street, NE., Washington, D.C., 20426, in accordance with §§ 1.8, 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 January 9, 1975. Petitions 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. Alabama’s filing is on file with the Commission and available for public inspection.

KENNETH F. PLUMB, Secretary.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974
NOTICES

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, Ohio, which, when completed, will have two 1000 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 or to file a letter of protest. Any hearing thereon must be held in accordance with the Commission's rules or 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:


The Hearing Date will remain as scheduled (February 25, 1975, at 10:30 a.m. e.s.t.).

KENNETH F. PLUMM, Secretary.

[FR Doc 74-29892 Filed 12-23-74;8:45 am]

SOUTHERN 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:


Hearing (Unchanged), January 23, 1975 (10 a.m. e.s.t.).

KENNETH F. PLUMM, Secretary.

[FR Doc 74-29993 Filed 12-23-74;8:45 am]

NEW YORK STATE ELECTRIC AND GAS CORP.

Notice of Amendment to Filing

December 18, 1974.

Take notice that on November 25, 1974, New York State Electric and Gas Corporation (New York) tendered for filing a letter agreement dated October 11, 1974, which constitutes an amendment to the agreement dated March 12, 1970, between the Power Authority of the State of New York and Niagara Mohawk Power Corporation (Niagara), New York State Electric and Gas Corporation (NYSEG) and Rochester Gas and Electric Corporation (RG&E). New York states that the earlier agreement provides for the sale by New York, Niagara and RG&E to the Power Authority of the State of New York of up to 200,000 kilowatts of power for supplying specified high load factor manufacturers for the period commencing with the date of initial service and terminating on March 31, 1974.

New York submits that the later agreement filed herewith extends the term of the earlier agreement to July 1, 1975. Niagara and RG&E concur. An effective date of November 1, 1974, is requested.

FEDERAL REGISTER, VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974

WISCONSIN PUBLIC SERVICE CORP.

Amendment to Interconnection and Emergency Energy Agreement

December 17, 1974.

Take notice that on December 6, 1974, Wisconsin Public Service Corporation (Wisconsin) tendered for filing a proposed amendment to Article VIII of the Interconnection and Emergency Energy Agreement between Consolidated Water Power Company and Wisconsin states that the agreement has been mutually agreed upon by the parties.

As several retroactive dates are requested, Wisconsin urges a waiver of the prior notice requirement as set forth in section 205(d) of the Federal Power Act.

Any person desiring to be heard or to protest said filing 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 §§ 1.8 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 30, 1974. Protests will be considered by the Commission in determining the appropriate action to be taken. All such protests or petitions or protests should be filed on or before December 30, 1974. Protests will be considered by the Commission in determining the appropriate action to be taken. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

KENNETH F. PLUMM, Secretary.

[FR Doc 74-29895 Filed 12-23-74;8:45 am]
NOTICES

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Power Commission, 801 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 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. FLUMS,
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. Any person wishing to comment on the application should submit views in writing to the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551 to be received not later than January 16, 1975.


[SEAL]
GRIFFITH L. GAWood,
Assistant Secretary of the Board.

[FEDERAL REGISTER VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974]

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)) of formation of a bank holding company through acquisition of 100 percent of the voting shares of the successor to the bank with which Bank is to be consolidated has no significance except as a means to facilitate the acquisition of the voting shares of Bank. Accordingly, the proposed acquisition of shares of the successor organization is treated herein as the proposed acquisition of the shares 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 5.62 percent of the 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 Michigan. Since the proposed transaction is essentially a reorganization of Bank's ownership and 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 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 commitment to inject $1.5 million of equity capital into Bank within one year after consummation of the proposal. The managerial resources and future prospects of Applicant, which will depend on the future prospects of the applicant. The Board concludes that competitive considerations are consistent with approval of the application.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall 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.

By order of the Board of Governors, effective December 16, 1974.

[SEAL]
THEODORE E. ALLESON,
Secretary of the Board.

[FEDERAL REGISTER VOL. 39, NO. 248—TUESDAY, DECEMBER 24, 1974]

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)) of formation of a bank holding company through acquisition of 100 percent (less directors' qualifying shares) 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 proposed acquisition of shares of the successor organization is treated herein as the proposed acquisition of the shares of Bank.

Notice of the application, affording opportunity for interested persons to submit comments and views, and the comments and views received, has been published. 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 corporation formed 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 5.62 percent of the 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 Michigan. Since the proposed transaction is essentially a reorganization of Bank's ownership and 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 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 commitment to inject $1.5 million of equity capital into Bank within one year after consummation of the proposal. The managerial resources and future prospects of Applicant, which will depend on the future prospects of the applicant. The Board concludes that competitive considerations are consistent with approval of the application.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall 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.

By order of the Board of Governors, effective December 16, 1974.

[SEAL]
THEODORE E. ALLESON,
Secretary of the Board.

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)) of formation of a bank holding company through acquisition of 100 percent (less directors' qualifying shares) 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 proposed acquisition of shares of the successor organization is treated herein as the proposed acquisition of the shares of Bank.

Notice of the application, affording opportunity for interested persons to submit comments and views, and the comments and views received, has been published. 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 corporation formed 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 5.62 percent of the 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 Michigan. Since the proposed transaction is essentially a reorganization of Bank's ownership and 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 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 commitment to inject $1.5 million of equity capital into Bank within one year after consummation of the proposal. The managerial resources and future prospects of Applicant, which will depend on the future prospects of the applicant. The Board concludes that competitive considerations are consistent with approval of the application.

On the basis of the record, the application is approved for the reasons summarized above. The transaction shall 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.

By order of the Board of Governors, effective December 16, 1974.

[SEAL]
THEODORE E. ALLESON,
Secretary of the Board.
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 so far as the pertinent application, the Board has fully considered the arguments offered by the Protestant as well as Applicant's response thereto. Protestant's main contentions appear to be as follows: (1) The close relationship of the top management of Bank and Deposit Guaranty National Bank, Jackson, Mississippi ("Deposit Guaranty") indicates that approval of this holding company formation is tantamount to a future merger between Bank and Deposit Guaranty; (2) financial and managerial resources of Bank are not satisfactory; and (3) the holding company formation will disadvantage present shareholders of Bank because the holding company will be incorporated in Delaware.

From the facts of record, it is the Board's view that, although a corresponding relationship does exist between the two banks, there is no substantial evidence to indicate that Deposit Guaranty controls or has a controlling influence over Bank within the meaning of the provisions of the Bank Holding Company Act. In fact, Deposit Guaranty does not own any of Bank's voting securities and it does not appear from the record that it controls or has the power to vote 5 percent or more of the voting securities of Bank. Thus, the Board would not regard the instant proposal as being tantamount to a future merger of the two institutions; furthermore, any such merger would have to be approved by the appropriate supervisory authorities under the Bank Merger Act. With respect to financial and managerial considerations, the Board finds, as noted above, that such factors are consistent with approval of the application. Finally, the Board finds no legal impediment, either under the Bank Holding Company Act or relevant State law, to a holding company formed for the purpose of acquiring a bank in Mississippi being incorporated in the State of Delaware. Accordingly, on 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, the application is approved for the reasons summarized above. The transaction shall not be made effective until the later of the 30th 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 Atlanta pursuant to delegated authority.

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

[SEAL]

ThomSHEO E. ALLISON,
Secretary of the Board.

[FR Doc.74-39913 Filed 12-23-74;8:45 am]

**NOTICES**

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 within the meaning of section 2(a) of the Bank Holding Company Act of 1956, as amended (12 U.S.C. 1841(a) ("Act")), has requested a Board determination, pursuant to section 2(g) (3) of the Act (12 U.S.C. 1841(g) (3)), that NCNB is not in fact capable of controlling Collier Cobb & Company, Inc., Chapel Hill, North Carolina ("Collier"), notwithstanding the indebtedness incurred by Collier to NCNB in connection with its purchase during April, 1974, from NCNB of all of the shares 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 loan to Collier. ACA is a general insurance agency to which NCNB has 16-year grandfather rights under section 4(a) (3) of the Act.

Under the provisions of section 2(g) (3) of the Act, shares transferred after January 1, 1966, by any bank holding company (or by any company which, but for such transfer, would be a bank holding company) directly or indirectly to any transferee that is indebted to the transferor, or has one or more officers, directors, trustees, or beneficiaries in common with or subject to control by the transferor, shall be deemed to be indirectly owned or controlled by the transferor unless the Board of Governors of the Federal Reserve System, after opportunity for hearing, determines that the transferor is not in fact capable of controlling the transferee.

Notice of receipt of this request, affording an opportunity for hearing and for interested persons to make written comments with respect to NCNB's request for a determination under section 2(g) (3), was published in the FEDERAL REGISTER on Thursday, February 14, 1974 (39 F.R. 5667). The time provided for requesting a hearing or for submission of written comments expired on March 4, 1974. No request for a hearing or written comments has been received by the Board, nor has any evidence been received to show that NCNB is in fact capable of controlling Collier.

It is hereby determined that NCNB is not in fact capable of controlling Collier. This determination is based on the documentary evidence of record in this proceeding, including commitments by NCNB that NCNB will have no employee, officer or director who is at the same time an employee, officer or director of either Collier or ACA.

1. NCNB will not own, control or hold with power to vote, directly or indirectly, any of the outstanding voting shares of either Collier or ACA.

2. Neither NCNB nor any of its subsidiaries will have any employee, officer or director who is at the same time an employee, officer or director of either Collier or ACA.

3. Neither NCNB nor any of its subsidiaries will control or exert a controlling influence over either Collier or ACA through the existing indebtedness of Collier Cobb to NCNB or in any other manner.

4. In the event Collier defaults on the loan from Bank or obligation to NCNB and Bank obtains title to the shares of ACA in its possession, pursuant to the pledge agreement, solely for purposes of affecting sale thereof, NCNB shall notify the Board of that fact and Bank shall sell such shares as soon as practicable, in any event, within a period not to exceed 18 months, and in accordance 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.74-22914 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...
NOTICES

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 nonoperating corporation, formed for the purpose of becoming a bank holding company through the acquisition of Bank. The purpose of the proposed transaction is to transfer ownership of Bank from individuals to a corporation owned by the same individuals with no change in the Bank’s management or operations. Bank (deposits of $17.6 million) is the 27th largest of 103 banking organizations in the relevant banking market, controlling less than one percent of the total commercial bank deposits therein.

By order of the Board of Governors, effective December 16, 1974.

[Seal] THOMAS E. ALLISON, Secretary of the Board.

Interstate Commerce Commission

Request for clearance of a new annual performance report to be filed by Hour- hold Goods Motor Carriers with the Interstate Commerce Commission and furnished each prospective customer. The purpose of the report is to provide information to prospective consumers which will permit them to intelligently compare the services of competing carriers. The required data and reports are in Prospective versus Current Carriers. The required data and reports are in the report are specified in 49 CFR 1056.7(b). Respondents will be 1,900 Household Goods Motor Carriers. Reporting burden is estimated at 600 man-hours for each respondent.

NORMAN E. HUTY, Regulatory Reports Review Officer.

[FR Doc.74-29928 Filed 12-23-74; 8:45 am]

GENERAL SERVICES ADMINISTRATION

Notice of Meeting

December 13, 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 7, January 18 and 19, 1975, from 9 a.m. to 4 p.m., Room 12A01, Federal Building, 619 Taylor Street, Fort Worth, Texas. The meeting will be devoted to the initial step of the procedures for screening and evaluating the qualifications of architects-engineers under consideration for selection to furnish professional services for the proposed Federal Youth Center, Bastrop, Texas, Project NTX746971. Frank and open discussion of the professional 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)(6) the meeting will not be open to the public.

L. N. STUWART, Acting Regional Administrator.

[FR Doc.74-29929 Filed 12-23-74; 8:45 am]

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 7, January 20, 1975, from 9 a.m. to noon, Room 711, John W. McCormack Post Office Courthouse Building, Post Office Square, Boston, Mass. 02109.

NOTICE

Further information about the items on this list may be obtained from the

1 The relevant banking market is approximated by the Minneapolis-St. Paul MSA.

2 Voting for this action: Chairman Burns and Governors Mitchell, Sheehan, Bucher, Holland, Wurlitch and Coldwell.
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 ensure 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.

[FR Doc.74-29991 Filed 12-23-74; 8:45 am]

NOTICES

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice (74-75)]

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 Subcommitte 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. These matters in a public session would invite 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) 755-8490.

BOYD C. MYERS, II
Assistant Associate Administrator for Organization and Management, National Aeronautics and Space Administration.

DECEMBER 19, 1974.

[FR Doc.74-29976 Filed 12-23-74; 8:45 am]

RESEARCH AND TECHNOLOGY ADVISORY COUNCIL 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 10, 1975, at NASA Headquarters, 650 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 was formed 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, 755-8900, or Mr. W. H. Woodward, Area Code 202, 755-8501.

January 10, 1975

Time:

8:30 a.m. Reports of working groups (Purpose: Chairman of the four working groups listed below will report to the Committee on the status of the work being done by the respective groups: (1) Energy Science and Propulsion, (2) NASA's terrestrial energy capabilities, (3) Potential joint industry/NASA terrestrial energy projects, and (4) NASA's surface propulsion technology.)

1 p.m. Discussion of issues raised by NASA (Purpose: To afford an opportunity for the Committee to discuss issues regarding: (1) Early distribution of NASA research results to U.S. manufacturers, (2) workshops and 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 remaining 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.

[FR Doc.74-29973 Filed 12-23-74; 8:45 am]

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 were developed and published by the Department of Commerce, to facilitate a more meaningful interpretation of the U.S. balance of payments and exchange rate developments each quarter. 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. 8249, September 1938 and Executive Order No. 10253, 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 advisory committees and panels of the Advisory Committee on the Balance of Payments Statistics Presentation is hereby delegated to the Deputy Associate Director for Statistical Policy. This authority may be redelegated.


ROY L. ASH,
Director.

[FR Doc.74-29974 Filed 12-23-74; 8:45 am]

CLEANER OF REPORTS

Lists of Requests

The following is a list of requests for clearance of reports intended for use in preparing the report of 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 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, (202-395-4528), or from the reviewer listed.
NOTICES

SECURITIES AND EXCHANGE COMMISSION

[File No. 609-1]

I-T-E IMPERIAL CORP.

Notice Amending Notice of Suspension of Trading

DECEMBER 12, 1974.

The Commission having determined to amend its notice of December 4, 1974, summarily suspending trading in the securities of I-T-E Imperial Corp., for the period December 5, 1974 through December 14, 1974.

Therefore, pursuant to sections 15(c) (5) and 19(a) (4) of the Securities Exchange Act of 1934, that trading in the common stock being traded on the New York and Pacific Stock Exchanges and the preferred 4.60 percent cumulative stock being traded on the Philadelphia national securities exchange is suspended, for the period from December 5, 1974 through the midnight (EST) December 12, 1974.

By the Commission.

[SEAL] GEORGE A. PITTMAN,
Secretary.
[FR Doc.74-29094 Filed 12-23-74;8:45 am]

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 the context of these developments, the Commission is now considering various questions concerning foreign access to United States markets by foreign brokers and dealers or through domestic subsidiaries. The purpose of this release is to invite comments which will assist the Commission in exploring the issues involved in regulation and registration of foreign investment companies under the Investment Company Act of 1940 (the "Act").

The investment company vehicle can be useful as an instrument to channel funds of a country's nationals into foreign investments. A foreign investment company, managed by experts familiar with the foreign economy, business atmosphere, political situation and the factors relevant to the analysis of the investment merits of the securities of the foreign issuers in the area of their operations, should be in a position to assist the investor to meet the risks and problems of investing abroad. Domestic investment companies have provided these services to foreign investors who have channeled substantial sums into securities of United States issuers through United States investment companies. In 1973, sales of United States operations of investment companies to foreigners aggregated $287.4 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 originated 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. Without this ability they cannot, in any meaningful way, serve as an instrument for private United States investment in foreign securities or as a vehicle for foreign economies 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 prohibited unless the Commission can make the special and often difficult, findings called for by section 7(d) of the Act (15 U.S.C. 80a-7(d)). As more fully discussed below, the United States has participated in a conference of the Organisation for Economic Cooperation and Development ("OECD") which resulted in the development of specific rules for the operations of investment companies and a recommendation, supported by the Commission, that member countries take those rules into account when considering their existing legislation or applications for permission to sell publicly in their own territory securities of foreign institutions for collective investments.

In line with this action, the Commission believes it appropriate to consider the extent to which it can 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 adopted. On the other hand, the Commission believes that it should not encourage the registration of foreign investment companies under circumstances where necessary regulatory modifications would significantly lessen investor protections or provide such companies with an unfair 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 governments, state regulatory authorities in the United States, and members of the financial community.

See footnotes at end of document.
The Commission has previously permitted a limited number 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 sections 8(a) and 7(d) of the Act (15 U.S.C. 80a-3(a), 80a-7(d)). Section 8(a) of the Act authorizes only a domestic investment company to register under the Act and makes a public offering of its securities, but only:

* * * If the Commission finds that, by reason of special purposes or circumstances, it is both legally and practically feasible effectively to enforce the provisions of this Act against such company and that the issuance of such order is otherwise consistent with the public interest and protection of investors, and the purposes fairly consistent with the protection of investors, and the purposes fairly in the public interest:

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 any person, security or transaction from any provisions of the Act if and to the extent that such exemption is necessary or consistent with the protection of investors and the purposes fairly intended by the policy and the provisions of the Act; and section 8(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 authority of section 7(a) to permit foreign investments and special arrangements to be entered into by Canadian management investment companies in order to enable 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 "in a line with the policy of the Commission to facilitate and encourage foreign investments and foreign investment companies while protecting investors."

"After extended discussions with certain Canadian companies which had applied for registration * * *": The Commission went on to state:

The conditions and arrangements have been established in the light of the high degree of comity that has prevailed between the United States and Canada by existing treaties, the proximity of the two countries, the joint heritage of the common law, and the essential standards 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, directors, or the majority of the officers and of the directors are required to be citizens of the United States and a majority of such majority must reside in the United States. The officers and directors must also agree to comply with the Act and consent to the enforcement of their agreements by shareholders in those jurisdictions. In furtherance of this purpose the rule also requires the company to maintain its assets in the United States and agree to their liquidation and distribution upon direction of the Commission, or the courts, upon a finding of noncompliance by the company or its officers or 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, equal to, though not necessarily identical with, the protection accorded by the Act to investors in the usual domestic company."

Although the provisions of Rule 7d-1 are applicable only to Canadian companies, they have come to be used as a model of a rule or guideline of the application of other foreign companies for permission to register.*

The OECD rules. The Commission has taken additional action leading 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 of that body of a set of "Standard Rules for the Operations of Institutions for Collective Investments in Securities." These Standard Rules are applicable to investment companies of the open-end type and, generally speaking, deal with minimum requirements for disclosure and the furnishing of periodic financial reports to investors and the filing of periodic reports with supervisory authorities. They also deal with the institutions' sales practices, administration of investment practices, including restrictions relating to short sales, borrowings and the writing of options. In addition, the Standard Rules deal with minimum capital requirements, issuance of warrants, custody of assets, management and distribution agreements, conflicts of interest, incentive performance fees, pricing of shares and assignment of member countries to provide that each member country provide official surveillance of the institutions domiciled there.

It can be seen therefore that the Standard Rules represent a significant step forward in the protection of investors in investment company securities although they do not provide many important provisions of the Act to be authorized by the Act.

Following the promulgation of the Standard Rules, the OECD recommended that member countries:

(1) Review, as appropriate, their existing regulations 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 to permit registration of foreign investment companies. This should enable the Commission to administer the Act in light of developments in foreign securities regulation and recent adoption of an OECD Code of practice to provide uniform standards for the regulation of investment companies."

**Sates abroad of securities of United States investment companies.** The Commission has 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 Offer and Sale outside of the United States of Shares of Registered Open-end Investment Companies" ("Guidelines") promulgated on June 23, 1970 (Investment Company Act Release No. 6832), the Commission indicated that it considered the charter of United States law to be applicable to United States investment companies even when selling outside 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 such companies must effect such offerings by means of a prospectus not substantially different from the one used in the United States printed in a language understood by that segment of the investing public being solicited. The Guidelines also expressed the Commission's view that while the provisions of the Act apply to an open-end company registered under the Act regardless of where its shares are sold, exemptive relief from the price maintenance provisions of the Act may be justified under appropriate circumstances with respect to overseas sales to foreign nationals.

In recognition of the Commission's position that the extensive pattern of investor protection provided by the United States securities laws was generally unavailable to foreign investors, German authorities have since permitted several United States investment companies to sell their shares in Germany. In addition, a number of United States companies are now selling in the European community outside of Germany. Most recently, several United States investment companies have been permitted to sell their shares in Japan.  

The current situation. Despite the action taken by the Commission looking to the registration of foreign investment companies and the substantial interest manifested in registering foreign investment companies, to date only a small number of foreign companies have actually registered under the Act.  

Recently, interest has been expressed in registering companies organized in Belgium, Germany, Japan, The Netherlands and Switzerland. However, it appears that the provisions of sections 7(d) of the Act and Rule 7d-1 (taken as guidelines) are considered formidable obstacles to obtaining the required permission of the Commission to register. The OECD Standard Rules are met, conflicts between the laws of the company's domicile and the United States securities laws raise substantial questions as to whether registration may be permitted.

In view of the foregoing, the Commission wishes to consider whether and how United States investors in foreign investment companies permitted to register under the Act can be provided with adequate protection without unduly impeding the public offering of the securities of such companies in the United States and the operation of such companies outside of the United States.

Issues to be addressed. American investors have for many years manifested an interest in investing in foreign securities and, in view of the increasing internationalization of the securities markets, this interest may be expected to increase. As pointed out above, foreign investment companies could provide a valuable medium for such investment. On the other hand, investors in investment companies are in need of special protections, extending beyond disclosure, and the Investment Company Act was a response to that need. Section 7(d) of the Act expresses a policy that American investors in foreign companies should have the same protection. As the Senate and House Committees in their reports on that Act put it:

Foreign investment companies may not register as investment companies or public offerings of their securities unless the Act provides that they also be subject to certain of the protections required by the Act.

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 constraints of the general law and market practice; other investment companies may be deterred by the requirements of section 7(d). As discussed above, the restrictions in the Act with respect to securities offered and sold, exemptive relief from the price maintenance provisions of the Act and, in certain respects, provide additional protections. The basic question, therefore, is whether or not it is desirable, under the circumstances, to relax certain of the restrictions in the Act with respect to foreign investment companies, particularly those domiciled in OECD member countries which adopt the regulatory framework provided in the Standard Rules, and, if desirable, how this can be done in a way which will not sacrifice essential investor protections.

In view of the foregoing, the Commission requests comments on the following questions:  

1. (a) What effect would increasing the number of foreign investment companies registered under the Act have on the United States securities laws, on domestic issuers of securities, and on the domestic investment company industry?  
(b) Would easing requirements for access by foreign investment companies to the United States facilitate the entry of United States investment companies into foreign markets?  
(c) Should the Commission permit foreign investment companies to register under the Act subject to certain conditions or arrangements which do not provide protections equal to those provided under the Act?  
(d) Should any foreign investment company established in an OECD member country which has conformed with the Standard Rules at a time when it complies with such rules be permitted to register under the Act?  
(e) If not, what additional protections should be required?  
(f) Is it feasible and practical to require a foreign investment company subject to regulation in another country to comply fully with bookkeeping, record keeping, valuation and capital structure requirements?  
(g) Should investors in investment companies of a company which has issued redeemable securities?  
(h) Is it feasible and practical to require a foreign investment company subject to regulation in another country to comply fully with the Act and, if so, what provisions of the Act should they not be required to meet?  
(i) Should any foreign investment company established in an OECD member country which has conformed with the Standard Rules at a time when it complies with such rules be permitted to register under the Act?  
(j) If not, what additional protections should be required?  
(k) Is it feasible and practical to require a foreign investment company subject to regulation in another country to comply fully with the Act if it can provide adequate safeguards from overreaching by affiliated persons in a manner equal to that contemplated by section 17A of the Act?  
(l) Can net asset value of the shares of a foreign investment company which invests in foreign securities be readily and reliably ascertained?  
(m) Must the Commission inquire into the adequacy of the foreign markets for the securities in the investment company's portfolio, particularly in the case of a company which has issued redeemable securities?  
(n) If it is not feasible and practical to apply these protections and safeguards with respect to a foreign investment company, what variations are possible in order to provide "equal" protections to United States investors.  

3. (a) A fundamental touchstone of the Commission's program for regulating United States investment companies is its involvement in a routine inspection. Can this be accomplished with respect to foreign investment companies?  
(b) Are the problems of surveillance and enforcement presented by permitting foreign investment companies to register under the Act, especially in view of the laws of their respective jurisdictions of origin (including "secrecy" laws), capable of solution? Among other things, these problems include access to information abroad to determine the nature of transactions and to verify the manner in which they are being conducted, the policy of foreign courts for relationships with customers to insure compliance with applicable United States law, and the extent to which foreign courts would honor judgments rendered by United States courts against foreign brokers doing business here?  
(c) Can foreign courts enforce, and if so, to what extent will court of last resort be recognized for the protection of United States investors?  
(d) What requirements are appropriate to assure adequate protection to United States investors under the Act?  

4. (a) To what extent would additional costs be incurred in regulating foreign investment companies and in enforcing the securities laws against them?  

See footnotes at end of document.
(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 company, what procedures should be used 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 it be that the price of problems adversely affect United States investors in foreign investment companies with respect to payment of dividends and ability to redeem shares and, if so, what protections are 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 of the same type, domestic and foreign, are not required to meet essentially the same regulatory standards under the Act, it is prevented from organizing or reorganizing under the Act, what would prevent any interests from originating or reorganizing 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 the enumerated questions from the perspective of companies that are subject to alternative regulations. Any such submissions should be made at the time and place and in the manner noted above.

By the Commission.

[SEAL] George A. Fitzsimmons, Secretary.

December 2, 1974.

[FR Doc.74-29953 Filed 12-23-74;8:45 am]

Public comments have been submitted to the Commission on this matter pursuant to the Commission's invitation. (Securities Exchange Act Release No. 10534, February 8, 1974.)


Id. at 2.


In 1973, Congressman Harley O. Staggers introduced this proposed bill as S. 8256. No further action has been taken in the Congress and the bill is still pending.


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NOTICES

Gold Purchasing and Investing

Recommendations

As of December 31, 1974 the Federal restrictions on the purchase, sale and ownership of gold were 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 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 and trading in securities related to gold. Federal laws against securities and mail fraud will be enforced by the FTC. Trading in gold commodity futures and transactions involving margin and leverage contracts in 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 undertaken 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. 20549. With respect to investment programs, prospective investors should insist upon a prospectus or offering circular before making an investment decision. A copy of the prospectus may be reviewed at the public reference facilities of the respective 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) 252-5500. 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. Seek independent advice from a person you trust and who is knowledgeable.
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 agencies.
8. Attempt to determine the seller's mark-up (or how much it cost the seller to purchase the gold).
9. Ascertain what costs, in addition to the cost 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 sales tax.
10. Demand a written guarantee concerning weight and fineness (purity).
11. Some gold bears a refiner's mark assaying its weight and fineness; however, there are no Federal standards.
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.
14. Ask whether there will be a ready market for the gold in the form being offered to you. You may have to pay to have your gold assayed, recast 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 utmost 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 57, 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 Federal 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.

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 avoiding in any manner, 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 C.F.R. 1065.1(a), and notice thereof to all interested persons is hereby given as provided in such rules.

An original and two copies of protests against the proposed elimination of any gateway herein described may be filed with the Interstate Commerce Commission on or before January 3, 1975. A copy must also be served upon applicant or its representative. Protests against the elimination of a gateway will not operate to stay commencement of the proposed operation.

Successively filed letter-notices of the same carrier under these rules will be numbered consecutively for convenience in identification. Protests, if any, must refer to such letter-notices by number.

No. MC 57203 (Sub-No. E7), (Correction), filed June 4, 1974. Applicant: MILLSTEAD VAN LINES, INC., P.O. Drawer 878, Bartlesville, Okla. 74003. Protestant: Cox, 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 Wyoming, on the one hand, and, on the other, points in Oklahoma on and east of a line beginning at the Kansas State line, thence along Interstate Highway 85, thence along Interstate Highway 35 to the Oklahoma-Texas State line. The purpose of this filing is to eliminate the gateways 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: Chemicals, in bulk, in tank vehicles, from points in Chicago to points in Wisconsin (on and east of Interstate Highway 94), then thence along Interstate Highway 94 to the Wisconsin-Michigan State line.

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: Chemicals, in bulk, in tank vehicles, from points in Chicago to points in Wisconsin (on and east of Interstate Highway 94), then thence along Interstate Highway 94 to the Wisconsin-Michigan State line.

No. MC 61403 (Sub-No. E9), 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, from points in Chicago to points in Wisconsin (on and east of Interstate Highway 94), then thence along Interstate Highway 94 to the Wisconsin-Michigan State line.

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, from points in Chicago to points in Wisconsin (on and east of Interstate Highway 94), then thence along Interstate Highway 94 to the Wisconsin-Michigan State line.

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, from points in Chicago to points in Wisconsin (on and east of Interstate Highway 94), then thence along Interstate Highway 94 to the Wisconsin-Michigan State line.

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, from points in Chicago to points in Wisconsin (on and east of Interstate Highway 94), then thence along Interstate Highway 94 to the Wisconsin-Michigan State line.

No. MC 61403 (Sub-No. E13), 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, from points in Chicago to points in Wisconsin (on and east of Interstate Highway 94), then thence along Interstate Highway 94 to the Wisconsin-Michigan State line.

No. MC 61403 (Sub-No. E14), 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, from points in Chicago to points in Wisconsin (on and east of Interstate Highway 94), then thence along Interstate Highway 94 to the Wisconsin-Michigan State line.

No. MC 61403 (Sub-No. E15), 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, from points in Chicago to points in Wisconsin (on and east of Interstate Highway 94), then thence along Interstate Highway 94 to the Wisconsin-Michigan State line.
No. MC 73688 (Sub-No. E13), filed May 14, 1974. Applicant: SOUTHERN TRUCKING CORP., P.O. Box 7188, Memphis, Tenn. 38107. Applicant's representative: Fred F. Bradley, Frankfort, Ky. 40601. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Structural steel, steel pipe, 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 indicated by asterisks above.

No. MC 76177 (Sub-No. E70), 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 Kentucky to points in Colorado, Utah, and points in Nevada. The purpose of this filing is to eliminate the gateways of Denver, Colo., 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 Mexico, Texas, Louisiana, and Mississippi, to points in Missouri. The purpose of this filing is to eliminate the gateway of Fort Smith, Ark., 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 Colorado and Utah. The purpose of this filing is to eliminate the gateway of Carthage, Mo., and points within 6 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 Oklahoma within 10 miles of Muskogee, Okla., and points within 15 miles thereof; (2) Wolf Lake, III., and points within 15 miles thereof; and (3) Carthage, Mo., and points within 6 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 and B explosives, and blasting supplies, from points in Alabama, Florida, and Mississippi to points in Tennessee. The purpose of this filing is to eliminate the gateway of Seneca and Memphis, Tenn. The purpose of this filing is to eliminate the gateway of Atlas, Mo., and points within 15 miles thereof.

No. MC 76177 (Sub-No. E75), 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 Virginia and West Virginia, to points in Pennsylvania. The purpose of this filing is to eliminate the gateway of Scottsville, Ky., and points within 5 miles thereof.

No. MC 76177 (Sub-No. E76), 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 Michigan and Pennsylvania. The purpose of this filing is to eliminate the gateway of Greenup, Ky., and points within 5 miles thereof.

No. MC 76177 (Sub-No. E77), 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 Kentucky, Virginia, and West Virginia, to points in Georgia. The purpose of this filing is to eliminate the gateways of (1) Grafton, Ill., and points within 15 miles thereof; (2) Wolf Lake, Ill., and points within 15 miles thereof.

No. MC 76177 (Sub-No. E78), 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 New Mexico, Texas, Louisiana, and Mississippi. 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 Ordid, Ill.

No. MC 76177 (Sub-No. E79), 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 to points in Illinois. The purpose of this filing is to eliminate the gateway of Points that are within 25 miles of Energy, Ill., and also within 15 miles of Wolf Lake, Ill.
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Georgia, North Carolina, and South Carolina to points in Nebraska. The purpose of this filing is to eliminate the gateways of (1) points in Alabama and (2) the plant site of Trojan-U.S. Powder, division of Commercial Solvents Corporation, at or near Ordill, Ill.

No. MC 95850 (Sub-No. E311), filed November 29, 1974. Applicant: WATKINS MOTOR LINES, INC., P.O. Box 1636, Atlanta, Ga. 30301. Applicant's representative: Jerome F. Marks (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Frozen foods (except commodities in bulk, in tank vehicles), from South Bend, N.Y., to points in Alabama and those points in Arkansas on and southwest of a line beginning at the Arkansas-Missouri State line and extending along Arkansas Highway 25 to its junction with U.S. Highway 63, thence along U.S. Highway 63 to the Arkansas-Missouri State line. The purpose of this filing is to eliminate the gateway of Calhounville, Ga.

No. MC 106398 (Sub-No. E29) (Correction), filed May 15, 1974, published in the Federal Register October 31, 1974. Applicant: NATIONAL TRAILER CONVOY, INC., P.O. Box 3329, Tulsa, Okla. 74101. Applicant's representative: Irvin Pull (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Prefabricated buildings, complete, knocked down, sections, and component parts, materials, supplies, and fixtures when shipped with such buildings, and accessories used in the erection, construction, and completion thereof, from points in New Jersey, Delaware, Maryland, and the District of Columbia, to points in Minnesota, South Dakota, Nebraska, and Kansas. The purpose of this filing is to eliminate the gateways of Hanover, Pa., and Des Moines, Iowa. The purpose of this correction is to correct the "E" number, previously published as E3.

No. MC 106398 (Sub-No. E143) (Correction), filed May 31, 1974, published in the Federal Register October 31, 1974. Applicant: NATIONAL TRAILER CONVOY, INC., P.O. Box 3329, Tulsa, Okla. 74101. Applicant's representative: Irvin Pull (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Plywood (except in bulk), from the plant site of General Plywood Corporation at New Albany, Ind., to the Upper Peninsula of Michigan and Wisconsin. The purpose of this filing is to eliminate the gateway of the facilities of the Celotex Corporation at Charles- ton, Ill. The purpose of this correction is to correct the "E" number, previously published as E144.

No. MC 106397 (Sub-No. E22) (Correction), filed May 15, 1974, published in the Federal Register July 25, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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 by-product materials, and radioactive materials, between points in the Lower Peninsula of Michigan on the one hand, and, on the other, points in that part of Illinois on and west of U.S. Highway 63, 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. The purpose of this correction is to omit the exception.

No. MC 106397 (Sub-No. E31) (Correction), filed May 15, 1974, published in the Federal Register July 25, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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 by-product materials, and radioactive materials, between points in the Lower Peninsula of Michigan on the one hand, and, on the other, points in that part of Illinois on and west of U.S. Highway 63, 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. The purpose of this correction is to omit the exception.

No. MC 106397 (Sub-No. E23) (Correction), filed May 15, 1974, published in the Federal Register July 25, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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 by-product materials, and radioactive materials, between points in the Lower Peninsula of Michigan on the one hand, and, on the other, points in that part of Illinois on and west of U.S. Highway 63, 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. The purpose of this correction is to omit the exception.

No. MC 106397 (Sub-No. E6) (Correction), filed May 15, 1974, published in the Federal Register July 25, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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 by-product materials, and radioactive materials, between points in Anderson and Roane Counties, Tennessee, and Statesville, North Carolina, to points in Arkansas on and southwest of a line beginning at the Arkansas-Missouri State line, thence along U.S. Highway 17, restricted to the transportation of traffic under Government bills of lading. The purpose of this filing is to eliminate the gateways of (1) the facilities of the General Electric Co., located near Morris, Grundy County, Ill., and (2) points in DuPage County, Ill. The purpose of this correction is to omit the exception.

No. MC 106397 (Sub-No. E7) (Correction), filed May 15, 1974, published in the Federal Register July 25, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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 by-product materials, and radioactive materials, between points in Anderson and Roane Counties, Tennessee, on the one hand, and, on the other, points in that part of Illinois on and north of Illinois Highway 17, restricted to the transportation of traffic under Government bills of lading. The purpose of this filing is to eliminate the gateways of (1) the facilities of the General Electric Co., located near Morris, Grundy County, Ill., and (2) points in DuPage County, Ill. The purpose of this correction is to omit the exception.

No. MC 106397 (Sub-No. E8) (Correction), filed May 15, 1974, published in the Federal Register July 25, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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 by-product materials, and radioactive materials, between the Cimarron facilities of Kerr-McGee Corporation at or near Crescent, Okla., and the facilities of the General Electric Co., located near Ordill, Ill., and those points in Michigan that part of Wisconsin on and east of U.S. Highway 41, and those parts of Indiana and Ohio on and part of Wisconsin on and east of a line beginning at the Michigan-Wisconsin State line, thence along U.S. Highway 41 to junction Wisconsin Highway 67, thence along Wisconsin Highway 67 to the Wisconsin-Illinois State line, restricted to the transportation of traffic under Government bills of lading. The purpose of this filing is to eliminate the gateway of (1) the facilities of the General Electric Co., located near Morris, Grundy County, Ill., and (2) points in DuPage County, Ill. The purpose of this correction is to omit the exception.
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north of U.S. Highway 30, restricted to the transportation of traffic under Government bills of lading. The purpose of this filing is to eliminate the gateways of (1) the facilities of the General Electric Co., located near Morris, Grundy County, Ill., and (2) the Argonne National Laboratory of the United States Atomic Energy Commission, near Lemont, Ill. The purpose of this correction is to omit the exception.

No. MC 109397 (Sub-No. E90) (Correction), filed May 15, 1974, published in the Federal Register July 29, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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: (1) Explosives, (2) from points in Arkansas, Florida, Georgia, Louisiana, Mississippi, New Mexico, Texas, and that part of Tennessee on and west of U.S. Highway 37, to points in New Jersey; (2) from points in Florida to points in Delaware, Maryland, and part of Virginia on Interstate Highway 95, to restricted hand, and, on the other, points in Illinois, restricted to the transportation of traffic 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. 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 June 20, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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 by-product materials, and radioactive materials, between points in Washington, Idaho, Oregon, Nevada, and that part of California on west, and north of Highway 95, to restricted 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. E89) (Correction), filed May 15, 1974, published in the Federal Register October 22, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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 by-product materials, and radioactive materials, between the Nuclear Generating Stations located near Morris, Grundy County, Ill., and (2) Sheffield, Ill. The purpose of this correction is to omit the exception.

No. MC 109397 (Sub-No. E11) (Correction), filed May 15, 1974, published in the Federal Register July 29, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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 by-product materials, and radioactive materials, between the Nuclear Generating Stations 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 6246, 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, unassembled, from points in Florida to 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 109397 (Sub-No. E36) (Correction), filed May 15, 1974, published in the Federal Register August 5, 1974. Applicant: TRI-STATE MOTOR TRANSIT 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: (A) Explosives, (1) from points in Arkansas, Florida, Georgia, Louisiana, Mississippi, New Mexico, Texas, and that part of Tennessee on and west of U.S. Highway 37, to points in New Jersey; (2) from points in Florida to points in Delaware, Maryland, and part of Virginia on Interstate Highway 95; and (B) Ammunition and explosives, and construction machinery, equipment, and supplies (except petroleum products and products in tanks, vehicles, or trailers, and except coal), from points in Ohio to points in Pocahontas County, W. Va. The purpose of this filing is to eliminate the gateway of points in Virginia. The purpose of this correction is to clarify the exception.

No. MC 113495 (Sub-No. E47) (Correction), filed June 3, 1974, published in the Federal Register December 9, 1974. Applicant: GREGORY HEAVY HAULER, INC., P.O. Box 60628, Nashville, Tenn. 37208. Applicant's representative: E. T. Gregory (same as above). Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Road-construction machinery, equipment, and supplies (except petroleum products and products in tanks, vehicles, or trailers, and except coal), from points in Ohio to points in Pocahontas County, W. Va. The purpose of this filing is to eliminate the gateway of points in Virginia. The purpose of this correction is to clarify the exception.

No. MC 114211 (Sub-No. E175) (Correction), filed June 4, 1974. Applicant: WARREN TRANSPORT, INC., P.O. Box 329, 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: Tractors (except those with vehicle beds, bed frames, or fifth wheels), agricultural machinery and implements, industrial and construction machinery and equipment, and trailers, designed for the transportation of the commodities described above (except those designed to be run by passenger automobiles), for the commodities described above. Authority sought to use common carrier, by motor vehicle, over irregular routes, transporting: Self-propelled articles, each weighing 5,000 pounds or more, unattached, and unassembled, from the points in Ohio to points in the foreign commerce only. The purpose of this filing is to eliminate the gateway of Grand Island, Neb.
thence along U.S. Highway 18 to junction South Dakota Highway 47, thence along South Dakota Highway 47 to the South Dakota-Nebraska State line, to points in that part of Iowa on and east of Iowa Highway 169. The purpose of this filing is to eliminate the gateway of Ft. Dodge, Iowa.

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, manufacturing, 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 in that part of Michigan on, south, and west of a line beginning at the Indiana-Michigan State line, thence along U.S. Highway 130 to junction Interstate Highway 96, thence along Interstate Highway 96 to Muskegon, that part of Indiana on and north of U.S. Highway 40, to points in Idaho, Utah, and Arizona. The purpose of this filing is to eliminate the gateway 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, manufacturing, 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 in that part of Missouri on, north and west of a line beginning at the Ohio-Illinois State line, thence along U.S. Highway 136 to junction Illinois Highway 84, thence along Illinois Highway 84 to junction U.S. Highway 24, thence along U.S. Highway 24 to junction Illinois Highway 99, thence along Illinois Highway 99 to junction Illinois Highway 104, thence along Illinois Highway 104 to junction Illinois Highway 29, thence along Illinois Highway 29 to junction Illinois Highway 16, thence along Illinois Highway 16 to junction Illinois Highway 32, thence along Illinois Highway 32 to junction Illinois Highway 70, thence along Illinois Highway 70 to the Illinois-Indiana State line, to points in Indiana, and that part of Utah on and north of a line beginning at the Colorado-Utah State line, thence along Interstate Highway 70 to junction Utah Highway 128, thence along Utah Highway 128 to junction U.S. Highway 163, thence along U.S. Highway 163 to junction Interstate Highway 70, thence along Interstate Highway 70 to junction U.S. Highway 69 to junction U.S. Highway 4, thence along U.S. Highway 4 to junction Interstate Highway 15, thence along Interstate Highway 15 to junction Utah Highway 49, thence along Utah Highway 49 to the Nevada-Utah State line. The purpose of this filing is to eliminate the gateways of the plant sites 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, as described in Appendix XXII 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 a line beginning at the Iowa-Minnesota State line, thence along U.S. Highway 27 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, Kansas, and Claremore, Oklahoma.

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. 459), from points in that part of Iowa on, north and west 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 Illinois Highway 84, thence along Illinois Highway 84 to junction Interstate Highway 70, thence along Interstate Highway 70 to the Iowa-Nebraska State line, thence along North Dakota Highway 63 to the Iowa-Minnesota State line, to points in Minnesota on, south, and north of a line beginning at the Iowa-Minnesota State line, thence along Interstate Highway 70 to junction Interstate Highway 30, thence along Interstate Highway 30 to junction Interstate Highway 49, thence along Interstate Highway 49 to junction Interstate Highway 15, thence along Interstate Highway 15 to junction U.S. Highway 69, thence along U.S. Highway 69 to the Nevada-Utah State line. The purpose of this filing is to eliminate the gateways of Council Bluffs, Iowa, and Omaha, Nebraska.

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: Farm 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 19 to junction 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, Minnesota, and Horson, Wisconsin.

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 83, thence along U.S. Highway 83 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. E263), 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, farm vehicles (except truck tractors, attachments and Accessories therefore, 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, Alabama, Utah, and Colorado, restricted to the transportation of self-propelled vehicles (except motor vehicles as defined in section 203(a)(1) of the Interstate Commerce Commission Act, as defined in the drivewheel service), equipment designed for use in conjunction with self-propelled vehicles (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 that part of Illinois on and north of a line beginning at the Iowa-Illinois State line, thence along U.S. Highway 24 to Junction Illinois Highway 116, thence along Illinois Highway 116 to junction U.S. Highway 24, thence along U.S. Highway 24 to the Illinois-Indiana State line, to points in Indiana.

To 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 that part of Illinois on and north of a line beginning at the Iowa-Illinois State line, thence along U.S. Highway 24 to Junction Illinois Highway 116, thence along Illinois Highway 116 to junction U.S. Highway 24, thence along U.S. Highway 24 to the Illinois-Indiana State line, to points in Indiana.

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 that part of Illinois on and north of a line beginning at the Iowa-Illinois State line, thence along U.S. Highway 24 to Junction Illinois Highway 116, thence along Illinois Highway 116 to junction U.S. Highway 24, thence along U.S. Highway 24 to the Illinois-Indiana State line, to points in Indiana.

No. MC 114211 (Sub-No. E271), 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 that part of Illinois on and north of a line beginning at the Iowa-Illinois State line, thence along U.S. Highway 24 to Junction Illinois Highway 116, thence along Illinois Highway 116 to junction U.S. Highway 24, thence along U.S. Highway 24 to the Illinois-Indiana State line, to points in Indiana.

No. MC 114211 (Sub-No. E272), 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 that part of Illinois on and north of a line beginning at the Iowa-Illinois State line, thence along U.S. Highway 24 to Junction Illinois Highway 116, thence along Illinois Highway 116 to junction U.S. Highway 24, thence along U.S. Highway 24 to the Illinois-Indiana State line, to points in Indiana.
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routes, transporting: Agricultural machinery, implements, and parts as described in Appendix I to the report. Authority sought to operate as a common carrier, by motor vehicle, over irregular routes, transporting: Farm tractor show displays, and experimental farm tractor show displays, and farm tractors (except those with vehicle beds, bed frames, or fifth wheels) equipment designed for use in conjunction with farm tractors and parts for farm tractors, and equipment designed for use therewith, from points in North Dakota to points in the United States and east of Indiana, Kentucky, Tennessee, Arkansas, and Louisiana, and points in that part of Michigan on and east of a line beginning at Hancock, thence along U.S. Highway 41 to junction U.S. Highway 141, thence along U.S. Highway 141 to the Michigan-Wisconsin State line, thence along Wisconsin on and east of a line beginning at the Michigan-Wisconsin State line, thence along U.S. Highway 141 to junction U.S. Highway 151, thence along U.S. Highway 151 to junction Wisconsin Highway 69, thence along Wisconsin Highway 69 to the Wisconsin-Illinois State line, that part of Illinois on and east of a line beginning at the Wisconsin-Illinois State line, thence along U.S. Highway 52 to junction Illinois Highway 84, thence along Illinois Highway 84 to junction Illinois Highway 67 to junction U.S. Highway 61, thence along U.S. Highway 61 to the Missouri-Illinois State line, that part of Iowa on and east of a line beginning at the Missouri-Illinois State line, thence along U.S. Highway 61 to junction Interstate Highway 55, thence along Interstate Highway 55 to the Missouri-Illinois State line, that part of Iowa on and east of a line beginning at the Missouri-Illinois State line, thence along U.S. Highway 61 to junction Missouri Highway 16, thence along Missouri Highway 16 to junction Missouri Highway 6, thence along Missouri Highway 6 to junction Missouri Highway 11, thence along Missouri Highway 11 to junction U.S. Highway 69 to junction U.S. Highway 24 to the Missouri-Kansas State line, and that part of Texas on and east of a line beginning at the Arkansas-Texas State line, thence along U.S. Highway 59 to junction Texas Highway 155, thence along Texas Highway 155 to junction U.S. Highway 84, thence along U.S. Highway 84 to junction Interstate Highway 20, thence along Interstate Highway 20 to the International Boundary line between the United States and Mexico. The purpose of this filing is to eliminate the gateway of Dobao, Iowa.

No. MC 114211 (Sub-No. E279), 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: Tractors, road making machinery, and contractors' equipment and supplies, in that part of Missouri on and south of a line beginning at the Minnesota-South Dakota State line, thence along Minnesota Highway 19 to junction U.S. Highway 71, thence along U.S. Highway 71 to the Minnesota-Iowa State line, to points in that part of Washington on and west of a line beginning at the Washington-Idaho State line, thence along Interstate Highway 90 to junction U.S. Highway 395, thence along U.S. Highway 395 to the Washington-Oregon State line, that part of Oregon on and west of a line beginning at the Washington-Oregon State line, thence along U.S. Highway 395 to the Oregon-California State line, that part of California on and west of a line beginning at the Oregon-California State line, thence along U.S. Highway 95 to junction Interstate Highway 5, thence along Interstate Highway

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5 to junction California Highway 99, thence along California Highway 99 to junction California Highway 58, thence along California Highway 58 to junction California Highway 12, thence along California Highway 12 to junction California Highway 14, thence along California Highway 14 to junction Interstate Highway 5, thence along Interstate Highway 5 to junction California Highway 10, thence along California Highway 10 to junction Interstate Highway 10, thence along Interstate Highway 10 to the California-Arizona State line, restricted to the transportation of self-propelled vehicles (except motor vehicles as defined in Section 203(a)(15) of the Interstate Commerce Act and commodities moving in drayage, 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 Colorado to points in Indiana, Kentucky, Ohio, Pennsylvania, New York (except points in Kings, Queens, Nassau, and Suffolk Counties), that part of Missouri on and south of a line beginning at the Missouri-Kansas State line, thence along U.S. Highway 61 to junction Missouri Highway 59, thence along Missouri Highway 59 to junction Missouri Highway 6, thence along Missouri Highway 6 to junction U.S. Highway 63, thence along U.S. Highway 63 to the Missouri-Arkansas State line, that part of Michigan on and east of Interstate Highway 75, that part of Ohio on and south of a line beginning at the Indiana-OHio State line, and in that part of Illinois 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 the Ohio-Indiana State line, 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. E282), 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 Indiana 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 19 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 Michigan 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 Kings, Queens, Nassau, and Suffolk Counties, that part of Indiana on and east of a line beginning at the Indiana-OHio State line, thence along Ohio Highway 59 to junction Interstate Highway 75, thence along Interstate Highway 75 to the Ohio-Michigan State line, and in that part of Illinois 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 the Ohio-Indiana State line, 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, 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 Indiana 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 the Lower Peninsula of Michigan, that part of the Upper Peninsula of Michigan, that part of Indiana on and west of a line beginning at the Indiana-OHio State line, thence along U.S. Highway 52 to junction Iowa Highway 150, thence along Iowa Highway 150 to junction Michigan Highway 25, thence along Michigan Highway 25 to junction Michigan Highway 142, thence along Michigan Highway 142 to Lake Huron. The purpose of this filing is to eliminate the gateway of Olwein, 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 Indiana to points in Indiana, Kentucky, Ohio, Pennsylvania, New York (except points in Kings, Queens, Nassau, and Suffolk Counties).
Interstate Highway 65 to junction U.S. Highway 50, thence along U.S. Highway 59 to junction Interstate Highway 69, thence along Interstate Highway 69 to junction Indiana Highway 18, thence along Indiana Highway 18 to junction Indiana Highway 37, thence along Indiana Highway 37 to junction Indiana Highway 257, thence along Indiana Highway 257 to the Indiana-Kentucky State line. The purpose of this filing is to eliminate the gateway of Olweo, 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: (1) Earth drilling machinery and equipment, (2) 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 wells or holes, (a) between points in Kansas, the one hand, and, on the other, points in Colorado on and east of a line beginning at the Colorado-Nebraska State line and extending along U.S. Highway 34 to its junction with U.S. Highway 85, thence along U.S. Highway 85 to its junction with U.S. Highway 66, thence along Colorado Highway 66 to its junction with U.S. Highway 36, thence along U.S. Highway 36 to its junction with U.S. Highway 40, thence along U.S. Highway 40 to its junction with Colorado Highway 318, thence along Colorado Highway 318 to the Colorado-Wyoming State line, (b) between points in Colorado on and east of a line beginning at the Colorado-New Mexico State line and extending along Interstate Highway 25 to its junction with U.S. Highway 6, thence along U.S. Highway 6 to its junction with Colorado Highway 71, thence along Colorado Highway 71 to the Colorado-Nebraska State line, on the one hand, and, on the other, points in Kansas on and east of a line beginning at the Colorado-Kansas State line and extending along Kansas Highway 51 to its junction with U.S. Highway 66, thence along U.S. Highway 66 to its junction with U.S. Highway 56, thence along U.S. Highway 56 to its junction with U.S. Highway 169, thence along U.S. Highway 169 to its junction with U.S. Highway 54, thence along U.S. Highway 54 to its junction with Kansas Highway 17, thence along Kansas Highway 17 to its junction with U.S. Highway 50, thence along U.S. Highway 50 to its junction with Kansas Highway 177, thence along Kansas Highway 177 to its junction with U.S. Highway 54, thence along U.S. Highway 54 to its junction with U.S. Highway 261, thence along U.S. Highway 261 to its junction with Kansas Highway 9, thence along Kansas Highway 9 to its junction with Kansas Highway 233, thence along Kansas Highway 233 to its junction with Kansas Highway 23, thence along Kansas Highway 23 to its junction with U.S. Highway 83, thence along U.S. Highway 83 to its junction with U.S. Highway 36, thence along U.S. Highway 36 to its junction with Kansas Highway 27, thence along Kansas Highway 27 to its junction with Nebraska State line, and (e) between points in Colorado, on the one hand, and,
on the other, points in Kansas 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 unnumbered highway, thence along unnumbered highway to its junction with U.S. Highway 77, thence along U.S. Highway 77 to its junction with Kansas Highway 9, thence along unnumbered highway to its junction with Kansas Highway 9 at its junction with unnumbered highway, thence along unnumbered highway 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 59, thence along U.S. Highway 59 to its junction with U.S. Highway 160, thence along U.S. Highway 160 to its junction with unnumbered highway near junction of U.S. Highway 160 and U.S. Highway 83, thence along unnumbered highway to its junction with U.S. Highway 56, thence along U.S. Highway 56 to the Kansas- Oklahoma State line. The purpose of this filing is to eliminate the gateway of points in Oklahoma. 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 used in, or in connection with the discovery, development, production, refining, manufacturing, 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, 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 Ontario. 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, refining, manufacturing, processing, storage, transmission, and distribution of natural gas and petroleum, and (2) Earth drilling machinery and equipment, and materials, supplies, and pipe incidental to, used in, or in connection with (a) the transportation, 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 New Mexico-Colorado State line. The purpose of this filing is to eliminate the gateway of points in Ohio. 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 discovery, development, production, refining, manufacturing, 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, between points in New Mexico, on the one hand, and, on the other, points in New Mexico. The purpose of this filing is to eliminate the gateway of 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 and extending along Louisiana Highway 31, thence along Louisiana Highway 84 to its Junction with Interstate Highway 46 to its junction with Louisiana Highway 39, thence along Louisiana Highway 39 to its junction with Interstate Highway 51, 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. 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, 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, other than pipelines used for the transmission of natural gas, petroleum, their products, and by-products, water, or sewerage, restricted to the transportation of shipments moving to or from pipeline rights-of-way; (2) Earth drilling machinery and equipment, materials, and 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, (a) between points in Illinois, Indiana, Iowa, Kentucky, Louisiana, Michigan, Minnesota, Mississippi, Missouri, North Carolina, South Carolina, Tennessee, Virginia, and Wisconsin and Buffalo, N.Y., and the District of Columbia, (b) between points in West Virginia on and west of a line beginning at the West Virginia-Virginia State line on U.S. Highway 50, thence west over U.S. Highway 50 to the junction of West Virginia Highway 50 and the West Virginia-Maryland State line, thence south and north along the West Virginia-Maryland State line to the junction of the West Virginia-Maryland State line and U.S. Highway 50, thence west over U.S. Highway 50 to the junction of U.S. Highway 50 and West Virginia Highway 16, thence north over West Virginia Highway 16 to the intersection of West Virginia-Ohio State line; (3) points in that part of Ohio on and west of a line beginning at the Ohio-West Virginia State line and Ohio Highway 80 to Ohio Highway 78, thence west over Ohio Highway 78 to junction Ohio Highway 78 and Ohio Highway 146, thence west over Ohio Highway 146 to junction Ohio Highway 146 and Ohio Highway 285, thence north over Ohio Highway 285 to junction Ohio Highway 285 and Ohio Highway 265, thence west over Ohio Highway 265 to junction Ohio Highway 265 and U.S. Highway 49, thence west over U.S. Highway 49 to junction U.S. Highway 49 and Interstate Highway 77, thence north over Interstate Highway 77 to junction U.S. Highway 250 and Interstate Highway 71, thence north over Interstate Highway 71 to junction U.S. Highway 250, thence U.S. Highway 250 and Interstate Highway 50 to U.S. Highway 250, thence north over U.S. Highway 250 to junction Interstate Highway 270 and U.S. Highway 250, thence west over U.S. Highway 250 to junction Interstate Highway 270 and U.S. Highway 250, thence west over U.S. Highway 250 to junction Interstate Highway 270 and U.S. Highway 250, thence south over U.S. Highway 250 to junction Interstate Highway 270 and U.S. Highway 250, thence north over U.S. Highway 93 and unnumbered Ohio Highway 3 miles south of U.S. Highway 21, thence west over unnumbered Ohio Highway to junction unnumbered Ohio Highway and Ohio Highway 94, thence north over Ohio Highway 94 to Smithville and junction unnumbered Ohio Highway, thence west over unnumbered Ohio Highway to junction unnumbered Ohio Highway and Ohio Highway 585, thence south over Ohio Highway 585 to Smithville and junction Ohio Highway 585 and unnumbered Ohio Highway, thence west over unnumbered Ohio Highway to junction unnumbered Ohio Highway and Ohio Highway 3, thence over Ohio Highway 3 to Madisonburg...
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 339, thence north over Ohio Highway 10 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 44532-44600 to Elizabethtown, and Lititz, Pa., and Dover, Pa., and the purpose of this filing is to eliminate the way to Sandusky and Lake Erie. The Ohio Highway 4, thence over Ohio Highway and unnumbered Ohio Highway, thence 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 101, thence north over Ohio Highway 101 to Junction 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 filling 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.

Robert L. Oswald, Secretary.

[FR Doc.74-29999 Filed 12-23-74; 8:45 am]

[Notice 20]

MOTOR CARRIER BOARD TRANSFER PROCEEDINGS

December 24, 1974.

Synopses of orders entered by the Motor Carrier Board of the Commission pursuant to sections 212(b), 206(a), 211, 312(b), and 410(g) of the Interstate Commerce Act, and rules and regulations prescribed thereunder (49 CFR Part 1132), appear below:

Each application (except as otherwise specifically noted) filed after March 27, 1972, contains a statement by applicants that there will be no significant effect on the quality of the human environment resulting from approval of the application. As provided in the Commission's special rules of practice any interested person may file a petition seeking reconsideration of the following numbered proceedings on or before January 13, 1975. Pursuant to section 17(b) of the Interstate Commerce Act, the filing of such a petition will postpone the effective date of the order in that proceeding pending its disposition. The matters relied upon by petitioners must be specified in their petitions with particularity.

No. MC FC 75530. By order of December 17, 1974, the Motor Carrier Board approved the transfer to Cedar Rapids Transfer and Storage Company, a corporation, Cedar Rapids, Iowa, of the operating rights in Certificate No. MC 75530 issued October 31, 1970, to Cedar Rapids and Iowa City Railway Company, a corporation, Cedar Rapids, Iowa, authorizing the transfer of commodities, with exceptions, between Cedar Rapids and Iowa City, Iowa, over regular routes serving all intermediate points.

William O. Gray, 867 American Bldg., Cedar Rapids, Iowa, 52401, Attorney for transferee.

John F. Gaston, P.O. Box 351, Cedar Rapids, Iowa, 52406, Attorney for transferor.

Robert L. Oswald, Secretary.

[FR Doc.74-29996 Filed 12-23-74; 8:45 am]

[Notice 21]

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 the date indicated below:

<table>
<thead>
<tr>
<th>Temporary authority application</th>
<th>Final action or certificate or permit</th>
<th>Date of action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Carriers, Inc., MC-4328 Sub-1</td>
<td>MC-2385 Sub-415</td>
<td>Nov. 30, 1973</td>
</tr>
<tr>
<td>Schneider Transport, Inc., MC-31169 Sub-2</td>
<td>MC-31169 Sub-21</td>
<td>Feb. 23, 1974</td>
</tr>
<tr>
<td>Remington Truck Line, Inc., MC-5282 Sub-1</td>
<td>MC-5282 Sub-1</td>
<td>Feb. 23, 1974</td>
</tr>
<tr>
<td>Bay Bros., Inc., MC-12284 Sub-3</td>
<td>MC-12284 Sub-3</td>
<td>Feb. 23, 1974</td>
</tr>
<tr>
<td>Amoco Transport Co., MC-12972 Sub-3</td>
<td>MC-12972 Sub-3</td>
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<td>B &amp; B Trucking, Inc., MC-30534 Sub-4</td>
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<td>Federated of Savannah, Inc., MC-3365 Sub-1</td>
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Robert L. Oswald, Secretary.

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Title 21—Food and Drugs
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 of May 5, 1972 (37 FR 2155), on the disclosure of information to the public in conformity with Public Law 89-487, revised by Public Law 93-23, the Public Information section of the Administrative Procedure Act, known commonly as the “Freedom of Information Act.”

The Commissioner received a total of 687 letters, 65 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 consumer groups, expressed support for the release of more information 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 now 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,” 455 F.2d 1076 (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. When the final regulations were promulgated, roughly 90 percent of the records in its files were 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. One 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 that are already the subject of regulations in other parts of Title 21 of the Code of Federal Regulations were incorporated directly into these provisions, such as the provisions relating to section 305 hearing records, food additive petitions, and new drug applications.

Upon review of the comments submitted on the proposal, the Commissioner concludes that this basic structure should be retained. Whenever possible, provisions relating to disclosure or non-disclosure of records should be incorporated into the general regulations dealing specifically with those types of documents.

3. The Commissioner has also concluded that the more general provisions in Parts 4 and 5 should be re-grouped 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 records and documents for which requests are frequently made.

4. Comments indicated that many Food and Drug Administration records and documents should not be disclosed because they could be distorted, misused, and quoted out of context.

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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 publish them without the threat of a prior disclosure of such data by the Food and Drug Administration. The Commissioner concludes that, once disclosure 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 person submitting it will have an opportunity to obtain an opinion from the agency under the procedure established in 4.44 of the regulations as to whether it will be disclosed upon request, or whether it falls within 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 from public disclosure solely on the ground that it is not yet published. According to the Commissioner, all within one of the specific statutory exemptions from disclosure, the only positive means for a scientist to protect his first publication rights is to submit the information before submitting it to the Food and Drug Administration.

7. A comment contended that some data and information submitted to the Food and Drug Administration may not properly be copied for distribution to the public because of the copyright rights to it.

The Commissioner concludes that, to the extent that the Freedom of Information Act and the copyright laws conflict, the specific requirements for public disclosure under the Freedom of Information Act must be construed to prevail.

8. It was asserted in comments that there is no legal support for the provision contained in several places in the proposed regulations that records shall be disclosed unless “extraordinary circumstances” exist. It was suggested that guidelines be adopted to establish the meaning of “extraordinary circumstances.”

The Commissioner advises that this type of provision creates a strong presumption of disclosure and requires any person who believes that a record falling within the rule should not be disclosed bears the burden of overcoming that presumption by showing unusual circumstances that justify nondisclosure. Because it is impossible to predict what facts would be sufficient to satisfy this burden, the Commissioner concludes that general guidelines are not feasible and that this type of provision will be administered on the basis of the facts shown in each case.

9. Several provisions in the proposed regulations published in May 1972 would have been unlawful within 180 days from the final regulations, any person who had previously submitted data or information to the Food and Drug Administration must review that material and, if it was desired and justified, submit a request that it be retained in confidence. Numerous comments objected to this provision on the grounds that it imposed an impossible burden on industry in light of the voluminous information submitted and that much of this information would never be requested anyway. It was almost uniformly suggested that this provision be handled on an ad hoc basis when requests for disclosure are received.

The Commissioner agrees with these comments, and has deleted all requirements for justifying the confidentiality of previously submitted material. When a request for information is received, and it clearly falls within the disclosure rules 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 on both the agency and persons who submit information.

10. Comments were received that the decision of the Assistant General Counsel, Food and Drug Division, on disclosure should constitute final agency action since the Commissioner for Public Affairs did not appear to have the necessary legal expertise. A comment also suggested that the power to make final decisions on disclosure be placed in the office of the Associate Commissioner for Compliance who would then delegate this power to an Administrative Law Judge operating out of that office.

11. One comment stated that the proposed regulations of the Food and Drug Administration appear to go beyond the spirit of existing regulations and the Freedom of Information Act, which contemplate and expects the Department of Health, Education, and Welfare, and contended that the Food and Drug Administration has no authority to promulgate regulations different from the Department regulations.

The Department published its final regulations in the Federal Register of August 19, 1973 (38 FR 22231). Section 5.1 of this proposed regulation expressly recognizes that the Food and Drug Administration may issue its own supplementary regulations as long as they are consistent with the Department regulations. The Commissioner concludes that these final regulations are entirely consistent with the Department regulations.

12. Questions have arisen about the availability for public disclosure of the various types of petitions filed with the agency pursuant to the Administrative Procedure Act. Section 1.6(c) of the proposed regulations, (3 CFR 5.11) expressly recognizes that the Food and Drug Administration may issue its own supplementary regulations as long as they are consistent with the Department regulations. The Commissioner concludes that these final regulations are entirely consistent with the Department regulations.

13. Questions have been asked as to whether data and information contained in a request for hearing on such matters as a food standard regulation, a food additive regulation, or withdrawal of a new-drug application, are available for public disclosure.

The Commissioner advises that this matter will also be handled in the new procedural regulations that will be published in the Federal Register in the near future. As a general rule, such data and information have the same status as they would if they had been submitted in a particular proceeding as provided by the type of involved in the proceeding.

14. Requests have been made for all regulations and other documents supporting a particular final or preliminary rule or final regulation issued by the Food and Drug Administration.

The Commissioner advises that this matter will also be handled in the proposed new procedural regulations to be published shortly in the Federal Register. Accordingly, no provision with respect to this matter is included in these final regulations.

Section 305 Hearing Records

15. Section 305 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) provides for an informal hearing before the Food and Drug Administration reports any violation of the Federal Food, Drug, and Cosmetic Act by the manufacturer, packer, or distributor of a food, drug, or cosmetic to the United States attorney for prosecution. Section 1.6(c) of the proposed regulations makes available for public disclosure factual information contained in the file relating to the proceeding held without a hearing after the file is closed or the statute of limitations runs, whichever occurs first.

The basic objection to §1.6(c) voiced in several comments was fear of what was variously termed "trial by newspaper" or "trial by press." It was argued that the effect of making public a section 305 citation would be to stigmatize the company without providing the company an opportunity for a public defense. This would be particularly true, it was asserted, if the section 305 hearing resulted in a determination that there was no basis for criminal prosecution. It was felt that the need for the public to know was outweighed by the potential injury to the manufacturer generated by a possible public or press stigmatizing of the company without providing the company an opportunity for a public defense. This would be particularly true, it was asserted, if the section 305 hearing resulted in a determination that there was no basis for criminal prosecution. It was felt that the need for the public to know was outweighed by the potential injury to the manufacturer generated by a possible public or press stigmatizing of the company without providing the company an opportunity for a public defense.

The Commissioner concludes that the legislative history of the Freedom of Information Act and the recent amendments shows that Congress considered the potential for harm caused by release to the public of government information, and found it to be outweighed by the public's right to gain public information. Accordingly, no provision is included in these regulations relating to such matters.

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16. Concern was expressed that the utility of the section 305 hearing, described in current Food and Drug Administration regulations as “private and informal” (21 CFR 1.6(a)), would be seriously impaired if the matter were publicly disclosed. In a private and informal setting, a manufacturer might be willing to admit unintentional technical violations of the act in order to place the full facts on the record. If there were to be a free disclosure of such factual information, it was stated, it would close the mouths of the manufacturers and prevent the section 305 hearing from accomplishing its purpose.

The Commissioner has no reason to believe that disclosure of this information after the matter is closed would impair the utility of the section 305 hearing. The Commissioner concludes that each of the section 305 hearing records after the matter is closed is particularly important where prosecution is not recommended, or is recommended but not filed in order to protect the public in some way, or to avoid a disclosure of the matter. Any regulatory matter must at some point in time be open to public scrutiny and public accountability.

17. One comment argued that the Freedom of Information Act provides an exemption for “investigatory files” was dispositive and prevented the Food and Drug Administration from providing for even limited release of records. The “Frankel” record, 460 F. 2d 813 (2d Cir. 1972), was cited as a bar to the disclosure. In the “Frankel” case, a shareholder sought the SEC investigatory files on a corporation against which the SEC had brought suit. Prior to the request for disclosure the suit had been concluded by a consent decree. The Court noted that one of the purposes of the exemption for investigatory files, as expressed in the House and Senate reports, was “* * * to keep confidential the procedures by which the agency conducted its investigation and by which it has obtained information” (460 F. 2d at 317) and reversed the District Court decision which held that the file was not being actively used for law enforcement purposes and was not subject to the investigatory file exemption.

The Commissioner notes that the exemption from disclosure for which the Freedom of Information Act provides is discretionary, not mandatory. The Commissioner has concluded, as a matter of discretion, that these records should be available for public disclosure after the matter is closed or the statute of limitations runs, whichever occurs first. See “Rayner & Shinlington, Inc. v. FDA,” No. 63–1959 (D.D.C. Pa. 1969). The “Frankel” decision merely holds that, where an agency does assert the investigatory file exemption, it may properly do so even after the matter is closed. The Commissioner does agree that those portions of investigatory records that would reveal confidential investigative techniques would be subject to the investigatory file exemption, but that this is not to be an automatic bar. The Freedom of Information Act, and the regulations have been revised to state that with regard to the nondisclosure of the names of individuals is clearly in accord with the holding in “Wisconsin v. Constantineau.” “Wellford v. Hardin,” 444 F.2d 21 (4th Cir. 1971). It was contended that the 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 after the enforcement action is completed. See, e.g., “Frankel v. SEC,” 460 F.2d 813 (2d Cir. 1972); “Welsberg v. Department of Justice,” 469 F.2d 1195 (D.C. Cir. 1973); “Department of Defense,” 491 F.2d 24 (D.C. Cir. 1973).

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 may not be directly available for public disclosure when investigatory records are released.

The Commissioner is aware that in some circumstances it may be impossible to distinguish between fact and opinion. An effort will be made to separate the two and to release under § 1.6(c) those portions of the section 305 hearing records which do not contain any subjective opinions, except where the Commissioner concludes, in his discretion, that release of such additional material would be in the public interest.

The Commissioner notes that the investigatory records exemption is discretionary, not mandatory. Accordingly, the Commissioner may determine to release opinions and subjective information if he concludes that it is in the public interest to do so. A new § 4.83 has been added to the final regulations explicitly to provide for such discretionary release.

21. A question has 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 deleted, except in rare circumstances where it is concluded that disclosure of such names would be inconsistent with the provisions of these regulations, e.g., it would endanger confidential sources of information. 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 from section 305 hearing records if the matter results in criminal prosecution.

The Commissioner concludes that such names will not be deleted if these specific individuals were involved in any section 305 investigation which led to a 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.

23. Questions have arisen as to whether all or any portion of section 305 hearing records may be disclosed before the matter is closed or the statute of limitations has run.

Although the Commissioner retains discretion to release such information before the file is closed, he concludes that this will be done only in rare circumstances where consideration of criminal prosecution is involved. Because a section 305 hearing raises the possibility of criminal prosecution, the Food and Drug Administration must take precautions to avoid prejudicial pretrial publicity. Accordingly, the Commissioner will only very rarely exercise his discretion to release such material before the file is
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 courts at which section 305 hearing records become “closed.” The Commissioner advises that the Food and Drug Administration has adopted general guidelines to govern the time when section 305 hearing records are closed. These guidelines are set out in § 1.6(e) of the final regulations and discussed in paragraph 13 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) disclose the identity of a confidential source, (C) disclose investigative techniques and procedures, or (D) 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 prosecution. The Food and Drug Administration must be careful to avoid prejudicial pretrial publicity with respect to criminal matters. See “United States v. Abbott Laboratories,” 369 F. Supp. 1396 (E.D.N.C. 1973), rev’d, No. 74-1230 (4th Cir. 1976). Accordingly, the Commissioner concludes that, except in rare circumstances, information should not be released from a section 305 hearing record before the matter is closed, in order to avoid prejudice to enforcement proceedings or prejudicing a person’s right to a fair trial and an impartial adjudication.

The Conference Report No. 93-1350, dated September 25, 1974, on the Freedom of Information Act amendments indicates that the purpose of this revision is to narrow some of the court decisions that had tended to expand the investigatory file exemption. The Commissioner notes that § 1.6(c) is considerably narrower than a number of the court decisions would permit, and that the agency has already concluded to exercise its discretion to release investigatory records when a case is closed. The information excluded from such release under the final regulations fails squarely 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 pertaining to the agency’s jurisdiction. The agency has no congressional mandate to assist private litigants. Accordingly, the Food and Drug Administration will ordinarily decline to authorize any employee to testify or otherwise participate in their official capacity in private litigation.

The Commissioner recognizes, however, that exceptions could 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 is thus concluded by the Food and Drug Administration to be in the public interest, or where the private litigation may have a significant impact on Food and Drug Administration policy or action, or where Food and Drug Administration action resulted in the lawsuit and the agency has revised its policies 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 the proposed regulations and incorporated 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 previously 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 these 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 shall be available to any member of the public, with only very limited exceptions. This approach guarantees equal access to all information available from the Food and Drug Administration.

The Commissioner concludes that this general policy should be explicitly stated in the final regulations. 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 information that is “leaked” from agency files or otherwise disclosed in an unauthorized manner. The internal memorandum given to a member of the press without authorization, and part of it reproduced in the public media, the entire memorandum or even the portion that has been reproduced, need not be made available for public disclosure. Any different policy would encourage unauthorized disclosures of agency material.

The Commissioner concludes that release by Congress of material that would not be disclosed by the Food and Drug Administration is nevertheless an 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 so authorized.

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 reasonably segregable portion 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. Minn.,” 410 U.S. 72, 1973.
RULES AND REGULATIONS

(1972). 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 § 4.42 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 and similar work routinely prepared for distribution are distributed free of cost to the public upon request and thus do not fall under the Freedom of Information Act, whether or not the Freedom of Information Act is mentioned in the request, and thus subject to the requirements of these new regulations. New § 4.23 clearly states this policy.

PREPARATION OF NEW RECORDS

34. Questions have been raised as to whether the Freedom of Information Act requires the creation of new records or documents that do not presently exist, in order to provide an adequate response to a request. The Commissioner concludes that the Freedom of Information Act pertains only to existing records. It does not create an obligation to prepare new compilations of information or otherwise to create new documents in order to respond to an inquiry.

On occasion, a request for documents that presently do not exist may raise questions of sufficient public interest to justify the diversion of agency time and effort necessary to prepare new documents that will provide an adequate response. The Commissioner may exercise his discretion in this regard whenever he concludes that it is in the public interest to do so. 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 ordinarily 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 solely 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 the Freedom of Information Act was in effect when the information was compiled.

INDEXES OF CERTAIN AGENCY RECORDS

37. The Freedom of Information Act amendments provide for the maintenance and distribution of current indices of documents identified as containing information with respect to final opinions by an agency made in the adjudication of cases, statements of policy and interpretations not published in the Federal Register, administrative manuals and instructions to staff that affect members of the public.

The Commissioner has ordered preparation of appropriate indices 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 (HPC-18), Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20852.

Since all final 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 in contested cases, new animal drug applications, and new drug applications, and not decisions in rule making proceedings such as food standards and antibiotic drugs. An index will also 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 contain only internal personnel rules and practices of the agency, which are specifically exempt from public disclosure under the Freedom of Information Act.

SUBMISSION OF RECORDS MARKED AS CONFIDENTIAL

38. Several comments contended that merely stamping documents submitted to the Food and Drug Administration as "confidential" or "privileged" or "trade secret material" would create a presumption of confidentiality or, at the very least, an obligation on the part of the Food and Drug Administration to review the material and to return it if the Food and Drug Administration disagreed with the requested status of the documents. In effect, the comments suggested that any such designation would trigger a request for a presubmission review, and that the failure of the agency to respond to any such designation would automatically require the Food and Drug Administration to retain those documents in confidence.

The Commissioner disagrees with these comments. New § 4.27 explicitly provides that any such designation is inadequate to trigger a presubmission review for confidentiality, and that the acceptance by the Food and Drug Administration of documents so designated creates no obligation whatever on the part of the Food and Drug Administration with respect to their subsequent handling under the Freedom of Information Act. A presubmission review of records submitted voluntarily to the Food and Drug Administration, to determine whether they may be disclosed to the public on request, may be obtained under the provisions of new § 4.44.

FOOD AND DRUG ADMINISTRATION DETERMINATIONS OF CONFIDENTIALITY

39. A number of comments objected to requirements contained in several provisions of the proposed regulations that confidential information be specifically marked "confidential" upon submission, and that such claims of confidentiality be justified in advance of any request for the information. It was contended that this would be a massive amount of paperwork, much of which may be needless.

The Commissioner agrees with this comment. Most determinations for confidentiality are already spelled out in the form of specific provisions in the final regulations and in this preamble, and many of the remainder will be settled by the new procedure for presubmission review specified in § 4.44 of the final regulations. Where close questions arise, moreover, § 4.45 will be utilized to permit consultation with the affected person. Accordingly, the final regulations do not require that data or information be stamped as confidential or that justification for confidentiality be submitted. Indeed, under § 4.27 of the final regulations, stamping material as confidential will have no effect whatever. New § 4.28 provides that the status of all records will be determined solely by the regulations and any presubmission review that is requested.

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.
The Commissioner notes that new § 4.44 makes it clear that any information which is confidential must be disclosed in the records of the Food and Drug Administration return any document submitted to it. The only circumstances under which any document will not be accepted confidential is that the information will not be disclosed, under no circumstances will the Food and Drug Administration return any document submitted to it. The only circumstances under which any request will be coordinated to this Center, and all responses will be promptly made available in accordance with published rules, the records shall be made promptly available.

The Commissioner concludes that this policy should be clearly stated in a new § 4.29, along with directions on where to file a request for any Food and Drug Administration record.

**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 Freedom of Information Act. All requests for records will be submitted to the Center, and all responses will be coordinated by it. Section 4.30 of the final regulations so provides.

**DISCLOSURE OF FOOD AND DRUG ADMINISTRATION EMPLOYEE NAMES**

43. Questions frequently arise as to whether the names of Food and Drug Administration employees are deleted from the agency's records. The Commissioner concludes that, except in extraordinary circumstances, the names of all government officials involved in any regulatory matter are properly deleted 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.

**PROCEEDURES AND FEES**

44. The Freedom of Information Act amendments contain a number of provisions pertaining to records 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 such records and which is made in accordance with published rules, the records shall be made promptly available.

The Commissioner concludes that this policy should be clearly stated in a new § 4.20, along with directions on where to file a request for any Food and Drug Administration record.

**TIME LIMITS**

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 important 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 (RFC-18), Room 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 diverted to the Public Records and Documents Center and are logged in there. 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 to what extent the information will be released, except in unusual circumstances. As soon as possible after that determination is made and the information is furnished, the record will be forwarded or made available to the person requesting it.

The Commissioner anticipates that in no instances will the specific record of the 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 procedure 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 case will be referred 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 payment, 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, only to be informed that the expense involved was too high.

49. The proposed regulations published in May 1972 contained uniform standard charges at or slightly 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 $5.00 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.
Upon reconsideration, the Commissioner has modified the fee schedule in some respects. The fees charged by the Department of Justice (16 C.F.R. 16.9) and the Department of Health, Education, and Welfare (45 C.F.R. 5.61) have been used as a model. The fees charged by the Department of Health, Education, and Welfare 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, fees must be based solely on 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 cost 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 questions have been raised with respect to the fee required for a computer printout of information that is available in this form.

The Commissioner advises that fees for computer printouts will 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) (2) states this policy.

52. Comments also urged that the hourly fee for search not be charged for administrative time spent in deciding whether to grant access to information and suggested 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 what records are requested, locating those records, and copying them. It will be the policy of the Food and Drug Administration not to charge for time spent by legal counsel or others in determining which information must be disclosed pursuant to the Freedom of Information Act. This policy is reflected in Section 4.42(b) of the final regulations.

53. Questions have been raised as to how a check or money order for documents should be made payable to the "Food and Drug Administration." The term "United States" or the initials "U.S." should not be included. Checks or money orders are to be mailed to the Accounting Operations Branch (HFA-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852. Section 4.42(c) of the final regulations states these requirements.

WAIVER OF FEES

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 former employee, will ordinarily be furnished without charge or at 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 provision (g) has been added to Section 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 information from individuals and organizations purporting to represent the consumer and general public interest. For example, requests have been made for all data and information in Food and Drug Administration files relating to the safety of cosmetics, and for all "Dear Doctor" letters required by the Food and Drug Administration to be sent to physicians to correct misleading advertising and labeling. It is apparent that, if all such requests were honored without the requirement of fees, they could be engulfsed by similar requests for information from large numbers of individuals and organizations, and that a major portion of its time would be spent answering such inquiries.

Thus, in applying this new provision, the Commissioner will require a demonstration of a broad public interest before fees will be waived or reduced. As part of this demonstration, the Commissioner will request a statement of the intended purpose to which the information will be put, in order to determine whether it is likely to be used in a manner that will benefit the public generally. Narrow and specific requests for documents will be far more likely to satisfy this standard than will be 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.

The Commissioner wishes to assist any inquiry that will genuinely advance the public interest. If this is to be done, however, the very limited resources 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 unless these documents. This policy is stated in Section 4.43(d).

PREAPPLICATION REVIEW OF REQUEST FOR CONFIDENTIALITY OF VOLUNTARILY SUBMITTED DATA OR INFORMATION

58. Section 4.28 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 as to whether it will be held in confidence or will be disclosed upon request to the public. The comments submitted on the proposal, and the decisions made thereon, have been published in the Federal Register. In the intervening 2 years, have made it clear that this provision has not been well understood by those who reviewed the proposal. Accordingly, the Commissioner concludes that this provision should be the subject of a separate procedural regulation and expanded to clarify its intended application. Section 4.44 has been added to the final regulations to accomplish this purpose.

The Commissioner concludes that any person who wishes to submit information on a voluntary basis to the Food and Drug Administration is entitled to a pre-submission determination of the status of the documents involved if that status is not available by other provisions in the regulations. Merely labeling a submission as “confidential” is insufficient to trigger this provision and raise the status of the documents to that of “confidential” within the agency. The provision is designed to clarify the intended purpose. This procedure should be spelled out to prevent unnecessary communications.

The Commissioner emphasizes that this procedure is not available where the status of the documents at that time or to return the information or otherwise to communicate with the person submitting it. Similarly, oral assurances of confidentiality by Food and Drug Administration employees will not be honored. If this procedure is to be invoked, it must be done in strict accordance with the requirements of new § 4.44. The Commissioner realizes that this is a stringent procedure but concludes that this is the only way that these matters can be handled in a manner both to persons submitting information and to the members of the public who subsequently request the information involved.

The Commissioner emphasizes that this procedure is not available where the status of a record is already determined by other provisions in the final regulations, and especially § 4.44 and § 4.111 Data and information voluntarily submitted to the Food and Drug Administration. For example, section 4.111(d)(2) states that no information on manufacturing processes is available for public disclosure, and thus precludes the use of this procedure. Any such information would be unnecessary and inappropriate.

Comments expressed concern that, although there is a policy in the event of permits to the Food and Drug Administration to accept information in confidence that it would not otherwise obtain, procedures should be spelled out to preclude abuses of this privilege.

The Commissioner agrees with this comment. Accordingly, the final regulations provide that such information may be accepted in confidence only if relevant to and important for agency activity, and only if the Assistant Commissioner for Public Affairs signs a letter pledging confidentiality. A determination of confidentiality will not be made orally or by any other agency official.

Comments pointed out that, if information submitted voluntarily on a pledge of confidentiality is already contained in other Food and Drug Administration records, the record will not be exempt from disclosure, those other records should be disclosed to the public.

The Commissioner advises that, under these circumstances, a determination of confidentiality is required only if the determination is made in writing. If a determination of confidentiality is mistakenly made, the information already available in the Food and Drug Administration will be released if it is not otherwise exempt from disclosure, promptly disclosed upon request.

61. Many comments indicated the need for a “meaningful” appeal procedure that would go to the highest level within the agency and to the courts, with provision 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 is reasonable, 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**

62. Proposed § 4.33 stated that, where disclosure is uncertain, the Food and Drug Administration will consult with the person who submitted the information in making a determination as to 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 created only 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 instances in which the material is clearly disclosed 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 referred to in the company record.

The Commissioner rejects this suggestion. Any such procedure would severely hinder implementation of the Freedom of Information Act. Section 4.45 is an appeal or declaratory judgment action contesting the validity of the regulations. Unless these regulations are challenged in court, the Food and Drug Administration is entitled to a pre-submission determination. If such an appeal or declaratory judgment action is made, the Commissioner concludes that the final regulations adequately state the basis on which disclosure will be made to the public in the future. The proper remedy for any person to pursue in the event that he has submitted data or information in the past which he believes to be confidential but which, under the final regulations, is included within a category for which public disclosure is permitted, is to bring a declaratory judgment action contesting the validity of the regulations. Unless these regulations are challenged in court, the Food and Drug Administration is entitled to implement them. Thus, all persons who have previously submitted records to the Food and Drug Administration may pursue the remedy of having such information will be handled in the future as set out in these final regulations and this preamble. For this reason, specific notice to a person that a particular record will be disclosed pursuant to these regulations is unnecessary as well as impracticable.

64. Comments contended that this provision shows the high value that the Food and Drug Administration puts on industry interests in information as opposed to the public welfare. Some interpreted this provision as the Food and Drug Administration asking to be persuaded that the information is confidential. It was suggested that, in situations where it has not been conclusively established that the information falls squarely within an exemption to the Freedom of Information Act, the information should be disclosed.

The Commissioner regards these comments as reflecting a lack of understanding of the law. The exemptions under the Freedom of Information Act relate to such important issues as personal privacy and other trade secrets. Congress has directed Federal agencies to consider these matters and the Commissioner regards this responsibility as important. In utilizing this provision the Food and Drug Administration will seek clarification in uncertain situations, not permission. If information does not fit within any exemption to the Freedom of Information Act, it will be disclosed.

**Judicial Review of Proposed Disclosure**

65. A number of questions have been raised with respect to the right of a person to obtain a court determination before the Food and Drug Administration discloses data or information submitted by that person which he believes should be protected by the Freedom of Information Act.

During the past 2 years the Commissioner has adopted a procedure of permitting any person who believes he would...
be adversely affected by disclosure of information to Institute suit in a United States District Court to enjoin such disclosure. The Commissioner has stated that, if any such suit is instituted, no disclosure will be undertaken until all court appeals are exhausted. The Commissioner believes that this procedure adequately balances the right of the public to obtain information against the right of a person to protect the confidentiality of material that he believes should not be publicly disclosed. Accordingly, 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. At the same time, it 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 may give rise to this procedure. The Commissioner notes that there are situations in which the administration may believe that experience with similar requests is sufficiently common that its refusal to act on them may be the proper course. The Commissioner believes that these circumstances would be recognized when they arise.

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 immediate interests of the person making the request, and to point out that respondents may request specific categories of documents that may require a substantial period of time. The Commissioner notes that the Freedom of Information Act provides for no such protection of public interests against an administrative efficiency, and contended that there is no justification for any provision dealing with "overly burdensome" requests, citing "Wellford v. Hardin," 444 F. 2d 21 (4th Cir. 1971).

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 immediate interests of the person making the request, and to point out that respondents may request specific categories of documents that may require a substantial period of time. The Commissioner notes that the Freedom of Information Act provides for no such protection of public interests against an administrative efficiency, and contended that there is no justification for any provision dealing with "overly burdensome" requests, citing "Wellford v. Hardin," 444 F. 2d 21 (4th Cir. 1971).

The Commissioner concludes that, government employees cannot be expected to locate and 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 intend that requests under the Freedom of Information Act receive a low priority or simply be ignored. They will be handled as expeditiously as is feasible. Sections 4.41 and 4.46 of the final regulations so provide.

REFERRAL TO PRIMARY SOURCE OF RECORDS

69. Comments on the proposed regulations asked what documents will be distributed 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 (USP), and National Formulary (NF).

The Commissioner notes that there are a wide variety of materials, including produce of the Freedom of Information Act, which are prepared by the Food and Drug Administration for distribution to the public. These will continue to be released and distributed without charge.

It should be noted that the Food and Drug Administration that if 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 the comments, i.e., the Federal Register, are available from the Government Printing Office. The two, U.S. P. and N.F., are available from the organizations that publish them. Since none of these are Food and Drug Administration materials and all are readily available 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 requests them to those places where they are available, pursuant to § 4.09 of the final regulations.

AVAILABILITY OF RECORDS AT NATIONAL TECHNICAL INFORMATION SERVICE

70. In a number of instances, the Food and Drug Administration has recognized that reports or information generated or received by the agency will receive widespread interest. The Department of Commerce has established the National Technical Information Service (NTIS), 5328 Port Royal Road, Springfield, VA 22152, to serve as a clearinghouse for such information. The Food and Drug Administration is, for example, collecting all scientific literature reviews and reports of the Select Committee on GRAS Substances of the Federation of American Societies for Experimental Biology to NTIS for reproduction and distribution to the public, as announced in the Federal Register of July 26, 1973 (38 FR 20054), April 17, 1974 (39 FR 13789), and September 23, 1974 (39 FR 34218).

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 answered 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 4.50 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 information 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 case of the Hearing Clerk. The Food and Drug Administration would have no way to determine whether materials loaned to individuals would be returned intact. Only where materials requested are contained 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.

72. Numerous requests have been received by the Food and Drug Administration during the past 2 years for an opportunity to review documents without the necessity of copying them. Such requests have pointed out that copying is expensive and that on occasion or any of the requested documents might be relevant to 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 to the Food and Drug Administration except where a record involved contains both disclosable and nondisclosable material. Under these circumstances, the only feasible way to make the record available for inspection is to copy it with the nondisclosable material blocked out. Accordingly, a new §4.52 is added to the final regulations to state this policy.

INDEXING TRADE SECRET AND CONFIDENTIAL COMMERCIAL OR FINANCIAL DATA AND INFORMATION

73. In recent court decisions, it has been suggested that, under the review of an agency decision to deny documents or portions thereof, the agency may be required to itemize and index the disputed material in order to permit adequate judicial consideration of the issues.

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, i.e., the person who submitted the documents. The Food and Drug Administration will require 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 4.53 states this policy.

The Commissioner concludes that the burden of defending the trade secret status of disputed documents is properly placed upon the person who submitted the documents. Trade secret status inures only to the benefit of that person. The Commissioner concludes that it should not be incumbent upon the government to defend the property right of a person in such a matter, 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 so designated (§4.60).
2. Related solely to the internal personnel rules and practices of an agency.
3. Specifically exempted from disclosure by statute.
4. Trade secrets and commercial or financial information from a person and privileged or confidential.
5. Interagency or intra-agency memoranda or letters which would not be available by law to a party other than 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) deprive a person of a right to a fair trial or an impartial adjudication, or (C) constitute an unwarranted invasion of personal privacy.
8. Disclose the identity of a confidential source, and in the case of a record compiled by a criminal law enforcement agency, (A) is contains evidence of a criminal law enforcement act, (B) is related to the course of a criminal investigation, or, by an agency conducting a lawful national security intelligence investigation, confidential information supplied or produced only by the confidential source, (C) disclose investigative techniques or procedures, or (D) endanger the life or physical safety of law enforcement personnel.
9. Contained in or related to examination, operating, or condition reports prepared by, or on behalf of, or for the use of an agency responsible for the regulation or supervision of commercial or financial institutions.

Geological and geophysical information and data, including maps, concerning wells, pipelines, seismic, magnetometric, and related data and material which are created and maintained by a person and that is privileged or confidential.

Of these nine exemptions, the four relating to trade secrets, internal memos, personal privacy, and investigatory files are of particular importance to the Food and Drug Administration.

In the proposed regulations published in May 1972, the provisions relating to trade secrets and confidential commercial or financial information referred to all three statutes: The general Federal confidentiality statute, 18 U.S.C. 552(b); the confidentiality provision 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 obtained from a person and 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.

RULES AND REGULATIONS

75. 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 who have submitted information to 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. 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 information are to be made, only the company is capable of making deletions. Frequently, it was stated, just the association of a trade name of a product with a certain composition may be a breach of confidentiality. In many records a complete rewriting would have to be done rather than a simple deletion because confidential material 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 who submitted it will, 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 final 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 "confidential data or information" in proposed §4.26, and the specific application of these definitions with respect to particular information received in petitions and applications as reflected in the proposed amendments to Parts 5, 7, and 8.

Numerous comments pointed out that the regulations must reflect the interaction of three statutes: The general Federal confidentiality statute, 18 U.S.C. 552(b); the confidentiality provision 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 obtained from a person and privileged or confidential." (5 U.S.C. 552(b)(4)).
The Commissioner concludes that this case does not present an instance where the confidentiality provisions in 21 U.S.C. 331(j) are applicable. The Commissioner agrees that there is no reason why it should be utilized for determining commercial damages but not for purposes of the Freedom of Information Act. He concludes that new § 4.61 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, which is the Freedom of Information Act. The Freedom of Information Act establishes specific exemptions, which are to be applied by objective criteria. The subjective standard proposed in the comments treated the Information as trade secrets, not as a matter of discretion to release such material.

The Commissioner concludes that the intent of the person who submits documents to the Food and Drug Administration does not control whether those documents may be released to the public upon request.
The Commissioner agrees that the official Comment on the Restatement definition is helpful in understanding the intended meaning of the definition. This Commissioner finds it important not to lose the broad view of the definition itself, but simply elucidates the various factors encompassed within that definition. The Commissioner concludes it is necessary to interpret the comments in 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.

82. 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 commentators.

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 such information by observation, experiment, or inference offers an opportunity to obtain an advantage over others who do not know or use it. Matter which otherwise constitutes a trade secret will not be so treated if it is disclosed by the trade secret owner to and accepted by an outsider in confidence.

The Commissioner concludes that there is no significant difference between this definition and the Restatement definition. Both place primary emphasis upon competitive advantage.

83. A number of comments cited case law dealing with trade secrets for the proposition that any technical or scientific information developed by a company may be considered a trade secret where it is not generally known or readily ascertained and when it is protected and maintained as confidential by the developer and is of value to him.

The Commissioner agrees with this general statement of the case law, and concludes that the definition set out in §4.61 of the proposed regulations adequately reflects it. In the Commissioner's opinion, the concept of commercial and competitive value is fully recognized by the courts.

84. Other comments contended that the Restatement definition of a trade secret is far too broad. One suggested that the definition of trade secret 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 1363 (2d Cir. 1971): 

* * * an unpatented, secret, commercially valuable plan, appliance, formula, or process, or the making, preparing, compounding, treating, or packaging 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 that arose under the predecessor Act.

There is no reason to consider that definition controlling for purposes of the Freedom of Information Act. Moreover, even this definition does not exclude clinical data which is commonly considered as part of a "plan" or a "process".

85. Comments stated that the Restatement definition of a 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 be obtained in a lawful manner. Accordingly, no modification in the definition in the final regulations is warranted.

86. Several comments took the position that, while the Restatement definition indicates that the information must give the opportunity to obtain an advantage over others, who do not know or use it, it does not mean that the information must give the 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 provides 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 by the definition set forth in the final regulations and does not fall within the trade secrets exemption. If the information is not currently providing a competitive advantage to the Food and Drug Administration, it will not be considered exempt. However, it should be noted that the matter of competitive advantage is often significant in determining whether commercial information is confidential within the meaning of §4.61(b) since confidential information per se is not exempt, but only confidential information that is commercial or financial in nature.

87. Several comments pointed out that the statutory exemption for trade secrets actually extends to two separate types of information, trade secrets and confidential commercial or financial information. They concluded that the definition in the final regulations reflected in the separate definitions for each given in §4.61(a) and (b) of the final regulations. If information falls within paragraph (a), 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 confidential within the meaning of §4.61(b) since confidential information per se is not exempt, but only confidential information that is commercial or financial in nature.

88. Numerous comments discussed an appropriate definition for "commercial or financial information" that is "privileged or confidential." Some argued that the definition should include any information received from a client or employee that is not generally known or readily ascertainable and when it is protected and maintained as confidential by the developer and is of value to him and that the information must give the opportunity to obtain an advantage over others, who do not know or use it. Matter which otherwise constitutes a trade secret will not be so treated if it is disclosed by the trade secret owner to and accepted by an outsider in confidence.

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 are different standards for determining whether the information is confidential. The Commissioner concludes that the definition set forth in the final regulations is adequately reflected in the separate definitions for each given in §4.61(a) and (b) of the final regulations. If information falls within paragraph (a), 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 confidential within the meaning of §4.61(b) since confidential information per se is not exempt, but only confidential information that is commercial or financial in nature.

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 technical or 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. 1955 and 21 U.S.C. 331(d) are properly interpreted in the same way. Accordingly, the Commissioner has revised the final regulations to reflect this approach to the matter.
RULES AND REGULATIONS

89. There was objection to the dependence of a confidential status upon whether or not any particular manufacturer handles information of that 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 actual handling of such information by each individual manufacturer, it 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 of the kind involved would be handled according to the customary and usual practice in the industry rather than according to the way that any particular firm regards it. Thus, it is 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 public release of the information automatically removes that information from the confidential status of the information.

90. Comments asserted that the need for the public disclosure of safety and effectiveness data is so great that no justification of trade secret or confidential commercial information 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 provide 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 serve as a general definition, and not an absolute test of 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 noted 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 control the ingredient as opposed to all other manufacturers in the industry. The comment also argued that it is frequently impossible for a company 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 evidenced by the trade or the injury to the company's competitive position. A representation by a company that it has no confidential information will be sufficient to create a prima facie case of confidentiality, which may be rebutted 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. 339 (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 exempt, and no contract is involved, no claims may properly be made against the government under the "Padbloc" or "Bofors" cases.

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 asserted that a final determination be subject to judicial review on the weight 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 scrutiny of such a 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, but that the trade secret exemption will under no circumstances be applicable to any such information.

96. A comment contended that information which may fall within the trade secret protection concern might be disclosed without notice, hearing, and judicial review, citing "American Sumatra Tobacco Corp. v. SEC," 93 F.2d 236 (D.C. Cir. 1937).

The Commissioner concurs with the substance of this comment. Notice and an opportunity to present comments on the rules to be utilized in determining whether any such information is protected are furnished by the proposed regulations published in May 1972. The possibility of judicial review has been extended, with rare exception, to affected persons when disclosure is mandated by the Food and Drug Administration in situations where the facts present a close question. Upon the receipt of any further material relevant to these regulations as provided in this final order, judicial review will be available through a declaratory judgment action challenging the final regulations or a declaratory judgment action in accordance with § 4.63 challenging the proposed release of specific records. Accordingly, the Commissioner concludes that the general principles laid down in the "Sumatra" case are fully satisfied.

INTER- AND INTRA-AGENCY MEMORANDUMS OR LETTERS

97. Section 4.27 of the proposed regulations, which dealt with the internal memorandum exemption from the Freedom of Information Act, is redesignated as § 4.63 in the final regulations. Comments stated that the term "memoranda" is unclear. Questions were asked whether it refers to all written communications, including an investigator's report, or only to a document entitled "memorandum." It was suggested that the preamble 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 4.63 has been revised accordingly.

98. One comment contended that if the explanatory portions of an internal agency memorandum are deleted and the remainder is disclosed, the "includable" information may be reported out of context. It was suggested that because of this consideration, all portions of agency memoranda should be exempt. 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 stated that “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. Courts have held that an entire agency memorandum that includes both factual and opinion information is not exempt from disclosure unless fact and opinion cannot be separated. The Commissioner intends to make liberal use of his discretion to disclose internal memoranda analyzing data or statements that would represent an unwarranted invasion of privacy, but will disclose only the deliberative and policy discussion, or will, at the very least, make available the document with the factual information intact and all of the deliberative and policy information deleted.

Thus, as discussed elsewhere in this preamble, the Commissioner has concluded to make available for public disclosure internal memoranda summarizing the safety and effectiveness data contained in previously approved new drug applications, with deletions only of the limited type mentioned above, since the underlying data and information are not available for public disclosure. 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 and summarize 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 contain 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 copies of 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 internal memoranda summarizing the safety and effectiveness data contained in previously approved new drug applications, with deletions only of the limited type mentioned above, since the underlying data and information are not 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).

103. A comment wanted to know the exemptions to the Freedom of Information Act upon which the deletion of names from records is based. The comment stated that names or identifying characteristics such as "personnel and medical files" only if disclosure would produce 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. "Getman v. NLRA," 450 F.2d 670 (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 bases the deletion of names upon both the privacy exemption under the Freedom of Information Act, and the intra-agency memorandum exemption to the Freedom of Information Act. The Commissioner concludes that names of individuals involved in criminal investigations will be deleted if no criminal charges are brought, in order to prevent unfair accusations.

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 they are to some extent inconsistent or, in any event, require clarification. Proposed § 4.26(f) provided for public disclosure of the identity of any person who writes to the Food and Drug Administration and proposed § 4.31 provided for deletion of the name of the person reporting adverse reaction and complaint information.

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 § 4.111(a) (3) (f) of the final regulations, all consumer letters received by the Food and Drug Administration and complaints received from lay persons, which relate to their own personal complaints, will be made public after deletion of names and other personal information, in order to protect their privacy.

With respect to complaints received voluntarily from third parties, usually health professionals, i.e., doctors, nurses, pharmacists, names may be deleted from such matters as adverse reactions they have observed, and which thus relate to complaints made on behalf of other persons, the Commissioner concludes on the
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(c) (3) (III) to provide. If such a pledge is not made, the possibility that health professionals voluntarily to submit important adverse reaction information on marketed products to the Food and Drug Administration is substantially diminished, and in some instances 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.

105. Comments stated that, even though a specific request for confidentiality may not be made, consumer complaint letters contain documents which are per se confidential. Some complaints contain medical records which were obtained by a patient's written release to doctors or hospitals. Such medical records may be confidential or such medical records may imply the confidentiality of the entire complaint. Release of medical records of complainants may violate the doctor-patient relationship of confidentiality. The comments pointed out that the Freedom of Information Act exempts 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 receives medical records of a complainant, they will be held as confidential even if the complainant fails to specifically request confidentiality, except that they may be disclosed to the complainant.

106. Comments on various provisions in the proposed regulations contended that manufacturer's 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 corporate identity confidential if they submitted a particular piece of information voluntarily. Comments requested that the requirement of a showing of "extraordinary circumstances" for disclosure of corporate names be deleted. Other comments urged, however, that a manufacturer should never be permitted to make a showing of "extraordinary circumstances" to justify nondisclosure of his identity.

The Commissioner concludes that the same treatment should not be given to corporate and product names as to individual names. The right to privacy applies only to individuals. If a corporation requests presubmission review of information it wishes to submit voluntarily pursuant to § 4.44, and makes a claim of confidentiality for the manufacturer or brand name which is rejected by the Food and Drug Administration, the corporation has the option of withdrawing that information.

The Commissioner concludes that the final regulations properly provide for a showing in a particular instance that a manufacturer's name constitutes confidential commercial information and thus, under § 4.61, is properly deleted from a record before it is made available for public disclosure.

107. Comments contended that the name of the investigator in 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 does not agree with this comment. The investigator is the person who is responsible for conducting the test or study. Names of investigators are customarily published in the scientific literature with regard to their work, and an investigator's curriculum vitae customarily refers to the research projects in which he has participated. Accordingly, the Commissioner concludes that disclosure of the identity of the investigator on a particular project is neither a clearly unwarranted invasion of personal privacy nor confidential commercial information.

108. 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 making a request.

The Commissioner advises that any such request is regarded as a clearly unwarranted invasion of personal privacy. A "fishing expedition" of this type will therefore not be permitted. In the event that a specific record relating to a specific individual is requested, it will be released in accordance with the various provisions established in the final regulations.

109. Comments suggested that § 4.31 (b) of the proposed regulations, which limits to a patient, that patients should not be disclosed in IND and NDA submissions, more properly belongs in other portions of Food and Drug Administration 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 § 4.04 (c). Accordingly, § 4.04 (c) of the final regulations states this policy in general terms.

INVESTIGATORY RECORDS COMPILED FOR LAW ENFORCEMENT PURPOSES

110. The proposed § 4.32, dealing with investigatory records, has been redesignated as § 4.64 in the final regulations.

The Commissioner will consider a number of comments and questions specifically directed to § 1.6(c) of the regulations, dealing with section 305 hearing records, are also generally applicable to other investigatory records compiled by the Food and Drug Administration for law enforcement purposes. Accordingly, the conclusions of the Commissioner stated in this preamble are equally applicable to § 4.64 of the final regulations, and appropriate conforming modifications have been made in § 4.64.

111. Numerous questions have been raised with respect to specific documents that will not be made available pursuant to the investigatory records exemption.

Each of the specific types of letters, reports, forms, worksheets, and other documents prepared or used by the Food and Drug Administration in the course of its regulatory activities has been reviewed in detail by the Commissioner, in light of the exemption for investigatory records. The proposed regulations published in May 1972 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 past 2 years has demonstrated that even greater disclosure would not harm the regulatory activities of the agency. Accordingly, the Commissioner has concluded that the final regulations should continue the broad disclosure policy reflected in the proposal, and indeed should provide greater release of confidential information. Thus, as discussed in relation to § 4.101, all records relating to administrative enforcement action will be released even though they may also be part of an investigatory file.

The sole exception to this rule applies where the possibility of criminal prosecution is under active consideration. As discussed above in this preamble, considerations of interference with enforcement proceedings and the right of an individual to a fair trial and an impartial adjudication lead the Commissioner to conclude that section 305 hearing records should not be released until the matter is closed. These same considerations apply to all investigatory records pertaining to an individual criminal prosecution.

This exception only applies, however, with respect to an individual criminal prosecution is under active and current consideration. The Commissioner recognizes that any records in any file within the Food and Drug Administration may at some point lead to, or become part of, a criminal prosecution. This is plainly an insufficient justification for retaining all such material as confidential. Thus, it is fully anticipated that in some instances investigatory records will be released before investigation of criminal prosecution is later considered and in fact instituted. The Commissioner concludes that this anomaly cannot be avoided if there is to be a policy in favor of the greatest possible disclosure of information to the public. The Commissioner believes that any disruption of enforcement proceedings by adherence to this policy will be insubstantial, and that
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 Mannan, "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 public article, there has been a reevaluation of the release of such information to the public. Whether or not to claim a particular exemption is information to the public. 'Whether or not the investigative records exemption has been a reevaluation of the release of such information 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, 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 (NA).
   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 (NA).

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 (NA), whether or not the sample was analyzed.
   b. A decision is made by higher review authority that the sample is not actionable (NA), 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 regulatory letter or an order 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 an administrative action are available to the public when filed, unless directed otherwise by the court.

5. Section 305 citation, when:
   A final agency decision has been made to seek no further action on the matter (PA). If further review of the matter is requested, the matter remains open until a decision is made by the reviewing office to close the case with no further action. If prosecution is sought, the matter remains open until that action is concluded.

Note: Providing a copy of the memorandum prepared by the Food and Drug Administration summarizing the hearing to the officer or his attorney, to assure the accuracy of the record, does not require release of that memorandum to the public.

6. Prosecution, 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 a prosecution are available to the public when filed, unless directed otherwise by the court.

7. 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.

8. Recall, when:
   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 to the press, specific press releases may be issued on certain recalls, and correspondence with the firm is available to the public upon request.

9. Imports, when:
   a. A refusal of entry has been issued.
   b. A final decision is made by the Department of Justice not to file the case.
   c. The case is adjudicated and all litigation is concluded.

Note: The product has been released into commerce.

114. A number of the regulations in the May 1972 proposal relate to limitations on the exceptions 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.
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 invoking 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. Section 4.80 sets out those 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 to Congress or to another party, however, disclosure to the public is not required.

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 regulations. 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 actual licensees, or during discovery, or to other government agencies, or to health authorities outside the United States. It was noted that the applicant himself may have received the information under contract from a third party. It was further suggested that the regulations 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 data and information is entirely appropriate and would not destroy the confidentiality of the information involved. Section 4.81 of the final regulations so 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 are 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 required 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 and any such 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 "any person."

The Commissioner advises that lawful disclosure to the public by any person is insufficient to destroy the confidentiality of the information. Disclosure of material only in an 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 of a scientific article of the product formula is not subjected to the manufacturing process information and quantitative formula submitted to 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. It was noted that the product formula submitted to the Food and Drug Administration constitutes public disclosure only of the information that appears in the article. Any information that has appeared in a published article has been publicly disclosed. The Commissioner concludes that it constitutes public disclosure of the information to the consumer who wishes on a widespread basis, simply through stating in his letters that receipt of the information constitutes agreement to a protective order or only to defense counsel.

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 was 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 confidentiality status of a trade secret will be broken if the information involved has been given to licensees, to Federal or State agencies or 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 privilege should not lose its confidential status if it is divulged to any member of the public pursuant to any type of "confidentiality agreement." This loose wording would permit a contractor to disseminate any information he wishes on a widespread basis, simply through stating in his letters that receipt of the information constitutes agreement to a protective order or only to defense counsel.

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, but the patent does not reveal the detailed commercial processes, the Food and Drug Administration would conclude that the detailed commercial process had been previously disclosed, and thus would release it to the public.

The Commissioner advises that the Food and Drug Administration will 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 has not in fact been published 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 this information available to the public. Shortly thereafter, when a physician requested the same information from the company, it was given 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 concluded that documents exempt from 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
added to the final regulations to authorize the discretionary release of documents which are lawfully kept confidential under the Freedom of Information Act, where the Commissioner concludes that such release would be in the public interest, and with such release is not prohibited by law.

125. Comments contended that the purpose of the Freedom of Information Act was to make the operations of Federal agencies more available to public scrutiny without subjecting information derived from private sources to unwarranted disclosure. Comments argued that the proposed regulations published in May 1972 released most information supplied by industry without releasing 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 exempt from disclosure under 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 the trade secrets exemption from the Freedom of Information Act are prohibited from public disclosure pursuant to 18 U.S.C. 1905 and 21 U.S.C. 331(j). These prohibitions are enforceable by criminal sanctions. Accordingly, new § 4.82 does not permit discretionary release of such material.

127. Questions have also arisen with respect to the discretionary release of names of witnesses that may constitute a clearly unwarranted invasion of privacy.

The Commissioner regards the right to privacy as a fundamental principle of law and ethics. Accordingly, new § 4.82 prohibits discretionary release of any information that falls within the personal privacy exemption.

128. Questions have arisen as to whether the written comments of a special government employee sent to the agency with respect to proposed regulations published in the Federal Register will be made public by filing them with the Hearing Clerk and Food and Drug Administration, along with all other comments on the proposal.

The Commissioner concludes that any written comments are properly filed with the Hearing Clerk. Similarly, any written comments by other governmental agencies are also properly filed with the Hearing Clerk. The Commissioner concludes that although these comments could be retained as confidential pursuant to the exemption for inter- and intra-agency memoranda, the policy of developing a full public record for discretionary release of proposed regulations should be paramount. Accordingly, the Commissioner concludes that he will exercise his discretionary authority, by way of § 4.82, to make all comments public display in the office of the Hearing Clerk.

129. Comment has been expressed that, if the Commissioner exercises his discretion to release certain types of documents even though they properly fall within an exemption from the Freedom of Information Act, e.g., internal memoranda, this may be regarded as precedent that will require the disclosure of all similar documents in the future.

The Commissioner advises that discretionary release of some documents does 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 guaranty confidentiality for any record, since a court may conclude that the information is subject to public disclosure.

The Commissioner concurs with this comment. § 4.83 states that a determination of confidentiality by the Food and Drug Administration pursuant to § 4.44, 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, Commissioners Pursuant to 21 U.S.C. 372(g), 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 recipients of such information are aware that the data must be treated on a confidential basis.

The Commissioner agrees with this comment, Sections 4.41 and 4.46 of the regulations provide that all government 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 a court or in an administrative 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 § 4.64 of the regulations for investigatory records for law enforcement purposes.

133. Comments stated that the Food and Drug Administration should clarify the conditions under which correspondence and summaries of calls and meetings with special government employees are not disclosable. It was suggested that there be disclosure unless the communication relates only and specifically to matters (a) upon which special government employees are consulting or advising and (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. To the extent to which a communication by or to a special government employee is not a communication by or to him in that capacity, such a communication is not covered by the inter- or intra-agency memorandum exemption, and is available for disclosure.

134. Questions have arisen with respect to release of data and information to contractors that is exempt from public disclosure.

The Commissioner concludes that, since contractors and special government employees, they stand in the same position as any other member of the public and are not subject to the provisions in § 4.64 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 all data and information contained in Food and Drug Administration files may properly be disclosed to other Federal government departments and agencies, without regard to the statutory exemption, or to triggering the necessity for releasing the information to the public generally, except for records subject to the confidentiality provisions contained in § 331(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(j)). Thus, for example, preliminary results of scientific testing may be exchanged by government agencies so that they will be kept
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 301(j) 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 limitation is contained in new § 4.85. Where another Federal government agency has concurrent jurisdiction over a matter, however, the agency also has legal authority to obtain and review material covered by section 301(j), 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 Administration makes available to other government agencies information that is exempt from public disclosure, those other agencies may disclose information contrary to a pledge of confidentiality given by the Food and Drug Administration in writing or in these final regulations.

The Commissioner advises that any data or information furnished to other government agencies that is not disclosed 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" (5 U.S.C. 552(a)). The rules of Congress provide that the House of Representatives and the Senate act through their committees and subcommittees. Accordingly, a request from Congress for records, i.e., from the chairman or a committee, acting on behalf of that committee or subcommittee, falls within the provision set out in 5 U.S.C. 552(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 local official, as well as the usual exemptions and fees. See "EPA v. Mink," 410 U.S. 73 (1973); "Aspin v. Department of Defense," 491 F.2d 18 (D.C. Cir. 1972). A new § 4.87 has been added to the final regulations to state this policy.

139. A question has arisen as to whether the General Accounting Office is within the exception 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 must nonetheless be disclosed to the House of Representatives and the Senate, as congressional committees and subcommittees. In particular, it has been pointed out that some years ago a congressional committee obtained from the Food and Drug Administration adverse reaction information which it subsequently published as part of the record of a hearing without deletion of the patient or physician names or other identifying information. As a result, physicians have expressed reluctance to supply such information to the Food and Drug Administration. The Commissioner concurs 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, the information was supplied by the Food and Drug Administration because of its interpretation of the act. 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. 522(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 State and local governments.

The Commissioner concludes that all information exchanged between the Food and Drug Administration and a commissioned State or local official or a State or local government under such a commission is exempt from disclosure under the Freedom of Information Act.
data or information available to the foreign government without making it available to the public at the same time. In all instances these matters have related to pending regulatory matters and the communications have represented an attempt to coordinate action on an international level.

The Commissioner notes that there is no specific exemption relating to communications with foreign governments under the Freedom of Information Act, except for classified material relating to national defense or foreign policy. The investigatory records exemption does recognize, however, that documents relating to current regulatory issues may properly be retained as confidential during the period necessary to ensure that enforcement activities are not disrupted. The Commissioner concludes that most, if not all, communications with foreign governments relating to pending regulatory matters properly fall within this exemption. Once the pending action is in fact taken, however, such communications and information would ordinarily become available for public disclosure, except where the foreign nation specifically requested information involved be retained as confidential for a longer period of time.

The Commissioner emphasizes the importance of maintaining good working relations with counterpart agencies throughout the world both to sound diplomatic relations with foreign nations and to the availability of important new information of regulatory significance. Such cooperation is encouraged by sections 301 and 308 of the Public Health Service Act (42 U.S.C. 241 and 242f). Unless regulatory information can be exchanged without required public disclosure, the Food and Drug Administration will lose its sources of important information that is vital to protect the public, and will be unable to disseminate preliminary information when it is first generated within this country in order to help protect the public health throughout the world.

143. A foreign regulatory agency suggested that any information submitted to the Food and Drug Administration by a foreign company, and certified by a foreign government as confidential, should be held by the Food and Drug Administration as confidential. The Commissioner concludes that the same rules with respect to confidentiality apply to foreign companies as to domestic companies under the Freedom of Information Act. An assertion by a foreign government that information submitted by a foreign company is confidential is insufficient, under the Freedom of Information Act, to require nondisclosure.

144. A comment urged that a special provision be added specifically to retain confidential any information that is submitted to the Food and Drug Administration by a foreign government in confidence or as a trade secret. There was particular concern that confidential information in foreign government inspection reports be automatically treated as confidential. Article 162 of the Swiss Penal Code was cited as subjecting Swiss authorities to a penalty for the disclosure of trade secrets.

The Commissioner advises that the Food and Drug Administration has authority to refuse to disclose any information specifically exempt from disclosure under the Freedom of Information Act. The Commissioner believes that § 4.89 reflects the current law in this area 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, particularly the Food and Agriculture Organization and the World Health Organization. The Commissioner notes that 22 U.S.C. 2560a(c) provides that "the archives of international organizations shall be inviolable." The Commissioner interprets this to mean that the United States and the other signatory countries to which the United Nations Convention applies are required to respect United Nations archives. 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 in his capacity as a representative of the Food and Drug Administration, and not in an individual capacity, their status as confidential propriety to available for public disclosure in accordance with the same 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 not included in Food and Drug Administration files, they are not available for public disclosure. Accordingly, the status of such records will be determined by the specific circumstances involved in each instance.

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 that would otherwise be exempt from public disclosure will nonetheless be released in connection with such enforcement action if necessary to implement the specific action involved. For example, 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.

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 specific categories were the subject of separate regulations published by the Food and Drug Administration, e.g., food additive petitions and new drug applications, and the detailed rules on the availability of these types of documents are therefore properly incorporated directly into those existing regulations. In many other instances, however, there are no specific regulations dealing with the types of documents involved, e.g., agency correspondence and administrative enforcement records, and therefore separate rules are included in Part 4 to cover these matters.

The Commissioner concludes that a new Subpart F should be established in Part 4 to include all of these provisions relating to specific categories of documents not dealt with elsewhere in Food and Drug Administration regulations. For convenience, a new provision in § 4.100(e) 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.

149. Numerous comments on the proposed regulations published in May 1972 expressed concern that some of the provisions dealing with specific categories of records did not directly incorporate all of the exemptions from disclosure.

The Commissioner advises that each of the exemptions from disclosure set out in Subpart D of Part 4 is applicable to each of the specific categories of records for which a provision is established in Subpart F of Part 4 or elsewhere in Food and Drug Administration regulations. Both §§ 4.60 and 4.100 state this policy.

150. Provisions in other parts of the Food and Drug Administration regulations also establish rules governing the availability for public disclosure of specific categories of records.
The Commissioner concludes that the term "informal" should be replaced by the term "administrative," in order to clarify the intent of the section. All administrative enforcement action will be governed by this section regardless whether it is considered informal or formal nature.

153. Many commenters cited the probability of an adverse effect upon a company's desire to cooperate with the Food and Drug Administration if such correspondence and recommendations are released to the public. Several stressed the importance of industry cooperation in order for the Food and Drug Administration effectively to regulate the industry. One suggested that the provision might interfere with voluntary compliance, since cooperation might, in the public's eye, indicate guilt. There would be, he stated, a tendency to resist and litigate rather than accept "trial by newspaper." It was suggested that manufacturers who previously fully cooperated in an inspection situation would attempt to use section 704 of the Federal Food, Drug, and Cosmetic Act against the Food and Drug Administration employee by questioning the "reasonableableness" of inspections, not setting anything beyond the letter of the law.

The Commissioner concludes, on the basis of experience in the 2 years during which the provision has been implemented, that the company, to protect against such possibilities, 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 a 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 agency's reasons for its action.

The Commissioner concludes that these comments are not persuasive, and that all records of administrative enforcement actions are disclosed to any person will be made available to the public. If accepted, the logic of the comments summarized above would require holding the pleadings in all court actions confidential until the matter was finally concluded, as well as all administrative actions. The Commissioner concludes that the approach suggested in the comments is in complete disregard of the intent of Congress as expressed in the Freedom of Information Act. See "Welford v. Hardin," 444 F.2d 21 (4th Cir. 1971).

The Commissioner also concludes that it is not feasible to furnish requested material to an affected person for review, prior to disclosing it to the public, nor is this required by law. Such a procedure would substantially reduce the availability of information to the public, contrary to the Freedom of Information Act.

152. Questions have been raised on the difference between "informal" and "formal" enforcement action.

The Commissioner concludes that like section 305 hearing files, they are not closely related to possible criminal prosecution in most cases. Such reports have been released routinely upon request during the past 2 years without prejudice to the agency's regulatory activities.

156. Similar questions have been raised with respect to the status of the establishment inspection report (EIR) prepared by a Food and Drug Administration employee after an inspection. The EIR is retained only in Food and Drug Administration files, and is not sent to the establishment or any other person.

The Commissioner concludes that the EIR is properly retained as confidential until the matter is closed, since it is both an intra-agency memorandum and part of an investigatory file. Unlike the information in Forms FD 483 and FD 2275, the EIR contains personal conclusions and recommendations for consideration only within the Food and Drug Administration, and is not disclosed outside the agency except other authorized governmental officials. It is not a simple factual list of observations, but rather a much longer description of conditions observed and conclusions and recommendations with respect to those observations. The Commissioner concludes that routine release of the EIR before the matter is closed would interfere with normal enforcement activities and could have an adverse impact on a fair trial and an impartial adjudication. In specific situations, an EIR may be released by the Commissioner as an exercise of his discretion pursuant to § 4.62.

The list of the Food and Drug Administration employee's observations on violative conditions, given to the responsible company official upon completion of the inspection on Forms FD 483 or FD 2275, contains at least part of the information subsequently incorporated in the EIR. Accordingly, the Commissioner concludes that the Food and Drug Administration will respond to any request for a non-disclosable EIR with an offer to furnish a Form FD 483 or FD 2275 covering the same inspection.

157. In some instances, a Food and Drug Administration employee will discuss matters with a firm during or at the conclusion of the inspection, and will subsequently note those and perhaps other matters in the EIR. Questions have arisen as to whether this requires that the EIR be made available for public disclosure.

The Commissioner concludes that an oral discussion of matters subsequently reduced to writing in an EIR does not require that the EIR be made available for public disclosure. If any part of the EIR is subsequently disclosed to the firm or any member of the public, however, the same portion of the EIR must then be made available to anyone who requests it, except for appropriate deletions for exempt material.

158. It is common practice for a representative of the Food and Drug Administration to write a high official in a company to bring to his personal attention any violation of the law that may
have been observed during a factory inspection and reported to an EIR.

In accordance with the Commissioner's conclusion that all correspondence with any person outside the Federal government is properly made public, all such postinspection correspondence is made publicly available upon request. Such letters are in the nature of warnings pursuant to section 306 of the act, and may well be such seizures. See "Welford v. Hardin," 444 F.2d 21 (4th Cir. 1971). Such letters have been re-

leased 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 action by 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 Administr-

ation Public Records and Documents Center, for public review. Additional correspondence and memoranda relating to such letters will be available upon request. 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 Food and Drug Administration often requests the recall of violative products from the market in lieu of seizure. The Commissioner concludes that all administrative enforcement records requesting recalls are properly released to the public under the reasons that regulatory letters and other administrative enforcement records are subject to public disclosure. The Commissioner believes that all such 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 recalls, however, the Commissioner will delete any confidential commercial information that may be included. For example, a list of customers of a particular company making a product is customarily regarded as confidential commercial information, and will not be disclosed to the public.

A number of comments noted the absence in proposed § 4.122 of a specific exemption for trade secret or confidential information and indicated that such an exemption should be added.

As § 4.120(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.

Comments suggested that some of the information covered by this section would also be covered by the section on the investigatory records exemption. The Commissioner concludes that there is no overlap between these sections. The investigatory records exemption in § 4.64 is explicitly limited only to data or information obtained by the Food and Drug Administration, retained solely in its files, and not shown to anyone outside the agency. Thus, § 4.64 covers 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 information contained in section 309 records and investigatory reports relating to an active and current criminal investigation. The provisions of §§ 4.64 and 4.101 have been revised to clarify this policy.

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 act.

The Commissioner advises that all such action levels have, to the best of his knowledge, now been made public. The action levels for national or 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 5, 1973 (38 FR 354), stated that, when finally revised, all such action levels will be published in the Federal Register for comment, and that, in the interim, they would be available upon request from the office of the Assistant Commissioner for Public Affairs, Food and Drug Administration, Rm. 163-49, 5600 Fishers Lane, Rockville, MD 20852.

Requests for publication of various enforcement actions under § 4.102 should be directed to the Food and Drug Administration Public Records and Documents Center.

The Commissioner has recently proposed a revision of Part 122 of the regulations (21 CFR Part 122), published in the Federal Register of December 6, 1974 (39 FR 42738), to provide for publication of all action levels for food products. The Commissioner believes that all such levels will be made publicly available 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 under 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 the announced tolerance or action level but would be taken if it exceeded the higher tolerance or action level. The legislative history of the Freedom of Information Act shows that such unannounced 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 remain 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 range. In other instances, such methodology yields variable results, and thus is accurate only within a specified range. For example, a list of customers that are available upon request from the office of the Assistant Commissioner for Public Affairs, Food and Drug Administration, Rm. 163-49, 5600 Fishers Lane, Rockville, MD 20852.

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.

COUNT ENFORCEMENT RECORDS

The Food and Drug Administration institutes many formal legal actions in the courts every year. These include injunctions, penalties, consent decrees, civil enforcement actions, etc. 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 courts 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.

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 documents 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 recommended complaints are available for public disclosure upon request. In accordance with the provisions of §1.7(c) of the Freedom of Information Act, except to the extent that portions may fall within the specific exemptions under the law.


correspondence to the public might well include such correspondence in which a member of Congress is not acting in an official capacity as a member of a duly authorized committee.

The Commissioner concludes that any letters to or from a member of Congress, as well as summaries of oral discussions, regardless of whether the member is acting in an official capacity as a member of a duly authorized committee, will be available for public disclosure except to the extent that the correspondence contains trade secrets or other nondisclosable information. The final Department regulations adopted this position.

The Commissioner has added a new §4.44 to the regulations to establish a procedure for determining those records which the agency will receive under a determination of confidentiality. Except where such procedure is followed, the Food and Drug Administration will not undertake to retain any information in confidence except specific types of records for which confidentiality is explicitly provided in the regulations, e.g., quantitative formulas that have not previously been made public. There is a close question with respect to possible confidentiality. The Commissioner will use the procedure set out in §4.45 of the final regulations to consult with the affected person, and that person may then request a court determination on the issue pursuant to §4.46 if he does not agree with the Commissioner's conclusion.

The Commissioner concludes that such correspondence and summaries constitute trade secret and confidential information which should be free from disclosure as containing a trade secret or constituting an invasion of personal privacy. Thus, confidential handling will exist only during the deliberative stage of the proceeding, and the agency's decision will be subject to full public scrutiny and public accountability once a decision is final.


correspondence. Thus, the 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 agency records. Any exempt material will be disclosed before it is approved. Public accountability, thus requiring a full disclosure of all such materials except where specific exemptions apply and cannot properly be waived, e.g., trade secrets or an invasion of personal privacy.

The Commissioner concludes that these comments misinterpreted the proposed regulations. Each of the statutory exemptions reflected in the proposed regulations is applicable only to the types of records contained in Food and Drug Administration files, including correspondence. Thus, the trade secrets and personal privacy exemptions will be applicable wherever the facts in a given situation show that they are applicable. For example, correspondence with a prospective employee concerning conflict of interest issues would be exempt from public disclosure under the personal privacy exemption.

172. Questions have arisen as to whether the general rules with respect to agency correspondence and summaries of telephone calls and meetings will be applicable when the subject of the correspondence or summary is a pending petition or application for an approval of the ingredient or product, e.g., a new drug application or a food additive petition.

The Commissioner advises that these general rules will not apply to such correspondence or summaries until the petition or application is approved. Security analyst, competitors, and many others are interested in the progress of such petitions and applications within the agency. Daily monitoring of such matters by outside individuals or organizations is not contemplated by the Freedom of Information Act. The Commissioner concludes that such correspondence and summaries constitute trade secret and confidential information that is privileged or confidential, until the approval of the ingredient or product is obtained or it is finally disapproved.

Once approval is obtained, or final disapproval results, the Commissioner concludes that all such correspondence and summaries shall be made available for public disclosure except to the extent that specific material may be exempt from disclosure because it contains a trade secret or constitutes an invasion of personal privacy. Thus, confidential handling will exist only during the deliberative stage of the proceeding, and the agency's decision will be subject to full public scrutiny and public accountability once a decision is final.

Sections 4.103 and 4.104 and other specific provisions dealing with petitions and applications have been modified to reflect this policy.

Summaries of Oral Discussions

173. Comments urged that the agency not totally withhold summaries of telephone calls and meetings if they contain both disclosed and nondisclosed information. It was suggested that the appropriate course in that circumstance would be to delete exempt material and disclose the remainder. Several cases
were cited for that proposition, "Grum-
man Aircraft Corp. v. Food and Drug 
Administration Board," 425 F.2d 978 (D.C. Cir. 

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 
are 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-

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 prop-
osal that summaries of telephone calls 
or meetings relating to 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 would 
not have taken place but for an 
asumption of confidential treatment of 
the information. Still another drew a 
parallel between disclosure of the sum-
maries and wiretapping and commented 
that, since evidence of this nature is not 
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 
provisions of the Freedom of Information 
Act apply only to specific records, not to 
entire files. Accordingly, it is improper 
to label a file as "confidential" and thus any subject matter to § 4.104 must be reviewed to determine 
whether, on its own merits, it is dis-
closable in any form.

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 
§ 4.64 of these regulations. No other 
form of confidentiality will be granted 
extcept 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 and disclosure of a summary of a 
telephone conversation and wiretapping. 
The public would not have to know all 
summaries are routinely maintained. 
In any event, these regulations and the new 
procedural regulations constitute public 
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in order to determine any appropriate ac-
time to prepare a responsible final re-
period of time is properly regarded as a
for public disclosure. The Freedom
Administration official, it represents an intra-
leased.
Administration to release raw test data
in which the court ordered the Veterans
results of testing
other similar working materials will be
available for a sufficient period of time
reports involved in that case had been
a contrary result. There, the data In-
approach to the matter, and a reasonable
port that reflects an institutional ap-
violation of the intent of the Freedom
event, not “final” for any significant pe-
information as incomplete or, in any
viability drafts from which a final report
public disclosure after the
report is released.
44626
The case of “Consumers Union v. Vet-
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
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 correspondence or in a
public meeting, the public has a right to talk,
all of such information reasonably re-
lated to the material disclosed must be
made publicly available at that time even
though a final report has not yet been
prepared. A disclosure of any data or informa-
tion to persons other than as provided in Subpart E of Part 4
breaks the internal memorandum ex-
ception and requires disclosure of such
data or information to any person who
requests it.
One comment expressed uncer-
tainty as to whether testing done on
marketed products would be disclosable
to the public. If so, it was argued that the
manufacturer should be given the op-
portunity to review the results and com-
municate them before the report was
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 by the manufacturer before
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 Fre-
dom of Information Act and the agency
cannot justify the expenditure of man-
power which would be required to create
such documents.
186. The Food and Drug Administra-
tion obtains two different types of prod-
uct samples in the course of its regulat-
ory activities. A Food and Drug Admin-
istration employee will often obtain a
sample during a factory inspection. The
Food and Drug Administration employee
must give a receipt for such a sample,
and a copy of the results of certain
analyses required by law to be fur-
nished 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
seizure, the Food and Drug Administra-
tion is required under section 304(o) of
the act to furnish the results of any
analysis to any party to the seizure ac-
tion. 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 ob-
tained 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 im-
mediately 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.
The Commissioner advises that § 4.61
of the regulations applies to disclosure of
trade secrets or confidential commer-
cial information in any agency docu-
ments, and §§ 4.60 and 4.100 of the final
regulations make this clear. The Com-
mmissioner concurs that trade secret
information may not be disclosed. This
does not mean, however, that agency re-
search or regulatory requirements can-
not be based upon 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
remains true even if the information
would not prevent the Food and Drug
Administration from conducting
and disclosing its own similar re-
search, however, or from imposing by
regulation new requirements for the drug
involved, in order to protect the public
health.
180. A comment pointed out that, in
its performance tests and analyses, the
Food and Drug Administration may in-
clude trade secrets or other confidential
commercial data in test protocols or rec-
ords 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.

STUDIES AND REPORTS PREPARED BY OR
WITH FUNDS PROVIDED BY THE FOOD
AND DRUG ADMINISTRATION

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 §4.108 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 disclosed upon their acceptance by the responsible agency official: Quarterly and annual reports of the agency; broad reviews of agency needs by external committees, such as the Ritts Committee; surveys, compilations, and summaries of industry trends and data obtained from various outside sources for purposes of establishing internal priorities and programs; surveys of consumers or industry and other similar markets to determine the need for or content of proposed new regulations or compliance programs; and compliance 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 plant. 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 actions to strengthen agency performance; records relating to the internal planning and budget process; and legislative proposals or comments unless and until 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 names of manufacturers.

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 activities.

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 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 amendments to 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 §4.20. A partial list of these manuals is as follows:

- Administrative Guidelines Manual
- Bacteriological Analytical Manual
- Drug Analysis Manual
- Inspector Operations Manual
- Inspector Programs Manual
- Instrument Operations Manual
- Laboratory Information Guidelines
- Laboratory Operations Manual
- Microanalytical Manual
- Pesticide Analytical Manual
- Regulatory Procedures Manual

194. A comment was made 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 legislative history of the Freedom of Information Act requires that all otherwise nonexempt 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 local 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 and available for public review at the Food and Drug Administration 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 by the Food and Drug Administration from a second person to whom the reports are sold will not furnish them 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 through a contract 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 which permit representatives of the agency to review data and information retained by an outside organization. Such contracts permit access to outside data and information, but do not permit the Food and Drug Administration to 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 that all information received 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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INFORMATION ABOUT FOOD AND DRUG ADMINISTRATION EMPLOYEES

198. Questions have arisen as to whether information is available about Food and Drug Administration employees.

The Commissioner advises that the name, title, grade, position description, salary, dates, and the Social Security number for every Food and Drug Administration employee is available for public disclosure. The home address and telephone number of each employee 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 research should be undertaken in order to respond adequately to inquiries of this type.

The Commissioner advises that the statistics obtained from this research are 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 raw 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 the final regulations.

Several comments objected to the concept of permitting information to be withheld as confidential simply because the manufacturer would refuse to submit it voluntarily. It was feared that the Freedom of Information Act makes no such distinction and that such an approach flouts the express intention of Congress to provide the public with all information in the hands of the agency which is not specifically exempt under the Freedom of Information Act.

The Commissioner agrees that a mere claim for confidential treatment does not bestow a confidential status upon information that is voluntarily submitted. Section 4.111 reflects the necessity for showing that the information falls within one of the exemptions set out in Subpart D of Part 4 of the regulations. A claim of nondisclosure based upon the trade secrets or confidential commercial information exemption or any other exemption to the Freedom of Information Act will not be automatically accepted. When the Food and Drug Administration makes a determination that information will be accepted in confidence, the agency is at that time exercising its judgment that the information properly falls within an exemption from disclosure and that the Commissioner will not exercise his discretion to disclose it pursuant to § 4.82.

201. The Food and Drug Administration has instituted a system of inspection of the food industry on the basis of hazard analysis and critical control points (HACCP). Food and Drug Administration employees regularly request, pursuant to this program, access to company records that are not required by law to be kept up to date on a periodic basis. Pursuant to the exemption for personal privacy, the records fall within § 4.111. Pursuant to the Freedom of Information Act after they become a part of Food and Drug Administration files.

The Commissioner advises that such records fall within the provisions in the final regulations relating to information voluntarily submitted to the government, except for those records required to be submitted by other provisions, e.g., § 80.20. Virtually all such records consist of information Concerning the manufacturing processes and controls, product formulations, and consumer complaints. Manufacturing processes and controls and product formulations are per se exempt from disclosure under the Freedom of Information Act, except to the extent that they have already been publicly disclosed. Consumer complaints are exempt from disclosure to the extent that they become a part of Food and Drug Administration files.

The Commissioner concludes that the Freedom of Information Act, except to the extent that they have already been publicly disclosed. Consumer complaints are exempt from disclosure to the extent that they become a part of Food and Drug Administration files.

The Commissioner concludes that information given voluntarily to a Food and Drug Administration employee during a factory inspection should be considered confidential unless the employee obtains consent from the manufacturer or physician to the extent that they have already been publicly disclosed. Consumer complaints are exempt from disclosure to the extent that they become a part of Food and Drug Administration files.

The Commissioner concludes that information given voluntarily to a Food and Drug Administration employee during a factory inspection should be considered confidential unless the employee obtains consent from the manufacturer or physician to the extent that they have already been publicly disclosed. Consumer complaints are exempt from disclosure to the extent that they become a part of Food and Drug Administration files.

The Commissioner concludes that information given voluntarily to a Food and Drug Administration employee during a factory inspection should be considered confidential unless the employee obtains consent from the manufacturer or physician to the extent that they have already been publicly disclosed. Consumer complaints are exempt from disclosure to the extent that they become a part of Food and Drug Administration files.
The Commissioner advises that the reports obtained pursuant to such contracts are not submitted voluntarily, and thus are subject to § 4.100, which establishes the disclosure rules for information obtained by contract. Pursuant to § 4.63 the names or other information which personally identifies the individual professional will also be disclosed if any such name is included in the report, but the contracts involved do not require the reporting of any such names.

207. One comment suggested that the provisions which permit names of those submitting adverse reaction data to remain confidential "applauds the steps" and that if an individual is unwilling to be identified he should not be heard to complain.

The Commissioner concludes that there are valid reasons why an individual might not submit information in confidence. It should be noted that if an individual is not identified 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 Administration 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 require such reports.

The Commissioner disagrees with this comment. Until new legislation is enacted authorizing the Food and Drug Administration to obtain adverse reaction reports from manufacturers on all products subject to its jurisdiction, the agency is justified in seeking such submission to protect the public health. Without such submission, the Food and Drug Administration'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 indicates that this law was intended to be applied in a way that would hinder regulatory activity or prevent an agency from taking action to protect the public health. The Commissioner believes that it is entirely appropriate to require manufacturers to submit 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, personal privacy, and investigatory records. Accordingly, the Commissioner has not pledged the confidentiality of such reports submitted voluntarily by the manufacturer to the Food and Drug Administration in order to assure that they will continue to be available to the agency for its regulatory purposes.

The Commissioner recognizes the anomaly created by classifying certain portions of adverse reaction reports not required by law to be submitted to the government as not confidential, while at the same time classifying those same portions of other adverse reaction reports that are required by law to be submitted to the government as not confidential. The Commissioner contends that this anomaly must continue to exist as long as the disparity in legal authority survives. The alternative would be to discourage voluntary submission by manufacturers of any adverse reaction reports not required by law. The Commissioner concludes that this alternative would not be in the public interest.

209. Comments suggested that adverse reactions should be disclosed by the Food and Drug Administration only to health professionals, and not to the general public, in order to protect individual privacy and damage to the public health.

The Commissioner concludes that limited distribution of this type is precluded by the Freedom of Information Act, and is not in the public interest.

210. Comments suggested that reports of adverse reactions submitted to the Food and Drug Administration by someone other than the manufacturer should be available for public disclosure only after probable cause has been established and documented and the manufacturer of the product involved has had an opportunity to comment with respect to the alleged reaction.

The Commissioner disagrees with this comment. The Freedom of Information Act now requires that reports of this type, which would severely hinder the dissemination of information that is clearly available for public disclosure under the Freedom of Information Act.

211. Comments contended that many consumer complaints are not based on fact, but are simply intended to obtain refunds on products or are, in any event, fraudulent. The Commissioner concluded that it would be unfair to reveal all such complaints because of the many inaccuracies they contain.

The Commissioner believes that both industry and consumer versions of complaints may be inaccurate. This is not a basis for exempting reports on complaints or adverse reactions from disclosure under the Freedom of Information Act.

212. Large numbers of requests are received from plaintiffs' attorneys in product liability lawsuits, requesting access to records relating to other injuries caused by the product that is the subject of the lawsuit.

The Commissioner advises that, in response to such requests, all such adverse reaction reports received on the product involved will be furnished, with identifying information deleted as provided in § 4.111(c) (3), except that those reports submitted voluntarily by the manufacturer to the Food and Drug Administration in order to make it available to the agency shall continue to be available to the agency other than as part of a blinding compilation. Section 4.111 of the final regulations reflects this policy.

213. Numerous requests are made for copies of investigations conducted by the Food and Drug Administration of specific consumer complaints.

The Commissioner concludes that such complaints fall within the rules for disclosure set out above. Accordingly, they will be released depending upon the source of the information that led to the investigation. The original consumer complaint that initiated an investigation will be released after deletion of the person's identity. No disclosure of the Food and Drug Administration report shall be made if it relates to a specific person or event without the express written consent of the person who was the original source of the information that resulted in the investigation, since otherwise it would not be possible to promise that such information will be held in confidence.

VOLUNTARY DRUG EXPERIENCE REPORTS SUBMITTED BY PHYSICIANS AND HOSPITALS

214. The Food and Drug Administration has given wide distribution of Form FD-1639, Drug Experience Report, to physicians for use in reporting adverse reactions relating to drug products to the Food and Drug Administration. This form is stamped "in confidence," and the Food and Drug Administration has pledged that no information on this form that would identify patients or physicians or institutions will be released to the public.

The Commissioner advises that this commitment will in all instances be honored under the personal privacy, confidential commercial information, and investigatory records exemptions, and that any release of information contained on this form will be through a compilation that will in no way disclose the identity of the individual patient, physician, or institution. A new § 4.112 has been added to the final regulations to state this policy.

215. Questions have arisen as to whether a copy of the form FD-1639, with all identifying information deleted, will be made available to the patient who is the subject of the report, or his attorney, if it is specifically requested.

The Commissioner concludes that no release of this report may be made to a patient or his representative without the permission of the physician who submitted the report. If the report were disclosed to the patient, for purposes of malpractice litigation, this entire voluntary reporting system could be destroyed. The Commissioner notes that, since all of the information contained in any such report can be obtained from the physician through discovery in the course of litigation, the patient has an equally effective alternative.

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RULES AND REGULATIONS

VOLUNTARY PRODUCT DEFECT REPORTS

216. The Food and Drug Administration has an ongoing program with the United States Pharmacopæa (U.S.P.) under which reports on drug product defects are furnished to the agency for use in determining whether regulatory action is warranted. Under this program, the Food and Drug Administration has pledged that the names and identifying characteristics of physicians, patients, pharmacists, and similar persons 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 drug defect reports received for one particular drug pursuant to the joint program undertaken by the United States Pharmacopæa 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 accompanied by 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 industry. These agreements provide that the company will disclose to the Food and Drug Administration certain 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 § 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 established by 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 the rules set out in §§ 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 processes and documents which 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 their products subject to regulation under the Radiation Control for Health and Safety Act of 1968.

The Commissioner advises that the keys to all such codes have been made available on the basis of the regulations revising 21 CFR 1002.10(b) and 1010.3(a) (2) which 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 should be used, do not fall within the trade secrets or confidential commercial information exemption. Accordingly, any key to such a code in Food and Drug Administration files will be available for public disclosure. A new § 4.115 has been added to the final regulations to state this policy.

DRUG LISTING INFORMATION

221. The Drug Listing Act of 1972 (Public Law 92-157, 86 Stat. 659), which amended section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), 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 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 § 4.118 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.

Copies 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 this computer printout that will be permanently available for public review, the following examples of information may be obtained in printout form upon special request:

a. An alphabetical list by trade name of the approved new drug applications and abbreviated new drug applications held by specific sponsors.

b. An alphabetical list of the trade names of drugs subject to approved new drug applications and abbreviated new drug applications showing either the NDA number or the approval date.

c. An alphabetical list of generic drugs showing approved new drug applications and abbreviated new drug applications held by specific 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 the use of this information by all investigators who have ever worked on investigational new drugs, without designating the specific drugs they investigated. A
 Similar request has been received for a list of the names and addresses of all drug companies which have ever filed an investigational new drug notice (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 provision in 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 proceedings, if not stenographically reported. The transcript or summary shall contain a record of the matters discussed and the conclusions reached, and copies of required and background information received, issued, or approved by the advisory committee. The accuracy of a summary shall be certified by an 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 or telephone call that relates, in whole or in part, to advisory committee business which was conducted at a time or place not covered by reasonable notice in the FEDERAL REGISTER as a time or place for a meeting of the advisory committee. This provision governs whether the meeting or telephone conversation involved advisory committee members or advisory committee staff. The version involved shall be certified by an advisory committee. Participants shall be given an opportunity to review and make corrections before such a summary is certified.

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 for 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 employed, officer, director, consulting director, trustee, advisor, or consultant.

f. A list of persons who were asked to become advisory committee members and to decline. The reason for declining, if any were given, will be disclosed.

The Commissioner will issue in the near future comprehensive new procedural regulations in 21 CFR Part 2 that will thus govern certain aspects of the activities of advisory committees. The Commissioner concludes that detailed consideration of the application of the Freedom of Information Act to advisory committee matters should properly be dealt with in those regulations, rather than in these regulations, and an appropriate cross-reference is included in 4.119 for that purpose.

**Rules and Regulations**

225. The proposed regulations published in May 1972 contained specific amendments to existing regulations dealing with color additives, food additives, new animal drugs, and antibiotic drugs. Many of 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 methods, adverse reaction reports, and manufacturing 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 common issues for purposes of analysis and discussion in this preamble.

226. Questions have also arisen with respect to the status of data and information submitted to the Food and Drug Administration in "master files" which are subsequently used to support product applications. It was suggested in comments that all master file material should remain confidential.

The Commissioner advises that data and information contained in a master file have the same status that they would have in a petition or application. The fact that they are included in a master file rather than directly in a petition or application is of no relevance.

227. Several comments questioned the source of the "public policy," referred to in paragraph 5 of the preamble to the proposal, which favors an expanded public disclosure of research data on safety, functionality, and effectiveness in contrast to the position the Food and Drug Administration has taken since 1938 that all such data and information ordinarily represent valuable commercial property and trade secrets that must be retained as confidential. It was suggested that the relevant "public policy" to be considered was that set forth in the House and Senate reports and in the Attorney General's Memorandum. The memorandum made in the House report that "a citizen must be able to confide in his Government" was stressed as was the statement in the Attorney General's Memorandum that "(t)he mere similarity of private hands would be held in confidence, such property in the hands of the United States should be covered under exemption (b) (4)."

The Commissioner advises that the "public policy" referred to in paragraph 5 of the preamble to the proposal is that expressed in the Freedom of Information Act. It is the responsibility of the Commissioner to determine which mandate of Congress regarding what its own past policies may have been.

The Commissioner concludes that the final regulations manifest a proper balance between the general statutory objectives of releasing all records unless it appears that release would impair the statutory exemptions for trade secrets. Those records that do represent valuable commercial information, in that they provide competitive advantage, will not be disclosed to the public.

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 and effectiveness, and all studies and tests conducted to establish the basic identity, stability, purity, potency, bioavailability, performance, and usefulness of the product. It does not include quality control tests continuously conducted on a manufacturing process and a product to establish its adherence to process and product specifications or adverse reaction reports obtained upon marketing of a drug or similar information. All of the regulations involved have been reviewed to reflect this policy.

Requests have been made for safety, effectiveness, and functionality data and information contained in letters requesting opinions on the food or drug additive or new drug or new animal drug status of product applications. The Commissioner advises that these materials 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 disclosable 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 a 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 it has previously been made public. This is the procedure presently being followed under the OTC drug review pursuant to §300.10(a) (2) of the regulations (21 CFR 300.10(a) (2)).

**Color Additive, Food Additive, Antimicrobial, and New Drug Petitions, Applications, and Forms**

229. Requests have been made for safety, effectiveness, and functionality data and information contained in color additive, food additive, and antimicrobial petitions and forms. (44631)

230. The proposed regulations published in May 1972 established the same rules for release of safety, functionality, and effectiveness data contained in color additive, food additive, and antibiotic petition 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.
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 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 considered for purposes of analysis and discussion in this preamble.

231. It was pointed out in some comments that there was a change in position 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 employees, and not to the public.

The Commissioner notes that there was no change in position in the past, and that in every event the policy of the Food and Drug Administration prior to enactment of the Freedom of Information Act is not determinative as 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 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 manufacturers, which are ordinarily so disclosed or made public.

232. Several comments objected to the statement in paragraph 5 of the preamble to the proposed regulations published in 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 release of safety and functionality data for food additives and color additives. In the intervening 2 years, all such data have been made available. Although affected manufacturers were permitted an opportunity to contest such disclosure in the courts, no such lawsuits were filed. Some manufacturers have, indeed, affirmatively agreed to the disclosure of such information: Information of this type is routinely published in the scientific literature or otherwise distributed to interested scientists, potential customers, and others. Accordingly, the Commissioner believes that it is not customarily regarded as confidential commercial information.

233. A comment suggested that safety, functionality, and effectiveness data for food and color additives and antibiotic drugs do provide an advantage over competitors because they can be referred to in promotional and selling activities.

The Commissioner rejects this comment. Once such ingredients or products are approved by the Food and Drug Administration for distribution generally, the use of such data by particular manufacturer for promotional activities cannot reasonably be regarded as providing a competitive advantage.

234. One comment contended that, even if food additive and color additive safety and functionality data provide no competitive advantage in the United States, they do provide a substantial competitive advantage in obtaining governmental approvals in foreign countries.

The Commissioner concludes that the possibility that such data and information may permit a particular manufacturer to determine that a competitive advantage in some foreign country is too conjectural and remote to permit the conclusion that all such data and information fall within the trade secrets exemption. In the event that specific facts are available to show such a competitive advantage with respect to a particular matter in a specific foreign country, the Commissioner will evaluate the situation to determine whether it presents the "extraordinary circumstances" under which the material will not be disclosed pursuant to the final regulations.

235. With regard to the safety, effectiveness, and functionality data for food and color additive petitions and antibiotic drug forms, comments stated that there was no justification for withholding information until the regulations are issued. It was argued that, if this information does not provide a competitive advantage in obtaining approval, since all manufacturers are then free to make the product, it is questionable whether the information provides any operational or marketing advantage to approval, since no manufacturer may market or use the product until then. It was argued that, when the approval is granted for minor variations in formulations of such ingredients or products, any competitive advantage is insignificant, considering the little time it would take a competitor to start production by using the information in obtaining approval. As a positive benefit, it was argued that release before the regulation was issued might trigger research which might cast some future time. The Commissioner will evaluate the likelihood that any such restrictions or relevant changes in the petition or antibiotic drug form.

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 sufficient information and further testing is required, the safety, functionality, and effectiveness data contained in an antibiotic drug form will be available for public disclosure after the review of the submission by the Food and Drug Administration is complete. In almost all circumstances, the petition will be 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 public disclosure is necessary. The need for the Food and Drug Administration for review and evaluation of the submission before it is released to the public for access to the data and information submitted in order to make meaningful comments on it within the time permitted.

236. Comments suggested that, if food and color additive petitions and antibiotic drug forms are not customarily privileged, manufacturers should not be permitted 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 was included in the event that, on rare occasions, circumstances may arise that cannot be foreseen at this time which would require, in fairness, that material not be disclosed. The Commissioner anticipates that this will happen on very few occasions, and that in almost all instances this type of information will promptly require disclosure to others, or that there is some remote future possibility of competitive advantage that he would otherwise enjoy, that he will be hurt financially as a result, and that it would be unlawful or unfair to release the information to others. The Commissioner also anticipates that the information may be embarrassing, or may require removal of a product from the market, or may disclose adverse reactions, or may be of interest to others, or that there is some remote future possibility of competitive advantage, and that the same argument and similar circumstances will be insufficient to justify nondisclosure.
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 § 4.37 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 substantive 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 in common for new and new animal drug applications. Under the Federal Food, Drug, and Cosmetic Act, these applications, and the notices relating to 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 is previously made aware the information public or the drug has been disapproved 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 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 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, or with securities analysts, or acknowledging the existence of an IND to any 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 difficult to maintain.

240. Questions have arisen as to whether the existence of an IND notice under these regulations can 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 of 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 with respect to 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 the progress of the investigation, or that patients 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 by outside interference.

242. A request was received for the curriculum vitae of a specific person who is publicly known to be an investigator for a particular new drug.

The Commissioner concludes that a curriculum vitae is properly available for public disclosure under these circumstances. Information contained in a curriculum vitae is customarily distributed in a public fashion, and accordingly such release does not constitute an unwarranted invasion of privacy.

243. A comment was received that all IND information should be available, whether or not the IND has been terminated, for the protection of the human subjects involved in the drug experiments. The Commissioner notes that information is lost to the investigator in testing subjects because of the Food and Drug Administration policy of allowing drug companies to experiment on human beings before animal tests are completed. Without disclosure, it was stated, there is also no incentive for following up on patients who have taken experimental drugs.

The Commissioner concludes that the present law precludes such release of the safety and effectiveness data in an active IND file unless it has previously been publicly disclosed. The remedy for the individual who has participated in the testing of a new drug is to obtain 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 has the option of not participating in the test unless there is full disclosure of all information, including, in particular, the trade secrets on other test subjects. Proposed regulations on the followup of test subjects, and a petition relating to requirements for animal tests before human tests, are presently under active consideration.

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 added that even the irrevocable and final termination of an IND in this country should not result in the disclosure of the safety and effectiveness information contained in it if the same drug is being marketed elsewhere in the world.

The Commissioner does not agree with this comment. Even the pharmaceutical industry comments generally stated that a summary of safety and effectiveness information can properly be disclosed to the public without violating the trade secrets exemption of the law. It is only the full reports that may not properly be disclosed, because the Federal Food, Drug, and Cosmetic Act requires that such full reports are necessary in order to obtain an approved NDA.

If the terminated IND contains adverse information with respect to safety and effectiveness, therefore, a summary of that information could properly be released, and would be as damaging to foreign marketing as would the full reports of such information.

Moreover, none of the comments submitted demonstrated any likelihood that the full reports of such information, as contrasted with summaries, are required under foreign law in order to justify marketing abroad. The Commissioner therefore concludes that any such 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 support 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 not be terminated for fear that such termination, in and of itself, would result in the information contained therein becoming available for public disclosure.

The Commissioner advises that the termination of an IND is not dispositive with respect to the availability of information contained therein. A company can demonstrate that the matter is still under active development, such information will retain its trade secret status.
247. In one instance, a request was made for information contained in an IND file for which human clinical studies had been done as a result of adverse animal findings. The company requested continued confidentiality of the information in the file on the ground that it was pursuing additional animal studies in order to revalidate the IND file and intended eventually to pursue an NDA.

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, and the data and information contained in an IND which are otherwise confidential will not be disclosed to the public as long as the matter remains open and active. Where the issue 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 intentions of that person with respect to the IND would be subject to the False Statements statute, 18 U.S.C. 1001.

248. One comment suggested that the IND provision 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 of 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.

On reconsideration, 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 "approved," and not for all pending new drug applications. The Commissioner states that confidentiality for a particular pharmaceutical company may be of great value to it in anticipation of a competing product. Therefore, the Commissioner concludes that there does not appear to be any legal or policy reason why a "competitive advantage" for purposes of determining whether information is a trade secret may not be obtained from a statutory scheme. The existing regulatory scheme is one created by the Congress and not by the Food and Drug Administration. Data that no longer provide a competitive advantage—because any competitor may lawfully market the product involved, or because the information has otherwise been made public, or for other reasons—no longer qualify as a trade secret under 18 U.S.C. 1005, 21 U.S.C. 331(j), or the Freedom of Information Act.

250. Comments stated that the fact that a company has filed an IND or is even interested in a particular pharmaceutical area 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 almost always afford a competitor an advantage because he will then be in a position to adjust his marketing strategy in anticipation of a competing product. The Commissioner concludes that such data pending will frequently be a trade secret.

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 before the agency and frequently a company will make such information public in its reports to stockholders.

252. Undoubtedly, the most persistent issues 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 properly pointed out that it is important to scientists and physicians. Comments opposing disclosure of this information quite properly pointed out that it is of enormous economic value. Reports to the Government Act, 18 U.S.C. 1001.

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Y. Food and Drug Administration permits, and Drug Administration to make an lease. The Federal Environmental Pest effectively data, but points out that release of this type of information such information should be released. Statistics recommended in scientific review. It was pointed out that are insufficient to afford adequate contended that summaries and effectiveness data or may license others to refer to it. company owns a property right it is well recognized that pharmaceutical industry. In any event, cross-licensing agreements within the legal authority to prevent any collusive the Federal Trade Commission have full provisions of the Food and Drug Administration Act are clearly applicable to the case of Morgan v. FDA, 495 F.2d 1075 (D.C. Cir. 1974). The District Court ruled that the data on safety and effectiveness, contained in a new drug application are exempt from disclosure under all three statutes. The Court of Appeals ruled that such data can properly be encompassed within the trade secrets exemption to the Freedom of Information Act.

The Commissioner advises that it is Congress, not the Food and Drug Administration, that has created the new drug licensing system. The Commissioner believes that the Department of Justice and the Federal Trade Commission have full legal authority to prevent any collusive the safety and effectiveness data contained in the Federal Environmental Pest. In any event, it is well recognized that a person who owns a property right of any type may contract with others for its use. Thus, a company may sell its rights in an NDA or may license others to refer to it.

257. Comments suggested that public policy supports the release of all safety and effectiveness data, but points out that contended that summaries of such data are insufficient to afford adequate scientific review. It was pointed out that the President's Commission on Federal Statistics recommended in 1971 that such information should be released. Comments suggested that the procedure for release of this type of information contained in the Federal Environmental Pesticide Control Act of 1972 (Pub. L. 92-516, 86 Stat. 973) should be used.

The Commissioner agrees that public policy supports release of all safety and effectiveness data, but points out that present statutory law, 18 U.S.C. 1905 and 21 U.S.C. 331(j), prohibits such release. The Federal Environmental Pesticide Control Act of 1972 contains a statutory prohibition on the disclosure of a manufacturer's property right in trade secret data. The Commissioner has no authority to institute such a system without statutory authorization from Congress.

258. The proposed regulations published in May 1972 would have required every holder of a previously approved NDA or NADA to submit a summary of confidential safety and effectiveness data, and every person submitting such an application to include such a summary, which would then be revised by the Food and Drug Administration and publicly disclosed. Present Food and Drug Administration regulations require a NDA contain a short or expanded summary of all of the information contained in the application. In addition, these applications are reviewed thoroughly by Food and Drug Administration personnel who prepare internal memoranda summarizing the information they contain, evaluating it, and setting out their conclusions and recommendations on it. During the past 2 years, requests have been made for the various summaries in NDA files prepared by the medical officer, the pharmacologist, the chemist and in some instances, the biostatistician.

The Commissioner concludes that, in view of the fact that the full reports of the safety and effectiveness data contained in an NDA that have not previously been disclosed to the public constitute trade secret information that is prohibited from public disclosure by 18 U.S.C. 331(j) and 18 U.S.C. 1905, it is important that summaries of all such data and information be made available so that scientists and members of the public who are interested will have an opportunity to determine the basis on which Food and Drug Administration decisions are made. Accordingly, the Commissioner concludes that summaries of such data and information on the basis of which an NDA or NADA has been approved should be made publicly available.

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 prepare new summaries at that time for each approval. Accordingly, for such prior approvals the Commissioner has concluded that internal agency records that describe such data and information will be made available for public release on request. It is not possible to state exactly which internal records will be adequate to convey this 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 records will include internal reviews of the data and information, action memoranda, a summary of the basis for approval, or other internal memoranda sufficient to describe the safety and effectiveness data and information for the drug involved.

The Commissioner also recognizes that many of these old memoranda were prepared solely for internal consideration, and may contain information that is unnecessary to convey the summary. 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 opportunity to respond and other inappropriate gratuitous comments, which is unnecessary to convey the summary. If these memoranda had been prepared for public dissemination, such information and comments would have been deleted. The Commissioner concludes that the names of patients and investigators and inappropriate comments will be deleted prior to public disclosure.

On the other hand, the Commissioner concludes that the analyses, discussion, conclusions, and recommendations contained in such memoranda should not be deleted. Such material could properly be withheld from public disclosure in accordance with the exemption for intra-agency memoranda, but the Commissioner believes that public disclosure of these matters is better served by disclosure of all of the conclusions and recommendations set out in the memoranda, with only the minimal deletions mentioned above included. The Commissioner believes that such disclosure will not harm the regulatory efforts of the agency, but indeed will serve to foster better public understanding of the internal discussion about scientific and medical issues that must always characterize 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, it is more appropriate to provide for preparation of a single institutional summary stating all of the data and information relating to the safety and effectiveness of the product on the basis of which the agency action was taken. The Commissioner concludes that until a request is made for such a summary, it will be publicly released when the approval is made. It is not administratively feasible immediately to implement this new requirement. Accordingly, the Commissioner concludes that NDA's and NADA's approved on or after July 1, 1975, will be the subject of such an institutional summary of the safety and effectiveness data and information. This will provide sufficient time for the Bureau of Drugs and the Bureau of Veterinary Medicine to prepare guidelines for such summaries and to implement this new policy for those applications now undergoing review within the agency.

The Commissioner concludes that, for those memoranda, the summary may be prepared in one of two alternative ways. First, the relevant bureau may request the applicant to prepare a summary of all of the data and information contained in the application. The applicant may then review, revise, and release at the time that the drug is approved. It would obviously be premature to require that
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, if the underlying data and information will have been submitted and fully considered.

The second alternative 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 goes into effect 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 approval of NDA's and NADA's. This institutional summary will collate and distill all of the numerous internal memoranda relating to the approval process into a single document set forth in a comprehensive way the basis for the approval. Since it will purposely be prepared for public dissemination, it is unnecessary or impracticable for the relations to state that these new summaries will not violate personal privacy or otherwise contain inappropriate matters.

c. Finally, the Commissioner notes that the rules pertaining to summaries set out in the final regulations apply to supplemental and abbreviated 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 in the 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.

239. 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, as suggested, rather than one that should be the summary already provided in the NDA.

The Commissioner concludes that the rules for preparation and disclosure of summaries so specified in the regulations are adequate to provide for information on the public on the safety and effectiveness data on the basis of which an NDA or NADA is approved, with minimum disruption to the applicant and the Food and Drug Administration. The Commissioner concludes that it would be

unduly burdensome to require preparation of new summaries for previously approved drugs, and that internal memoranda should be sufficient to describe the basis for these past decisions. The Commissioner also concludes that the institutional summary to be prepared and released to the public for all approvals after July 1, 1975, may properly be prepared solely by the bureau involved, or may be prepared by a summary specifically submitted by the applicant for that purpose. None of these summaries will be sufficient for a competitor to satisfy the statutory requirement for "full reports" of safety and effectiveness in order to obtain his own approved application, and thus the trade secret status of the underlying data and information will be preserved. If the Commissioner determines that this is not successful in providing adequate summaries of the safety and effectiveness data to the public, the matter will be reopened for consideration of alternative methods of achieving this purpose.

260. The question was raised in comments as to what was meant by "a summary of information submitted" which was proposed to be submitted with each NDA for release to the public. It was suggested that a "general" summary should suffice for the needs of the prescribing physician, the consumer, and the scientific community. A "detailed" summary, it was believed, would ease the burden of a subsequent new drug applicant in this country and might also enable such a manufacturer to market in other countries with little or no testing. It was also indicated that the 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, because of the trade secret and otherwise confidential nature of the underlying data involved, that the manufacturer should be responsible for the content of any such summary, and that no summary change 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 concludes that the possibility of competitive advantage abroad is speculative and that in 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. Comments asked whether submission of a summary is required each time a supplemental NDA is approved. Although this was indicated, would be an unnecessary duplication since the supplement is often directed to some rather minor change in the labeling of the product with no relation 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 has a significant impact on safety and effectiveness. It is unnecessary specifically to mention any supplements in the regulations because a supplemental application becomes part of the original application. Thus, 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 no safety and effectiveness information, since release of such information is "unnecessary" under the Freedom of Information Act and might also enable such a manufacturer to market in other countries with little or no testing. It was also indicated that the 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, because of the trade secret and otherwise confidential nature of the underlying data involved, that the manufacturer should be responsible for the content of any such summary, and that no summary change be made without the consent of the manufacturer.

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264. Foreign governments have discussed with the Food and Drug Administration the possibility of exchanging drug 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 information to foreign governments as apply to disclosure to the public. This will permit the Food and Drug Administration to provide full summaries of safety and effectiveness data for all approved NDA's, and revised 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 international exchange of important regulatory information of this type.

265. Comments were received that 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 customarily held in strict confidence.

266. A comment stated that for an NDA which is not approved, a summary of the basis of the refusal should be released.

267. Comments contended that all data and information contained in an NDA which has received final agency disapproval will be available for disclosure. After all administrative and judicial appeals are 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.

268. Comments contended that the fact that a product is not currently being marketed or has been withdrawn from the market does not prevent that product from being entitled to trade secret protection. The Commissioner concludes that terminations of an IND or NDA refer to final termination or disapproval, not to some intermediate step. As is discussed elsewhere in this preamble, continued pursuit of the IND or NDA will be sufficient to justify the continued confidentiality of the safety and effectiveness information involved.

269. The Commissioner concludes that the legislative history of 21 U.S.C. 331(j) shows that Congress simply did not decide the issue raised in these regulations. Although Congress stated that all trade secrets in new drug applications were to remain confidential, it did not, in its reports or legislative debate, consider or define the intended scope of the term "trade secret."

270. The Commissioner concludes that the Food and Drug Administration has since 1938 decided that all trade secret information contained in a new drug application will be held in confidence, and has stated that animal and human data and the metabolite investigations voluntarily terminated here may be continued abroad. The Commissioner concludes that 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.

271. 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. The Commissioner concludes that a number of competitive advantages continue to exist or later accrue after such an event occurs. It was argued that simply knowing a competitor does not work is worth hundreds of thousands of dollars and years of research to a competitor. Further, such information could be used to develop marketing and sales literature and provides a definite advantage to its owner in obtaining foreign product registrations. The advantage was thought to be especially strong with respect 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 the patent status or the drug under study is more active and more effective, and that initial investigations may be authorized to re-enter the field. The Commissioner concludes 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 fact 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 this preamble, continued pursuit of the IND or NDA will be sufficient to justify the continued confidentiality of the safety and effectiveness information involved.

272. In the "Ferroline" case, the company had conveyed by contract its rights 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 gravamen of its complaint was that the misappropriation of the trade secret in question, 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 Commissioner concludes 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 fact 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 this preamble, continued pursuit of the IND or NDA will be sufficient to justify the continued confidentiality of the safety and effectiveness information involved.

273. The Commissioner concludes that the term "trade secret" as defined in the statute, and the provisions for confidential investigative use of such information, including the definitions of "Udall v. Tallman," 137 F. Supp. 179 (W.D. Ark. 1957); and "Ferroline Corp. v. General Aniline Corp.," 207 F.2d 912 (7th Cir. 1953). The Commissioner concludes that the term "trade secret" as defined in the statute, and the provisions for confidential investigative use of such information, including the definitions of "Udall v. Tallman," 137 F. Supp. 179 (W.D. Ark. 1957); and "Ferroline Corp. v. General Aniline Corp.," 207 F.2d 912 (7th Cir. 1953). The Commissioner concludes that the term "trade secret" as defined in the statute, and the provisions for confidential investigative use of such information, including the definitions of "Udall v. Tallman," 137 F. Supp. 179 (W.D. Ark. 1957); and "Ferroline Corp. v. General Aniline Corp.," 207 F.2d 912 (7th Cir. 1953). The Commissioner concludes that the term "trade secret" as defined in the statute, and the provisions for confidential investigative use of such information, including the definitions of "Udall v. Tallman," 137 F. Supp. 179 (W.D. Ark. 1957); and "Ferroline Corp. v. General Aniline Corp.," 207 F.2d 912 (7th Cir. 1953).
reason for the termination being only temporary, data and information will not be disclosed. The regulations also permit a showing of "extraordinary circumstances" why data in a terminated file should not be disclosed. A situation in which one IND or NDA directly affects another might be viewed as an extraordinary circumstance. Again, the possibility of foreign competitive advantage is too speculative and remote to justify a broad exemption from disclosure under the Freedom of Information Act.

270. Many comments based objections to the release of any safety and effectiveness data whatever on an affidavit by Henry E. Simmons, M.D., former Director of the Bureau of Drugs, dated April 5, 1971, filed in the United States District Court in the case of "Morgan v. FDA.

The Commissioner advises that the position taken in that affidavit no longer represents the policy of the Food and Drug Administration. Subsequent to the preparation of that affidavit, the Food and Drug Administration made a comprehensive, exhaustive review of the status of safety and effectiveness data for drugs under the Freedom of Information Act for the first time since that law was passed. That evaluation was set out in the proposed regulations, published in May 1972 and in the brief subsequently filed by the Food and Drug Administration in the United States Courts of Appeals in the "Morgan" case. The recent decision of the United States Court of Appeals in the "Morgan" case explicitly recognizes that, because of the procedural posture of that case, it does not provide precedent for determining the status of all safety and effectiveness data for new drugs. The Commissioner advises that the proper way to decide this issue will be through a declaratory judgment action contesting either the validity of those final regulations or the propriety of proposed disclosure of particular information or for an old drug may no longer be a "trade secret," they can still be regarded as "confidential commercial information" because they are not customarily divulged publicly.

The Commissioner rejects this comment. Such data no longer have any commercial value, and indeed no comment suggested any reasonable rationale for such value. Moreover, scientific data are customarily published in the scientific literature or in any event are made available to physicians and scientists for review, and accordingly are not customarily regarded as privileged information.

272. Comments contended that confidentiality of safety and effectiveness data should not cease once a drug becomes an old drug, particularly in light of the fact that, under the decision in "Saxen v. Westex Pharmaceuticals, Inc. v. Simmons," 465 F.2d 363 (4th Cir. 1972), the Food and Drug Administration has no authority to determine old drug status.

The Commissioner notes that, upon appeal in that case, the Supreme Court held that the Food and Drug Administration has no authority to decide whether a new drug has become the new drug/old drug status of a drug. "Welnberger v. Bentex Pharmaceuticals, Inc.," 412 U.S. 665 (1973). Since the agency will be in a position to settle this question for the first time, 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 no special status for patented products, nor does the Federal Food, Drug, and Cosmetic Act. The status of a new drug for which an NDA is effective but which is currently subject to the drug efficacy study implementation (DESIS) review program. Some of these data have been submitted after publication of an Initial DESIS notice but prior to a notice of opportunity for hearing. The Commissioner concludes that such data and information have the same status as any other data and information contained in NDA's in the NDA. Prior to final action revoking 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 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.

274. Questions have arisen as to whether an approval of an antibiotic drug for animal use is a public license or a public regulation, and thus whether the safety and effectiveness data are or are not available for public disclosure upon such approval.

The Commissioner concludes that, although an IND or NDA for animal use was formerly subject to the same form of approval contained in section 507 of the Federal Food, Drug, and Cosmetic Act as that used for human use, i.e., public regulation, the Animal Drug Amendments of 1968 (Pub. L. 90-399, 82 Stat. 343) were subject to the disclosure rules established for those 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 140.16. The Animal Drug Amendments changed the law by requiring approval of an individual new animal drug application for every new animal drug.

The Commissioner advises that the rules for disclosure will depend upon the nature of the approval obtained. Accordingly, the 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. 343) 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 140.16. The Animal Drug Amendments changed the law by requiring approval of an individual new animal drug application for every new animal drug.

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A PROTOCOL FOR A TEST OR STUDY

279. A comment contended that the amount of money expended in developing a product is irrelevant to the fact that the only factors that should properly be considered in making the determination is whether the owner has an opportunity to objective 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 attempt to specify all of the relevant factors involved.

280. Comments also contended that uniqueness is not necessary for a trade secret, and thus that this element should not be included in the criteria for determining whether a protocol constitutes a trade secret. The Commissioner concludes that a protocol is not 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 whether the standards set out in §4.61 are met.

281. A comment stated that the criteria for determining 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, they cannot be withheld under any other exemption.

The Commissioner notes that the criteria proposed in order to show that a protocol is a trade secret were intended to amplify the Restatement definition, not to replace it. The Restatement definition does not preclude this as to any other type of information for which trade secret status is claimed. The final regulations make this clear.

ADVERSE REACTION REPORTS, PRODUCT EXPERIENCE REPORTS, CONSUMER COMPLAINTS, AND OTHER SECULAR DATA AND INFORMATION

282. The primary concern expressed in comments about release of this type of information was the possibility that it may frequently be "misinformation." It was pointed out that the occurrence of reaction "B" does not mean that "A" caused it, particularly in a situation where the person may have been consuming more than one product. It was further asserted that, when taken out of context, adverse reaction data are subject to misinterpretation, particularly by a layman unqualified to analyze them. As protection against misinterpretation, it was suggested that the Food and Drug Administration not release any adverse reaction report until a scientific evaluation has been made of the reaction and its probable causation. Industry, it was asserted, had a right to expect this type of protection from "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 required to analyze reports by third parties, and reply to the agency before the reports are made public, in order to provide a fair and balanced discussion.

The Commissioner rejects the proposition upon which the bulk of the criticism in the comments is based, i.e., that the public, scientists, and the Food and Drug Administration are capable 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 reports 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 284 of the Federal Food, Drug, and Cosmetic Act. The Commissioner concludes that 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 same law.

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 been raised as to whether adverse reactions reported to an IND file are available for public disclosure.

The Commissioner concludes that the same rules with respect to disclosure of adverse reactions should apply whether the reaction is related to an IND file or a pending NDA. Such information is not available for public disclosure until the NDA is approved or finally disapproved or withdrawn, except that an individual who participates in a study involving an investigational new drug will be given a copy of any adverse reaction report relating to him. Such reports are required by law to be furnished to the Food and Drug Administration. The Commissioner concludes that furnishing adverse reaction reports under these limited circumstances would not pose any issue under the exemptions for privacy or trade secrets and confidential commercial information.

PRODUCT INGREDIENTS

285. Comments stated that even a simple list of ingredients in a product constitutes confidential commercial information which provides a competitive advantage, and that the exemption for a particular ingredient is not helpful because it may be a minor ingredient 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.

286. One comment stated that this provision in the proposed regulation "is just another way of saying that excipient materials that are well known do not contribute significantly to the performance of the product." The choice of excipients, it was asserted, was arrived at by a combination of experience of funds and it was stated that, with the increasing attention paid to bioavailability, this process would become more costly. This regulation, it was concluded, would make it easier for generic drug manufacturers to arrive at superior products without having to spend more for research and experience development costs. It was suggested that qualitative information be exempt except to the extent that it was disclosed on the label or labeling since the information required for public health already appears there, and that a manufacturer should not have to defend the confidentiality of any ingredient information by proving it unique.

The Commissioner agrees that undisclosed inactive ingredients in drugs will be handled as trade secret information.

287. A comment contended that an ingredient should be regarded as a trade secret if it provides a competitive advantage, and suggested that the criteria of uniqueness, importance to the product, and knowledge to competitors should be deleted.

The Commissioner intends 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

288. 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 which are frequently published in the scientific literature. Accordingly, methods of this type are not customarily regarded as confidential information. Moreover, such methods are needed by State and local officials as well as by Federal 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 whatsoever. The final regulations have been revised to state this policy.

A comment indicated that it was not clear whether the Restatement definition of a trade secret must be met before assay methodology information 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 and therefore cannot be regarded as exempt.

The Commissioner advises that, as with any other information in the possession of the Food and Drug Administration which is to be exempt from disclosure as a trade secret, the information must be a trade secret within the meaning of § 121.51(h). The Food and Drug Administration has determined that assay methods are discloseable 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

Several comments noted that, although manufacturing methods and processes, quality control procedures, and quantitative formulas are specifically exempt from disclosure unless there has been a prior public disclosure, the proposed regulations also required 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 quantitative formulas are per se exempt from disclosure unless previously disclosed and need not be marked as confidential or specially justified. A manufacturer need not submit a statement on prior public disclosure or subsequent abandonment unless so required by the situation by the Food and Drug Administration.

The technical question was raised in comments as to whether adjuvants, such as catalysts or polymerization modifiers used in a secret manufacturing process for a polymer used as a food packaging material, would be available to the public.

The Commissioner concludes that, if the adjuvants are necessary to the manufacturing of a safe product, the food additive regulation itself must disclose their use. If they are not necessary for a safe product and are exempt from regulation as food additives but are described as part of the manufacturing process in a food additive petition on the same terms and conditions as the food, such data need not be disclosed to the public because, under § 121.51(h) (3) (I) of the final regulations, a manufacturing process is regarded as a trade secret that will not be disclosed.

Production, Sales, Distribution, and Similar Data and Information

No comments contended that production, sales, distribution data, and information should be available for public disclosure.

The Commissioner concludes that such information is per se exempt from public disclosure unless it is released in a blind compilation that does not disclose confidential information, and that it need not be marked as confidential or otherwise specially justified. The only form in which such information may be disclosed to the public is through a compilation which aggregates data from several sources, in a way that does not reveal the data from any single source. This form of blind compilation of confidential commercial information is often prepared and made public by trade associations and commerce organizations.

Questions have been raised about the release of otherwise confidential commercial information, such as sales figures and manufacturing data, after a product has been withdrawn from the market and abandoned.

The Commissioner concludes that such information ordinarily no longer represents confidential information or trade secret data once the product has been removed from the market and abandoned. It will be the Commissioner’s practice to consult with the company involved before making a final decision on release of such information, however, to determine whether there are future plans for marketing the product or whether the data in some way also disclose confidential information about other products that remain on the market.

One comment requested an amendment to the petition form to provide that the amounts and the identity of recipients of refunds from advance deposits of fees paid to the Food and Drug Administration for the manufacture of proprietary information, exempt 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

Questions have arisen about the availability for public disclosure of petitions received pursuant to § 10.5 of the regulations (21 CFR 10.5) requesting 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 these records contain information that is exempt from disclosure, e.g., manufacturing procedures or quantitative formulas. Prior to a notice in the Federal Register granting the petition, the petition is properly regarded as confidential commercial information, since it would disclose the intent of the company to pursue the marketing of a new product. Once such a notice is published, however, the petition can no longer be regarded as confidential. Similarly, a request for extension of the permit shall be available for public disclosure if and when it is granted, since granting such an extension permits other manufacturers to begin marketing under the same terms and conditions as the first manufacturer. A new paragraph (3) is added to § 10.5 to state this policy.

Processing Records for Low-Acid Canned Foods

The Commissioner published in the Federal Register of May 14, 1973 (38 FR 12716) and subsequently amended in the Federal Register of January 10, 1974 (39 FR 2750) 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 118.20). 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 (1) is added to § 90.20 in this final order.

Cosmetic Product Information

The Commissioner has promulgated regulations relating to voluntary
registration of cosmetic product establishments, voluntary filing of cosmetic product ingredient and cosmetic raw material ingredient information, and voluntary filing of cosmetic product experiences in the Federal Register of April 11, 1972 (37 FR 7151) and October 17, 1972 (37 FR 28914). The recodification of the regulations under a new Subchapter G—Cosmetics was published in the Federal Register of March 18, 1974 (39 FR 9684). Cosmetic manufacturers, the Food and Drug Administration that they have delayed the filing of ingredient 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 the provisions at this time is appropriate in order to conform them with the provisions of Part 4.

298. Section 710.7 of the regulations (21 CFR 710.7) provides that a copy of Form FD-2811 (Registration of Cosmetic Product Establishment) is available for public inspection in its entirety. It is the Commissioner's understanding that no question has been raised about the public disclosure of this document because it does not contain information relating to specific products. Accordingly, no modification in this provision is warranted.

299. Section 720.8 of the regulations (21 CFR 720.8) provides that Forms FD-2313 (Cosmetic Raw Material Composition Statement), and FD-2314 (Discontinuance of Commercial Distribution of Cosmetic Product or Cosmetic Raw Material), and amendments thereto, must be clearly marked as confidential if trade secret status is claimed.

The provision states that, if the Food and Drug Administration determines that an item so marked is not exempt from disclosure, the matter may be appealed within the agency for a final decision.

The Commissioner concludes that § 720.8 should be revised to make it consistent with the general provisions contained in new Part 4 as promulgated by these final regulations. The Commissioner further concludes that, by incorporating the procedural safeguards contained in new § 4.44 and clarifying the status of voluntary ingredient disclosures in § 4.111 and the provision for disclosure enunciated in the other provisions of Part 4, any questions about the status of the information contained in these forms will be resolved.

300. Section 730.7 of the regulations (21 CFR 730.7) provides that Forms FD-2704 (Cosmetic Product Experience Report), FD-2705 (Cosmetic Product Unusual Experience Report), and FD-2706 (Summary Report of Product Experience by Product Categories) shall be handled in accordance with the final regulations to be published by the agency under the Freedom of Information Act.

The Commissioner is therefore amending § 701.7 (70 FR 11510) in order to clarify the rules laid down in the final regulations established in Part 4. The Commissioner concludes that these rules will adequately protect against the divulgence of material regarded by the industry as constituting important confidential commercial information and at the same time assure that information which is a major importation is protected in 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 available for public disclosure pursuant to the Freedom of Information Act.

The Commissioner concludes that the procedure established in new § 4.44 is properly used to resolve any issues of this nature, prior to submission of the information involved. The Commissioner controls the question whether the ingredient(s) involved must be labeled pursuant to § 701.3 (21 CFR 701.3). As stated in the Federal Register of October 17, 1972 (37 FR 28912), an adverse determination constitutes final agency action that may be challenged in the courts. Section 720.9 is revised to reflect these conclusions.

The Commissioner realizes that a number of cosmetic companies have already submitted ingredient information with a request for confidentiality pursuant to Part 720. In order to deal fairly with all of these submissions, the Commissioner has concluded that all such requests for confidentiality will now be handled pursuant to the procedure established in new § 4.44. In the event that it is determined that the information involved is not confidential, the company will have the opportunity to withdraw the confidentiality request and, if the information is labeled by the Food and Drug Administration files relating to approval of Particular lot of a biologic.

The Commissioner concludes that all forms used within the Bureau of Biological Drugs to show what testing has been undertaken by the Bureau on a particular lot, the results obtained, and whether approval was granted, are available for public disclosure. All documents showing the manufacturer's testing of a particular lot will also be released, except to the extent that it would show the volume of the drug produced, manufacturing procedures and controls, yield from raw materials, costs, or other similar confidential commercial information. New §§ 601.7 and 601.8 are added to the existing regulations for biologics to state this policy.

303. During the past 2 years, requests have been made for various types of information contained in Food and Drug Administration files relating to approval of particular lots of a biologic.

The Commissioner concludes that all forms used within the Bureau of Biological Drugs to show what testing has been undertaken by the Bureau on a particular lot, the results obtained, and whether approval was granted, are available for public disclosure. All documents showing the manufacturer's testing of a particular lot will also be released, except to the extent that it would show the volume of the drug produced, manufacturing procedures and controls, yield from raw materials, costs, or other similar confidential commercial information. New § 601.8 reflects this policy.

FEDERAL HAZARDOUS SUBSTANCES ACT

304. Jurisdiction over the Federal Hazardous Substances Act has been transferred to the Consumer Product Safety Commission pursuant to the Consumer Product Safety Act (Pub. L. 92-573, 86

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 on the proposed regulations published in May 1972, and upon the numerous requests for documents received 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 on preparing 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 needed for implementation. The Food and Drug Administration is therefore obligated to disclose documents not specifically exempt from disclosure regardless of the existence of published rules of the type promulgated in this final order.

Accordingly, the Commissioner concludes that these regulations will become effective 30 days after publication in the Federal Register.

Nevertheless, the Commissioner recognizes that it has been over 2 years since these regulations were first proposed, that the final regulations incorporate some not specifically dealt with in the proposal or the comments, and that sound public policy supports allowing time for comment wherever feasible. Accordingly, the Commissioner is providing an additional 60 days within which to present further brief comments on issues not raised by the initial comments and discussed in this preamble. The Commissioner will then rule on these comments expeditiously and will publish an additional order ruling upon any such matters.

The Commissioner advises that comments submitted within this additional period should address new issues, and should not reopen matters raised by the initial proposal and fully discussed in this preamble. The Commissioner is particularly interested, for example, in any comments on the new portions of the procedural regulations contained in Subpart B of Part 4 and on the new provisions relating to biological drugs, as well as on any other similar provisions which were not covered in the proposal and the comments received on it.

The Commissioner concludes that the entire final order will become effective with the 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 are raised, 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 settle the status under the Freedom of Information Act of every category of document contained within Food and Drug Administration files. The Commissioner utilized the Freedom of Information Act in order to avoid ad hoc decisions and to facilitate prompt 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 concludes that, after receipt of the additional comments permitted and any record being closed in a result thereof, all 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 by 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 may be 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., 21 Stat. 1040 et seq., as amended; 21 U.S.C. 321 et seq.), the Federal Food, Drug, and Cosmetic Act (Public Law 90–92, 81 Stat. 54–56 as amended by 88 Stat. 1501–1505; 5 U.S.C. 552) and under authority delegated to the Commissioner (21 CFR 2.130), Parts 1, 2, 4, 8, 10, 12, 131, 132, 131, 343, 601, 729, and 730 are amended as follows:

SUBCHAPTER A—GENERAL

PART 2—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG AND COSMETIC ACT AND THE FAIR PACKAGING AND LABELING ACT

1. In Part 1, 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 investigative records for law enforcement purposes and may include 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 prior to the consideration of criminal prosecution based upon that record being closed, except as provided in § 4.82 of this chapter. The Commissioner concludes that an individual, all names and other information specifically reflecting consideration has been instituted and the matter of this chapter prior to the consideration of criminal prosecution being closed only very rarely and only under extraordinary circumstances that demonstrate a compelling public interest.

(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 within the meaning of this section when a final decision has been made not to recommend criminal prosecution to a United States attorney based upon that hearing, or such recommendation has been finally refused, or 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 investigation 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, other information, and (5) States and localities of which would identify a Food and Drug Administration employee shall be deleted from section 305 hearing records prior to public disclosure only pursuant to § 4.35 of this chapter.
PART 2—ADMINISTRATIVE FUNCTIONS, PRACTICES, AND PROCEDURES

Subpart C—Public Information

Subpart E—Limitations on Exemptions

Sec. 4.50 Applicability of limitations on exemptions.
4.51 Data and information previously disclosed to the public.
4.52 Discretionary disclosure by the Commissioner.
4.53 Disclosure required by court order.
4.54 Disclosure to governmental advisory committees, State and local government officials, and other special governmental employees.
4.55 Disclosure to other Federal government departments and agencies.
4.56 Disclosure in administrative or court proceedings.
4.57 Disclosure to Congress.
4.58 Communications with State and local government officials.
4.59 Use of data or information for administrative or court enforcement purposes.

Subpart F—Availability of Specific Categories of Records

4.591 Applicability; cross-reference to other regulations.
4.601 Administrative enforcement records.
4.602 Court enforcement records.
4.603 Correspondence.
4.604 Summarization of oral discussions.
4.605 Testing and research conducted by or with funds provided by the Food and Drug Administration.
4.606 Studies and reports prepared by or with funds provided by the Food and Drug Administration.
4.607 Food and Drug Administration manuals.
4.608 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.
4.609 Data and information obtained by contract.
4.610 Data and information about Food and Drug Administration employees.
4.611 Data and information submitted voluntarily to the Food and Drug Administration.
4.612 Voluntary drug experience reports submitted by physicians and hospital pharmacists.
4.613 Voluntary product defect reports.
4.614 Data and information submitted pursuant to cooperative quality assurance program.
4.615 Product codes for manufacturing or sales dates.
4.616 Disclosure of information.
4.617 New drug information.
4.618 Advisory committee records.

Subpart G—Official Testimony and Information

Sec. 4.109 Data and Information obtained by contract.
4.110 Data and information submitted voluntarily to the Food and Drug Administration.
4.111 Data and information submitted voluntarily to the Food and Drug Administration.
4.112 Voluntary drug experience reports submitted by physicians and hospital pharmacists.
4.113 Voluntary product defect reports.
4.114 Data and information submitted pursuant to cooperative quality assurance program.
4.115 Product codes for manufacturing or sales dates.
4.117 New drug information.
4.118 Advisory committee records.

Subpart H—Procedures and Fees

Sec. 4.121 Voluntary drug experience reports submitted by physicians and hospital pharmacists.
4.122 Voluntary product defect reports.
4.123 Data and information submitted pursuant to cooperative quality assurance program.
4.124 Product codes for manufacturing or sales dates.
4.125 Disclosure of information.
4.126 New drug information.
4.127 Advisory committee records.

Subpart J—Uniformity of Access to Records

Sec. 4.131 Uniform access to records.
4.132 Partial disclosure of records.
4.133 Request for existing records.
4.134 Preparing new records.
4.135 Uniform access to records.
4.136 Uniformity of access to records.

Subpart K—Application of Limitations on Exemptions

Sec. 4.141 Applicability of limitations on exemptions.
4.142 Data and information previously disclosed to the public.
4.143 Discretionary disclosure by the Commissioner.
4.144 Disclosure required by court order.
4.145 Disclosure to governmental advisory committees, State and local government officials, and other special governmental employees.
4.146 Disclosure to other Federal government departments and agencies.
4.147 Disclosure in administrative or court proceedings.
4.148 Disclosure to Congress.
4.149 Communications with State and local government officials.
4.150 Use of data or information for administrative or court enforcement purposes.

Subpart L—Availability of Specific Categories of Records

Sec. 4.151 Applicability; cross-reference to other regulations.
4.161 Administrative enforcement records.
4.162 Court enforcement records.
4.163 Correspondence.
4.164 Summarization of oral discussions.
4.165 Testing and research conducted by or with funds provided by the Food and Drug Administration.
4.166 Studies and reports prepared by or with funds provided by the Food and Drug Administration.
4.167 Food and Drug Administration manuals.
4.168 Agreements between the Food and Drug Administration and other departments, agencies, and organizations.
4.169 Data and information obtained by contract.
4.170 Data and information about Food and Drug Administration employees.
4.171 Data and information submitted voluntarily to the Food and Drug Administration.
4.172 Voluntary drug experience reports submitted by physicians and hospital pharmacists.
4.173 Voluntary product defect reports.
4.174 Data and information submitted pursuant to cooperative quality assurance program.
4.175 Product codes for manufacturing or sales dates.
4.177 New drug information.
4.178 Advisory committee records.

Subpart M—Procedures and Fees

Sec. 4.179 Voluntary drug experience reports submitted by physicians and hospital pharmacists.
4.180 Voluntary product defect reports.
4.181 Data and information submitted pursuant to cooperative quality assurance program.
4.182 Product codes for manufacturing or sales dates.
4.183 Disclosure of information.
4.184 New drug information.
4.185 Advisory committee records.

Subpart N—Uniformity of Access to Records

Sec. 4.191 Uniform access to records.
4.192 Partial disclosure of records.
4.193 Request for existing records.
4.194 Preparing new records.
4.195 Uniform access to records.
4.196 Uniformity of access to records.

Subpart O—Application of Limitations on Exemptions

Sec. 4.201 Applicability of limitations on exemptions.
4.202 Data and information previously disclosed to the public.
4.203 Discretionary disclosure by the Commissioner.
4.204 Disclosure required by court order.
4.205 Disclosure to governmental advisory committees, State and local government officials, and other special governmental employees.
4.206 Disclosure to other Federal government departments and agencies.
4.207 Disclosure in administrative or court proceedings.
4.208 Disclosure to Congress.
4.209 Communications with State and local government officials.
4.210 Use of data or information for administrative or court enforcement purposes.

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The rules 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 acquired 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 production of any record, such officer or employee shall appear 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 is 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. 6-62, 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 of 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 is available for 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 § 4.16(c) (1) of this chapter for section 305 hearing records, in § 4.60 (b) regarding certain limitations on exemptions, or in § 4.109(b) for certain correspondences under § 4.109(c) shall not be subject to the special rules stated therein.

§ 4.22 Partial disclosure of 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) 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 order, 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 interpretation 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. 6-62, 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, while not necessary to prevent disclosures to the public, does not relieve the Government of its obligations under the Freedom of Information Act to respond appropriately to a request for records. Records that are marked as confidential or with other similar terms shall be sent in writing to the Public Records and Documents Center (HFC-18), Food and Drug Administration, Rm. 6-62, 5600 Fishers Lane, Rockville, MD 20852.

§ 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 procedures 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 prehearing 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 Public Records and Documents Center.

(a) The agency 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. 6-62, 5600 Fishers Lane, Rockville, MD 20852.

(b) All requests for agency records shall be made in writing to this office.

§ 4.31 Permanent file of requests for Food and Drug Administration records.

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 discloseable 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. 6-62, 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. A request should include all pertinent details that will help identify the records sought.
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If the description is insufficient to locate the records requested, the Food and Drug Administration will so notify the person making the request and request the additional information needed to identify the records requested.

Every reasonable effort shall be made by the Food and Drug Administration to assist in the identification and location of the records sought.

Upon receipt of a request for records, the Public Records and Documents Center shall enter it in its 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 § 4.40(c), 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). An oral request for records shall not begin any time requirement. A written request for records sent elsewhere within the agency 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 (excluding 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 therefore.

(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 to disclose or not disclose any such petition are subject to the False Certification or Authentication of Records Act.

(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.

(6) The Assistant Commissioner for Public Affairs may waive payment of fees when he determines, based upon a petition, that the person making the request for records is indigent and that there is public interest. All statements made in any such petition are subject to the False Reports to the Government Act, 18 U.S.C. 1001. A person shall be deemed to be indigent for purposes of this section if he does not have income or resources sufficient to pay the fees involved. Determinations pursuant to this provision will be made within the discretion of the agency.

(7) The Assistant Commissioner for Public Affairs may reduce or waive payment of fees when he determines, based upon a verified petition, that the person requesting the records is indigent and that there is public interest because furnishing the information can be considered primarily as benefiting the general public.

(8) 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 necessary and 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 of the records requested, or different records from the records 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 is in the public interest.

(3) In making a determination of the public 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.

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 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 to determine whether the Food and Drug Administration will or will not make part or all of them available for public disclosure upon request if they are submitted. Any such request shall state why the data or information involved fell within an exemption from public disclosure set out in Subpart D of this part and shall enclose the records involved.

(b) Pending a determination upon such request, the records involved shall be held confidentially and separately by the Food and Drug Administration and shall not be received as part of Food and Drug Administration files.

(c) Pursuant to such a request, the Food and Drug Administration shall make a determination of confidentiality of the request for public disclosure but that are submitted voluntarily instead are not subject to the provisions of this section and will be handled as if they had been required to be submitted.

(h) No request under this section shall be accepted if the status of the records involved is already determined by § 4.111 or by any other regulation published or cross-referenced in this part.

§ 4.45 Situations in which confidentiality is uncertain.

In situations where the confidentiality of data or information is uncertain and there is a request for public disclosure, the Food and Drug Administration will consult with the person who has submitted or divulged the data or information or who would be affected by disclosure before determining whether or not such data or information is available for public disclosure.

§ 4.46 Judicial review of proposed disclosure.

Where the Food and Drug Administration consults with a person who will be affected by a proposed disclosure of data or information contained in Food and Drug Administration records pursuant to § 4.45, and rejects the person’s request that part or all of the records not be disclosed, the decision constitutes final agency action that is subject to judicial review pursuant to 5 U.S.C. chapter 7.

The person affected will be permitted 5 days after receipt of notification of such decision within which to institute suit in a United States District Court to enjoin release of the records involved. If suit is brought, the Food and Drug Administration will not disclose the records involved until the matter and all related appeals have been concluded.

§ 4.47 Denial of request for records.

(a) A denial of a request for records, in whole or in part, shall be signed by the Assistant Commissioner for Public Affairs.

(b) The name and title or position of each person who participated in the denial of a request for records shall be set forth in the letter denying the request.

(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 5.82.

(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 Non-specific and overly burdensome requests.

The Food and Drug Administration will make every reasonable effort to comply fully with all requests for disclosure of nonexempt records. Non-specific requests or requests for a large number of documents that require the deployment of a substantial amount of agency man-hours 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 that this diversion will have upon 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 submitted will be made after balancing the public benefit to be gained by the disclosure against the public loss that will result from diverting agency personnel from their other responsibilities. A determination in which it is determined that a request for voluminous records would unduly burden and interfere with the operations of the Food and Drug Administration, the person making the request will be asked to be more specific and to narrow the request, and to agree on an orderly procedure for the production of the requested records, in order to satisfy the request without disproportionately adverse effects on agency operations.

§ 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 record or document 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), 5225 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
§ 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 these circumstances, the Food and Drug Administration will charge only for the costs of searching and copying 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 only 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 reimburse the costs of searching and copying 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 or of another regulation cross-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 or exceptions specified in Subpart E of this part. For example, correspondence that is ordinarily disclosable under § 4.103 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 disclosable 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 shall be deleted before the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure.

§ 4.62 Inter- or intra-agency memos or letters.

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 the 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 on which 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 in accordance with the provisions of this section to the extent that such deletion may be justified under an exemption established in Subpart E of this part.

(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 as provided in § 4.61.

(d) Names of individuals conducting investigations, studies, or tests on products or ingredients shall not be deleted prior to disclosure of any record to the public unless extraordinary circumstances are shown.

(e) A request for all records relating to a specific individual will be denied as a clearly unwarranted invasion of personal privacy unless accompanied by the written consent of the individual named.

§ 4.64 Investigatory records compiled for law enforcement purposes.

(a) An investigatory record for law enforcement purposes may be withheld from public disclosure pursuant to the provisions of this section to the extent that disclosure of such records would:

(1) Interfere with enforcement proceedings.

(2) Deprive a person of a right to a fair trial or an impartial adjudication.

(3) Constitute an unwarranted invasion of personal privacy.

(4) 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 intelligence investigation, confidential information furnished only by the confidential source.

(5) Disclose investigative techniques and procedures.

(b) Investigatory records include all records relating to regulatory enforcement action, including both administrative and court actions, that have been disclosed to any member of the public, including any person who is the subject of the investigation.

(c) Any investigatory record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time in accordance with the rule established in § 4.41, 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 only in accordance with the provisions of § 4.66 of this chapter.

(d) Investigatory records for law enforcement purposes shall be subject to the following rules:

(1) No such record is available for public disclosure prior to the consideration of regulatory enforcement action based upon that record being closed, except as provided in § 4.82. The Commissioner will exercise his discretion to disclose records relating to possible criminal prosecution pursuant to § 4.82 prior to consideration of criminal prosecution being initiated only very rarely and only under circumstances that 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
confidentiality are available for public disclosure.

(3) The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed within the meaning of this section:

(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 or such 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 paragraphs (d)(1) and (d)(2) of this section have occurred.

(d) 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 from such record and the record shall be submitted to the United States attorney for further consideration. It is concluded 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 consultant who has received such information shall have been limited to the purposes for which such information is furnished and to the persons for whom such information is furnished. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

(2) Exempt from public disclosure pursuant to § 4.81, data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to Subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.

(b) The Commissioner shall not make available for public disclosure any record that is:

(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 oblige 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 of the agency, may be disclosed in a lawful manner 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 oblige the Commissioner to exercise his discretion to disclose any other record that is exempt from disclosure.

§ 4.84 Disclosure to consultants, advisory committees, State and local government officials, 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, and other special government employees for use only in their work with the Food and Drug Administration. Such persons are thereafter subject to the same restrictions with respect to the disclosure of such data and information as any other Food and Drug Administration employee.

§ 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. 351(f) 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 be pursuant to an agreement that the record shall not be further disclosed by the other department or agency except with the written permission of the Food and Drug Administration.
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§ 4.85 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 where the data or information are relevant. The Food and Drug Administration will request that the data or information be submitted and that any other appropriate measures 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 prohibited 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 chairman of a committee or subcommittee of Congress acting pursuant to committee business.

(c) An individual member of Congress who requests a record for his own use or on behalf of any constituent shall be subject to the same rules in this part that apply to any other member 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 § 4.64.

(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) Investigations records compiled for law enforcement purposes by State and local government officials who perform counterpart functions to the Food and Drug Administration 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.

(b) Disclosure of investigatory records compiled for law enforcement purposes by the Food and Drug Administration to foreign government officials who perform counterpart functions to the Food and Drug Administration in a foreign country shall prevent the Food and Drug Administration from disclosing 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.

§ 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.

§ 4.100 Applicability; cross-reference to other regulations.

(a) The provisions set forth in this subpart or cross-referenced in paragraph (e) of this section state the way in which specific categories of Food and Drug Administration records are handled upon a request for public disclosure. The exemptions established in Subpart D of this part and the limitations on exemptions established in Subpart E of this part shall be applicable to all Food and Drug Administration records, as provided in §§ 4.49 and 4.50. Accordingly, a record that is ordinarily available for public disclosure in accordance with this part or under other regulations is not available for such disclosure to the extent that it falls within an exemption contained in Subpart D of this part except as provided by the limitations on exemptions specified in Subpart E of this part.

(b) The Commissioner, on his own initiative or on the petition of any interested person, may amend this subpart or promulgate and cross-reference additional regulations to state the status of additional categories of documents to settle pending questions or to reflect court decisions.

(c) In addition to the provisions of this part, rules on the availability of the following specific categories of Food and Drug Administration records are established by regulations in this chapter:

(1) Section 365 hearing records, in § 1.6(d) of this chapter.

(2) Flavor ingredient records and notes, in § 1.12(1) (4) (iv) of this chapter.

(3) Environmental impact analysis reports and draft and final environmental impact statements, in §§ 6.1(h) and 6.6 of this chapter.

(4) Color additive petitions, in § 8.9 of this chapter.

(5) Food standard temporary permits, in § 10.5(c) of this chapter.

(6) Information on thermal processing of low-acid foods packaged in hermetically sealed containers, in § 19.20(c) (4) of this chapter.

(7) Food additive petitions, in § 121.51 (b) of this chapter.

(8) Action levels for natural and unavoidable defects in food for human use, in § 128.106(c) of this chapter.

(9) Drug establishment registrations and drug listings, in § 132.9 of this chapter.

(10) Investigational new animal drug notices, in § 153.33 of this chapter.

(11) New animal drug application files, in § 153.33a of this chapter.

(12) New animal drug notice, in the Commission's animal drug application file for an antibiotic drug, in § 146.16 of this chapter.

(13) Methadone patient records, in § 310.505(g) of this chapter.

(14) Investigational new drug notice, in § 312.5 of this chapter.

(15) Labeling for and lists of approved new drug applications, in § 314.10 of this chapter.
(16) Master files for new drug applications, in § 314.11 of this chapter.
(17) New drug application file, in § 314.14 of this chapter.
(18) Data and information submitted for in vitro diagnostic products, in § 328.4 of this chapter.
(19) Data and information submitted for OTC drug review, in § 330.10(a)(2) of this chapter.
(20) Investigational new drug notice for an antibiotic drug, in § 431.70 of this chapter.
(21) Antibiotic drug file, in § 431.71 of this chapter.
(22) Data and information submitted for biologies review, in § 601.25(b)(2) of this chapter.
(23) Investigational new drug notice for a biological product, in § 601.59 of this chapter.
(24) Applications for establishment and product licenses for biological products, in § 601.51 of this chapter.
(25) Commitment registrations, in § 710.7 of this chapter.
(26) Cosmetic product ingredient and cosmetic raw material composition statements, in § 720.5 of this chapter.
(27) Cosmetic product experience reports, in § 730.7 of this chapter.
(28) Electronic product information, in §§ 1003.4 and 1003.42 of this chapter.

§ 4.101 Administrative enforcement records.
(a) All Food and Drug Administration records relating to administrative enforcement action disclosed to any member of the public, including the person who is the subject of such action, are available for public disclosure at the time such disclosure is first made. Such records include correspondence with companies following factory inspection, recall of products, in § 4.82.
(b) To the extent that any of such records fall within the exemption for Investigatory records established in § 4.64, the Commissioner determines that they are subject to discretionary release pursuant to § 4.82.
(c) Records relating to administrative enforcement action that are not disclosed to any member of the public constitute investigatory records that are subject to the rules for disclosure established in § 4.64. For example, an establishment inspection report is an investigatory record and thus subject to § 4.64 except insofar as the Commissioner exercises his discretion to release it pursuant to § 4.82.

§ 4.102 Court enforcement records.
(a) All records and documents filed in the courts are available for public disclosure unless the court orders otherwise. The Food and Drug Administration will make available for public disclosure such records or documents if the agency can determine that it has an accurate copy of the actual record or document filed in the court. If the Food and Drug Administration cannot determine whether it has an accurate copy of such a record or document, the person requesting a copy shall be referred to the court.
(b) After a recommendation for court action has been finally refused by a United States attorney, the correspondence with the United States attorney and the Department of Justice with respect to that recommendation, including the pleadings recommended for filing with the court, is available for public disclosure. 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.

§ 4.103 Correspondence.
(a) All correspondence to and from members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal Government and special government employees, is available for public disclosure.
(b) Any such correspondence is available for public disclosure at the time that it is sent or received by the Food and Drug Administration unless a different time for such disclosure is specified in another rule established or cross-referenced in this part, e.g., correspondence relating to an IND notice or an NDA in § 314.14(a)(7) of this chapter.

§ 4.104 Summaries of oral discussions.
(a) All written summaries of oral discussions, whether in person or by telephone, with members of the public, members of Congress, organization or company officials, or other persons, except members of the Executive Branch of the Federal government or special government employees, are available for public disclosure.
(b) Any such summary is available for public disclosure at the time that it is prepared by the Food and Drug Administration unless a different time for such disclosure is specified in another rule established or cross-referenced in this part, e.g., summaries of oral discussions relating to a food additive petition in § 121.51(h)(3) of this chapter.
(c) If more than one summary of an oral discussion exists in a Food and Drug Administration file, all such summaries shall be disclosed in response to any request for such summary.

§ 4.105 Testing and research conducted by or with funds provided by the Food and Drug Administration.
(a) Any list that may be prepared by the Food and Drug Administration of testing and research being conducted by or with funds provided by the Food and Drug Administration is available for public disclosure.

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index of all such manuals is available at the Food and Drug Administration Public Records and Documents Center in accordance with § 4.26.

(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 § 4.82.

(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 field offices may request legal action directly to the office of the General Counsel, are available for public disclosure.

§ 4.103 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) A permanent file of all such agreements and understandings is available for public review during working hours in the Food and Drug Administration Public Records and Documents Center.

(c) All agreements and understandings shall be published in the Federal Register.

§ 4.104 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. The home address and home telephone number of any such employee are not available for public disclosure.

(b) Statistics on the prior employment experience of present agency employees, and subsequent employment of past agency employees, are available for public disclosure.

§ 4.105 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 another time, and not as a part of an application, 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 are not 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 will be made available for public disclosure unless extraordinary circumstances are shown:

(1) All safety, effectiveness, and functionality data and information for a marketed ingredient or product, except as provided in § 330.10(a) of this chapter for OTC drug.

(2) A protocol for a test or study, unless it is shown to fall within the exemption established in § 4.61 for trade secrets and confidential commercial or financial information.

(3) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information shall be disclosed as follows:

(i) (1) If submitted by a consumer or user of the product, the record is available for public disclosure after deletion of names and any information that would identify the person submitting the information.

(ii) 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 information that would identify the manufacturer or the brand designation of the product, but not the type of product or its ingredients.

(3) If submitted by a third party, such as a physician or hospital or other institution, 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.

(iv) If obtained through a Food and Drug Administration investigation, the record shall have the same status as the initial report which led to the investigation, i.e., it shall be disclosed in accordance with paragraph (c)(3)(i) through (iii) of this section.

(v) Any compilation of data, information, and reports prepared in a way that does not reveal data or information which is not available for public disclosure under this section is available for public disclosure.

(vi) If a person requests a copy of any such record relating to a specific individual or a specific incident, 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.

(d) A list of all ingredients contained in a food or cosmetic, whether or not it is in descending order of predominance, or a list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 4.81 contained in a drug, or a list of all ingredients or components in a device. A particular ingredient or group of ingredients or components shall be deleted from any such list for a cosmetic or device prior to public disclosure upon a determination made pursuant to § 4.44 that the ingredient or ingredients and within the exemption established in § 4.61 for trade secrets and confidential commercial information, and a notation shall be made that any such ingredient list is incomplete.

(e) 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.

(f) The following data and information submitted voluntarily to the Food and Drug Administration are not available for public disclosure unless they have been previously disclosed to the public as defined in § 4.81 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:

(1) All safety, effectiveness, and functionality data and information for a developmental ingredient or product that has not previously been disclosed to the public as defined in § 4.81.

(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 section is available for public disclosure.

(4) Quantitative or semiquantitative formulas.

(5) For purposes of this regulation, safety, effectiveness, and functionality 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.

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§ 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 FD-1639 shall be handled in accordance with the rules established in § 4.111(a) and (b).

(b) If a person requests a copy of any such record relating to a specific individual or a specific incident, 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, deletion of data and information falling within the exemptions established in § 4.61 for trade secrets and confidential commercial or financial information and in § 4.64 for personal privacy.

(b) If the report is submitted by any person 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 shipping.

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's 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 drug first marketed 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, showing the same information as is specified in paragraph (a) of this section and showing the last time that it does not show a withdrawal date.

(c) 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, 312.5, 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 5 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 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:

(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 and 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 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 or other institution.

(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 be within the exemption established in § 4.61 of this chapter, and a notation shall be made that such ingredient is incomplete.

(b) The following data and information in a color additive petition are not available for public disclosure unless they have been previously disclosed to the public 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 requantitative 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 regulation is 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 (t) to § 10.5 as follows:

§ 10.5 Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.

(t) 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. Such disclosure shall be in accordance with the rules established in Part 4 of this chapter.

PART 90—EMERGENCY PENNIT CONTROL

6. In Part 90, by adding a new paragraph (l) to § 90.20 as follows:

§ 90.20 Thermal processing of low-acid foods packaged in hermetically sealed containers.

(l) 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 § 4.61 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 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. (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.

(b) (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 the deficiencies in it, after the petitioner is informed that it will not be filed because of the deficiencies involved: (i) All safety and functionality data and information submitted with or incorporated by reference in the petition. (ii) 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. (iii) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, 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) A list of all ingredients contained in a food 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. (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. (2) 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 § 4.61 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: (i) Manufacturing methods or processes, including quality control procedures. (ii) 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. (iii) Quantitative or semiquantitative formulas.

All correspondence and written summaries of oral discussions relating to a food additive petition are available for public disclosure in accordance with the provisions of Part 4 of this chapter where the food additive regulation is published in the Federal Register.

(4) For purposes of this regulation, safety and functionality data include all studies and tests of a food additive on animals and humans and all 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 adding new § 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 file.

(a) For purposes of this section the “NADA file” includes all data and information submitted with or incorporated by reference in the NADA, NADA’s, 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 a NADA file has been publicly disclosed or acknowledged before an approval is published in the Federal Register, no data or information contained in the file 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 § 4.61 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:

(i) For an NADA approved prior to July 1, 1975, internal agency records that describe such data and information, e.g., a summary of basis for approval or internal reviews of the data and information, after deletion of: (a) Names and any information that would identify the investigators. (b) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(ii) For an NADA approved on or after 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:

(a) 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.

(b) The Bureau of Veterinary Medicine may prepare its own summary of such data and information.

(iii) 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.

(iv) Adverse reaction reports, product experience reports, consumer complaints,
and other similar data and information, after deletion of: (1) Names and any information that would identify the person using the product.
(2) Names and any information that would identify any third party involved with the registrant such as a physician, hospital, or other institution.
(3) A list of all active ingredients and any inactive ingredients previously disclosed to the public as defined in § 4.61 of this chapter.
(4) 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.
(5) All correspondence and written summaries of oral discussions relating to the NADA, in accordance with the provisions of Part 4 of this chapter.
(6) 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:
(I) The NADA has been abandoned and no further work is being undertaken with respect to it.
(II) The NADA has been abandoned and no further work is being undertaken with respect to it.
(II) The NADA has been abandoned and no further work is being undertaken with respect to it.
(6) The existence of an NDA file with regard to the confidentiality of an investigational new animal drug notice and a new animal drug application file for an antimicrobial drug.
(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 to such notice and file 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.

PART 146—ANTIBIOTIC DRUGS FOR VETERINARY USE: PROCEDURAL AND INTERPRETIVE REGULATIONS

9. In Part 146, by adding the following new section:
§ 146.16 Confidentiality of data and information in an investigational new animal drug notice and a new animal drug application file for an antibiotic drug.
(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 notice and file 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 any 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 any record that contains an investigational new drug that 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 901(c) of the act makes it an offense to divulge to unauthorized persons any information acquired from any 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 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 may require information in the master file for judicial or administrative proceedings concerning the drug, the Food and Drug Administration will not withhold such information from the applicant when its need for it arises and the applicant has requested for it. The Food and Drug Administration will inform the person who submitted the data of any such requests.

By adding new § 314.16 to read as follows:
§ 314.16 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 incorporated into the NDA, supplemental NDA’s, and reports under §§ 310.300 and 310.31 of this chapter, master files, and other related submissions. The availability for public disclosure of any record in the NDA file shall be handled 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 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 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 approvable 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 Administration 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:
(I) All safety and effectiveness data and information previously disclosed to the public, as defined in § 4.61 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:

(i) For an NDA approved prior to July 1, 1976, internal agency records that describe such data and information, e.g., a summary of basis for approval of internal reviews of the data and information, after deletion of:

(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.

(ii) For an NDA approved on or after July 1, 1976, a summary of such data and information prepared in one of the following two alternative ways shall be publicly released when the approval letter is sent:

(a) 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, revised by the Bureau.

(b) The Bureau of Drugs may prepare its own summary of such data and information.

(3) 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.

(4) 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 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 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:

(a) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(b) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(6) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(7) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(8) An appropriate, revised NDA.

(9) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(10) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(11) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(12) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(13) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(14) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(15) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(16) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(17) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(18) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(19) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(20) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(21) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(22) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(23) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(24) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(25) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(26) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(27) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(28) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(29) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

(30) Any inappropriate gratuitous comments unnecessary to an objective analysis of the data and information.

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.

A. Subpart E—Confidentiality of Information

§ 431.70 Confidentiality of data and information in an investigational new drug notice for an antibiotic drug.

(a) The existence of an IND notice for an antibiotic drug 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 for an antibiotic drug shall be handled in accordance with the provisions established in § 431.71.

(c) Notwithstanding the provisions of § 431.71, the Food and Drug Administration shall disclose upon request to an individual on whom an investigational 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 in the antibiotic 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 available for public disclosure of pending Forms 5 for which an approvable letter has been sent to the applicant.

(c) If the existence of an antibiotic drug file has not been publicly disclosed or acknowledged, no data or information in the antibiotic drug file is available for public disclosure.

(d) If the existence of an antibiotic drug file has been publicly disclosed or acknowledged before an approvable 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 Administration 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 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 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:

(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.
(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.

(7) All records showing the testing of and action on a particular lot of a certifiable antibiotic drug by the Food and Drug Administration.

(8) The following data and information in an antibiotic drug 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:

(a) Manufacturing methods or processes, including quality control procedures.

(b) 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.

(c) Quantitative or semiquantitative formulas.

(d) 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 F to read as follows:

Subpart F—Confidentiality of Information

Sec. 601.50 Confidentiality of data and information in an investigational new drug notice for a biological product.

601.51 Confidentiality of data and information in applications for establishment and product licenses.


Subpart F—Confidentiality of Information

§ 601.50 Confidentiality of data and information in an investigational new drug notice for a biological product.

(a) 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.

(b) 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 §601.51.

(c) 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 supplied 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.

(a) 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 shall be handled 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 before 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 is 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.

(f) Adverse reaction reports, product experience reports, consumer complaints, and other similar data and information, after deletion of:

(1) Names and any information that would identify the person using the product.

(2) Names and any information that would identify any third party involved with the report, such as a physician or hospital or other institution.

(3) A list of all active ingredients and any inactive ingredients previously disclosed to the public, as defined in §4.61 of this chapter.

(4) An assay method or other analytical method, unless it serves no regulatory or compliance purpose and it is shown to fall within the exemption established in §4.61 of this chapter.

(g) 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.

(h) 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.

(i) All records showing the testing of and action on a particular lot by the Food and Drug Administration.

(j) 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 §4.81 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.

(4) For purposes of this regulation, safety and effectiveness data include all studies and tests of a biological product 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.

(a) The availability for public disclosure of all data and information contained in forms filed in accordance with the provisions of this chapter are submitted voluntarily to the Food and Drug Administration and are thus subject to the specific provisions for the presubmission review of a request for confidentiality of voluntarily submitted data under §4.44 of this chapter.
RULES AND REGULATIONS

§ 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, as well as 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, as well as to the provisions concerning data and information 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. SCHNEIDER,
Commissioner of Food and Drugs.

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